OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
February 11, 2026
4:00pm

Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

Viewing Access Only:
Please register for the webinar at:
https://oklahoma.zoom.us/webinar/register/WN_B7-m8jKcQWaA9HEiV7QRQA
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The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – February 11, 2026

DATE: February 4, 2026

NOTE: The DUR Board will meet at 4:00pm at the Oklahoma Health Care Authority (OHCA) at 4345 N. Lincoln Blvd. in Oklahoma City, Oklahoma.

There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.

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Enclosed are the following items related to the February meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit – Appendix B

Academic Detailing (AD) Program Update – Appendix C

Narrow Therapeutic Index (NTI) Drug List – Appendix D

Action Item – Vote to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib) and Update the Approval Criteria for the Thrombocytopenia Medications – Appendix E

Action Item – Vote to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the Hereditary Angioedema (HAE) Medications – Appendix F

Action Item – Vote to Prior Authorize Atmeksi® (Methocarbamol Oral Suspension), Metaxalone 640mg Tablet, and Tanlor® (Methocarbamol 1,000mg Tablet) and Update the Approval Criteria for the Muscle Relaxant Medications – Appendix G

Action Item – Vote to Prior Authorize Imaavy™ (Nipocalimab-aahu) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents – Appendix H

Action Item – Vote to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution) and Update the Approval Criteria for the Antidepressants – Appendix I

Action Item – Vote to Prior Authorize Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) and Opdivo Qvantig™ (Nivolumab/ Hyaluronidase-ipdl) and Update the Approval Criteria for the Skin Cancer Medications – Appendix J

Action Item – Vote to Update the Gastrointestinal (GI) Cancer Medications – Appendix K

Action Item – Vote to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib) and Update the Approval Criteria for the Non-Malignant Solid Tumor Medications – Appendix L

Action Item – Vote to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas) and Xembify® (IGSC, Human) – Appendix M

Action Item – Vote to Prior Authorize Redemplo® (Plozasiran) and Update the Approval Criteria for the Antihyperlipidemics – Appendix N

Action Item – Vote to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection) and Update the

Approval Criteria for the Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) – Appendix O

Actin Item – Vote to Prior Authorize Zepbound® (Tirzepatide) and Update the Approval Criteria for the Adiposity-Based Chronic Disease (ABCD) Medications – Appendix P

Action Item – Vote to Prior Authorize Levofloxacin Ophthalmic Solution and Update the Approval Criteria for the Ophthalmic Antibiotic Medications – Appendix Q

Action Item – Vote to Prior Authorize Estradiol 0.06% Gel (Generic EstroGel®) and Lynkuet™ (Elinzanetant) and Update the Approval Criteria for the Vasomotor Symptom (VMS) Medications – Appendix R

Action Item – Vote to Prior Authorize MoviPrep® [Polyethylene Glycol 3350 (PEG 3350)/Sodium Sulfate/Sodium Chloride/Potassium Chloride/Sodium Ascorbate/Ascorbic Acid for Oral Solution] and Update the Approval Criteria for the Bowel Preparation Medications – Appendix S

Action Item – Vote to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ [Hydrochlorothiazide (HCTZ) Oral Suspension], Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution), and Univasc® (Moexipril) and Update the Approval Criteria for the Antihypertensive Medications – Appendix T

Action Item – Annual Review of Cholestatic Liver Disease and Bile Acid Disorder Medications – Appendix U

Action Item – Annual Review of Anticonvulsants – Appendix V

Action Item – Annual Review of Insomnia Medications – Appendix W

30-Day Notice to Prior Authorize Cardamyst™ (Etripamil Nasal Spray) – Appendix X

Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector] – Appendix Y

Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation) – Appendix Z

Annual Review of Crenessity® (Crinecerfont) – Appendix AA

Annual Review of Kebilidi™ (Eladocagene Exuparvovec-tneq) – Appendix AB

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – Appendix AC

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – February 11, 2026 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

NOTE: ***The DUR Board will meet at 4:00pm at OHCA (see address above). There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.***

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Cassidy Blaiss –	participating in person
Dr. Christen Ground –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Bethany Holderread –	participating in person
Dr. Matt John –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Jennifer Weakley –	participating in person

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Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 928 6649 0447
Passcode: 80744869

Public Comment for Meeting:

- Speakers who wish to sign up for public comment at the OHCA DUR Board meeting may do so in writing by visiting the DUR Board page on the OHCA website at www.oklahoma.gov/ohca/about/boards-and-committees/drug-utilization-review/dur-board and completing the Speaker Registration Form. Completed Speaker Registration forms should be submitted to DURPublicComment@okhca.org. Forms must be received after the DUR Board agenda has been posted and no later than 24 hours before the meeting.
- The DUR Board meeting will allow public comment and time will be limited to 40 minutes total for all speakers during the meeting. Each speaker will be given 5 minutes to speak at the public hearing. If more than 8 speakers properly request to speak, time will be divided evenly.
- Only 1 speaker per manufacturer will be allowed.
- Any speakers who sign up for public comment must attend the DUR Board meeting in person at OHCA (see above address). Public comment through Zoom will not be allowed for the DUR Board meeting.

Items to be presented by Dr. Haymore, Chairman:

2. **Public Comment Forum**
   A. Acknowledgement of Speakers for Public Comment

Items to be presented by Dr. Haymore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. December 10, 2025 DUR Board Meeting Minutes
   B. December 10, 2025 DUR Board Recommendations Memorandum
   C. January 14, 2026 DUR Board Recommendations Memorandum

Non-presentation items reviewed by Dr. Moss, Dr. Haymore, Chairman:

4. **Update on Medication Coverage Authorization Unit – See Appendix B**
   A. Pharmacy Help Desk Activity for January 2026
   B. Medication Coverage Activity for January 2026

Items to be presented by Dr. Travers, Dr. Haymore, Chairman:

5. **Academic Detailing Program Update – See Appendix C**
   A. Background
   B. Current Topic: Pediatric Obesity
   C. Results: Obesity-Related Care
   D. Provider Satisfaction
   E. Academic Meeting Presentation(s)
   F. Summary

Non-presentation items reviewed by Dr. Moss, Dr. Haymore, Chairman:

6. **Narrow Therapeutic Index (NTI) Drug List – See Appendix D**
   A. Introduction
   B. SoonerCare NTI Drug List
   C. College of Pharmacy Recommendations

Items to be presented by Dr. O'Halloran, Dr. Haymore, Chairman:

7. **Action Item – Vote to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib) and Update the Approval Criteria for the Thrombocytopenia Medications – See Appendix E**
   A. Market News and Updates
   B. Wayrilz™ (Rilzabrutinib) Product Summary
   C. College of Pharmacy Recommendations

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

8. **Action Item – Vote to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the Hereditary Angioedema (HAE) Medications – See Appendix F**
   A. Market News and Updates
   B. Product Summaries
   C. Estimation of Savings
   D. College of Pharmacy Recommendations

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

9. **Action Item – Vote to Prior Authorize Atmeksi® (Methocarbamol Oral Suspension), Metaxalone 640mg Tablet, and Tanlor® (Methocarbamol 1,000mg Tablet) and Update the Approval Criteria for the Muscle Relaxant Medications – See Appendix G**
   A. Market News and Updates
   B. Product Summaries
   C. Cost Comparison: Carisoprodol Products
   D. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

10. **Action Item – Vote to Prior Authorize Imaavy™ (Nipocalimab-aahu) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents – See Appendix H**
    A. Market News and Updates
    B. Imaavy™ (Nipocalimab-aahu) Product Summary
    C. Cost Comparisons
    D. College of Pharmacy Recommendations

Items to be presented by Dr. O'Halloran, Dr. Haymore, Chairman:

11. **Action Item – Vote to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution) and Update the Approval Criteria for the Antidepressants – See Appendix I**
    A. Market News and Updates
    B. Cost Comparisons
    C. College of Pharmacy Recommendations

Items to be presented by Dr. Sinko, Dr. Haymore, Chairman:

12. **Action Item – Vote to Prior Authorize Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) and Opdivo Qvantig™ (Nivolumab/ Hyaluronidase-nvhy) and Update the Approval Criteria for the Skin Cancer Medications – See Appendix J**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

Items to be presented by Dr. Sinko, Dr. Haymore, Chairman:

13. **Action Item – Vote to Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications – See Appendix K**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

Items to be presented by Dr. Sinko, Dr. Haymore, Chairman:

14. **Action Item – Vote to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib) and Update the Approval Criteria for the Non-Malignant Solid Tumor Medications – See Appendix L**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

15. **Action Item – Vote to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas) and Xembify® (IGSC, Human) – See Appendix M**
    A. Cost Comparison: IGIV Products
    B. Cost Comparison: IGSC Products
    C. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

16. **Action Item – Vote to Prior Authorize Redemplo® (Plozasiran) and Update the Approval Criteria for the Antihyperlipidemics – See Appendix N**
    A. Market News and Updates
    B. Redemplo® (Plozasiran) Product Summary
    C. College of Pharmacy Recommendations

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

17. **Action Item – Vote to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection) and Update the Approval Criteria for the Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) – See Appendix O**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

Items to be presented by Dr. O'Halloran, Dr. Haymore, Chairman:

18. **Action Item – Vote to Prior Authorize Zepbound® (Tirzepatide) and Update the Approval Criteria for the Adiposity-Based Chronic Disease (ABCD) Medications – See Appendix P**
    A. Market News and Updates
    B. Zepbound® (Tirzepatide) Product Summary
    C. Cost Comparison: MASH/NASH Medications
    D. College of Pharmacy Recommendations

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

19. **Action Item – Vote to Prior Authorize Levofloxacin Ophthalmic Solution and Update the Approval Criteria for the Ophthalmic Antibiotic Medications – See Appendix Q**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

20. **Action Item – Vote to Prior Authorize Estradiol 0.06% Gel (Generic EstroGel®) and Lynkuet™ (Elinzanetant) and Update the Approval Criteria for the Vasomotor Symptom (VMS) Medications – See Appendix R**
    A. Market News and Updates
    B. Product Summaries
    C. Cost Comparisons
    D. College of Pharmacy Recommendations

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

21. **Action Item – Vote to Prior Authorize MoviPrep® [Polyethylene Glycol 3350 (PEG 3350)/Sodium Sulfate/Sodium Chloride/Potassium Chloride/Sodium Ascorbate/Ascorbic Acid for Oral Solution] and Update the Approval Criteria for the Bowel Preparation Medications – See Appendix S**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

22. **Action Item – Vote to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ [Hydrochlorothiazide (HCTZ) Oral Suspension], Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution), and Univasc® (Moexipril) and Update the Approval Criteria for the Antihypertensive Medications – See Appendix T**
    A. Market News and Updates
    B. Cost Comparisons
    C. College of Pharmacy Recommendations

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

23. **Action Item – Annual Review of Cholestatic Liver Disease and Bile Acid Disorder Medications – See Appendix U**
    A. Current Prior Authorization Criteria
    B. Utilization of Cholestatic Liver Disease and Bile Acid Disorder Medications
    C. Prior Authorization of Cholestatic Liver Disease and Bile Acid Disorder Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Cholestatic Liver Disease and Bile Acid Disorder Medications

Items to be presented by Dr. O'Halloran, Dr. Haymore, Chairman:

24. **Action Item – Annual Review of Anticonvulsants – See Appendix V**
    A. Current Prior Authorization Criteria
    B. Utilization of Anticonvulsants
    C. Prior Authorization of Anticonvulsants
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Anticonvulsants

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

25. **Action Item – Annual Review of Insomnia Medications – See Appendix W**
    A. Current Prior Authorization Criteria
    B. Utilization of Insomnia Medications
    C. Prior Authorization of Insomnia Medications

D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Insomnia Medications

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

26. 30-Day Notice to Prior Authorize Cardamyst™ (Etripamil Nasal Spray) – See Appendix X

A. Introduction
B. Cardamyst™ (Etripamil Nasal Spray) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

27. Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector) – See Appendix Y

A. Current Prior Authorization Criteria
B. Utilization of Anti-Migraine Medications
C. Prior Authorization of Anti-Migraine Medications
D. Market News and Updates
E. Cost Comparison: DHE Products
F. College of Pharmacy Recommendations
G. Utilization Details of Anti-Migraine Medications

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

28. Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation) – See Appendix Z

A. Current Prior Authorization Criteria
B. Utilization of Pulmonary Hypertension Medications
C. Prior Authorization of Pulmonary Hypertension Medications
D. Market News and Updates
E. Yutrepia™ (Treprostinil Powder for Inhalation) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Pulmonary Hypertension Medications

Non-presentation items reviewed by Dr. O'Halloran, Dr. Haymore, Chairman:

29. Annual Review of Crenessity® (Crinecerfont) – See Appendix AA

A. Current Prior Authorization Criteria
B. Utilization of Crenessity® (Crinecerfont)
C. Prior Authorization of Crenessity® (Crinecerfont)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Crenessity® (Crinecerfont)

Non-presentation items reviewed by Dr. DeRemer, Dr. Haymore, Chairman:

30. Annual Review of Kebilidi™ (Eladocagene Exuparvovec-tneq) – See Appendix AB

A. Current Prior Authorization Criteria
B. Utilization of Kebilidi™ (Eladocagene Exuparvovec-tneq)
C. Prior Authorization of Kebilidi™ (Eladocagene Exuparvovec-tneq)
D. College of Pharmacy Recommendations

Non-presentation items reviewed by Dr. Moss, Dr. Haymore, Chairman:

31. U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – See Appendix AC

Items to be presented by Dr. Adams, Dr. Haymore, Chairman:

32. Future Business* (Upcoming Product and Class Reviews)

A. Dry Eye Disease (DED) Medications
B. Fesilty (Fibrinogen, Human-chmt)
C. Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers
D. Growth-Related Disorder Medications
E. Hemophilia Medications
F. Leukemia and Lymphoma Medications
G. Muscular Dystrophy Medications
H. Topical Antibiotic Products
I. Waskyra (Etuvetidigene Autotemcel)

*Future product and class reviews subject to change.

33. Adjournment

NOTE: An analysis of the atypical [Aged, Blind, and Disabled (ABD)] patient subgroup of the Oklahoma Medicaid population has been performed pertaining to all recommendations included in this DUR Board meeting packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.

NOTE: Oklahoma Medicaid transitioned from a fee-for-service (FFS) pharmacy benefit to a managed care pharmacy benefit for most members on April 1, 2024. At that time, the majority of SoonerCare members were transitioned to one of the three managed care SoonerSelect plans: Aetna, Humana, or Oklahoma Complete Health. SoonerSelect data has been provided to the College of Pharmacy and has been used in analyses throughout this DUR Board meeting packet. The data included in this DUR Board meeting packet combines FFS and managed care utilization data. The managed care utilization and prior authorization (PA) data reported in this packet is based solely on the data provided by the SoonerSelect plans. SoonerSelect PA data only includes medications billed as pharmacy claims (NDC) and does not include those billed as medical claims (HCPCS), where applicable.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING DECEMBER 10, 2025

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP		X
Christen Ground, D.O.	X	
Bret Haymore, M.D.; Chairman	X	
Bethany Holderread, Pharm.D.	X	
Matt John, Pharm. D., MBA	X	
T. Craig Kupiec II, M.D., MSPH	X	
Lee Muñoz, D.Ph.	X	
Edna Patatanian, Pharm.D., FASHP; Vice Chairwoman		X
Jennifer Weakley, M.D., DipABLM		X

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Alanah Canfield Miller, Pharm.D.; Clinical Pharmacist		X
Michaela DeRemer, Pharm.D., MBA, BCIDP, BCPS; Clinical Pharmacist	X	
Darius Dorsey, Pharm.D.; Pharmacy Resident		X
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist	X	
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Whitney Bueno, Pharm.D., BCOP		X
Christine Hughes, Pharm.D., MBA, BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.		X
Mark Wendelboe	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Josh Anderson, Chief of Staff		X
Mark Brandenburg, M.D., MSC; Medical Director	X	
Clay Bullard; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Darla Koone	X	
Melissa Miller, State Medicaid Director		X

Christine Picart	X	
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer		X
Laura Short	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Sharon Smith, Pharm.D.; Clinical Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
***Legal representative**		
Travis Dennis, J.D.; Deputy General Counsel		X
Gentry Kincade, J.D.; Deputy General Counsel	X	
Gwendolyn Maxey, J.D.; Deputy General Counsel		X
Conner Mulvaney, J.D.; Deputy General Counsel		X

OTHERS PRESENT:	
Andrew Delgado, Bristol Myers Squibb	Jamie Tobitt, Apellis
Priya Rangan, Novartis	Brent Milovac, Leo Pharma
Bryan Steffan, Boehringer	Julie Vandaveer, Johnson & Johnson
Scott Burns, Johnson & Johnson	Kristen Winters, Centene
Kellie Vazzana, Alkermes	David Prather, Novo Nordisk
Brent Parker, Merck	Kenneth Berry, Alkermes
Lee Stout, Chiesi	Irene Chung, Aetna
Deidra Williams, Humana	Jenna Doerr, Artia Solutions
Melissa Abbott, Galderma	Porscha Showers, Gilead
Mike Thiem, Incyte	Valerie Willard, Glaukos
Pam Storey, PTC Bio	Shawn Akey, Concis Labs
Melanie Kitto, BioCryst	Michael Pericozzi, Sanofi
John Suelzer, Leo Pharma	Dave Miley, Teva
Jennifer Tamburo, AstraZeneca	Lindsey Walter, Novartis
Gary Parenteau, Dexcom	Payal Tejani, Biogen
Sherry Andes, Insmed	Mathhew Grew, Leo Pharma
Steve Kahn, Sobi	Michael Zarob, Argenx
Jeff Forshey, Rhythm	Nick Trombold, Alexion

PRESENT FOR PUBLIC COMMENT:	
Priya Rangan, Novartis	Brent Milovac, Leo Pharma
Andrew Delgado, Bristol Myers Squibb	Jamie Tobitt, Apellis
Julie Vandaveer, Johnson & Johnson	

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: ROLL CALL

Dr. Haymore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

2A: AGENDA ITEM NO. 10 PRIYA RANGAN
2B: AGENDA ITEM NO. 12 BRENT MILOVAC
2C: AGENDA ITEM NO. 16 ANDREW DELGADO
2D: AGENDA ITEM NO. 17 JAMIE TOBITT

2E: AGENDA ITEM NO. 22 JULIE VANDAVEER
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 3:</u> APPROVAL OF DUR BOARD MEETING MINUTES
3A: NOVEMBER 12, 2025 DUR MINUTES
Materials included in agenda packet; presented by Dr. Haymore
Dr. Muñoz moved to approve; seconded by Dr. Kupiec
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 4:</u> UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT
4A: PHARMACY HELPDESK ACTIVITY FOR NOVEMBER 2025
4B: MEDICATION COVERAGE ACTIVITY FOR NOVEMBER 2025
Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> ACADEMIC DETAILING PROGRAM UPDATE
5A: BACKGROUND
5B: CURRENT TOPICS: CO-PRESCRIBING OPIOID MEDICATIONS WITH BENZODIAZEPINES (BZD) AND NALOXONE
5C: PRESCRIBER MAILINGS AND RESULTS: CO-PRESCRIBING OPIOID MEDICATIONS WITH BZD AND NALOXONE
5D: SUMMARY
Materials included in agenda packet; presented by Dr. Snyder
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> SOONERCARE MAINTENANCE DRUG LIST
6A: INTRODUCTION
6B: SOONERCARE MAINTENANCE DRUG LIST
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE BRINSUPRI™ (BRENSOCATIB)
7A: MARKET NEWS AND UPDATES
7B: BRINSUPRI™ (BRENSOCATIB) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE BILDYOS® (DENOSUMAB-NXXP), BILPREVDA® (DENOSUMAB-NXXP), BOMYNTRA® (DENOSUMAB-BNHT), CONEXXENCE® (DENOSUMAB-BNHT), OSENVELT® (DENOSUMAB-BMWO), AND STOBOCLO® (DENOSUMAB-BMWO) AND UPDATE THE APPROVAL CRITERIA FOR THE BONE DENSITIY REGULATORS
8A: MARKET NEWS AND UPDATES
8B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE FORZINITY™ (ELAMIPRETIDE)**

9A: MARKET NEWS AND UPDATES
9B: FORZINITY™ (ELAMIPRETIDE) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE RHAPSIDO® (REMIBRUTINIB)**

10A: MARKET NEWS AND UPDATES
10B: RHAPSIDO® (REMIBRUTINIB) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: **VOTE TO PRIOR AUTHORIZE HARLIKU™ (NITISINONE), ORFADIN® (NITISINONE), NITYR® (NITISINONE), AND SEPHIENCE™ (SEPIPTERIN) AND UPDATE THE APPROVAL CRITERIA FOR THE AMINO ACID DISORDER MEDICATIONS**

11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COST COMPARISONS
11D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss
Dr. Ground moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: **VOTE TO PRIORI AUTHORIZE ANZUPGO® (DELGOCITINIB 2% CREAM) AND UPDATE THE APPROVAL CRITERIA FOR ATOPIC DERMATITIS (AD) MEDICATIONS**

12A: MARKET NEWS AND UPDATES
12B: ANZUPGO® (DELGOCITINIB 2% CREAM) PRODUCT SUMMARY
12C: COST COMPARISONS
12D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Kupiec
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: **VOTE TO PRIOR AUTHORIZE OMLYCLO® (OMALIZUMAB-IGEC) AND UPDATE THE APPROVAL CRITERIA FOR THE ASHTMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS**

13A: MARKET NEWS AND UPDATES
13B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: **VOTE TO PRIOR AUTHORIZE BORUZU® (BORTEZOMIB) AND LYNOZYFIC™ (LINVOSELTAMAB-GCPT) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE MYELOMA MEDICATIONS**

14A: MARKET NEWS AND UPDATES
14B: LYNOZYFIC™ (LINVOSELTAMAB-GCPT) PRODUCT SUMMARY
14C: COST COMPARISON: BORTEZOMIB PRODUCTS
14D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Sinko
Dr. Muñoz moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: **ANNUAL REVIEW OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)**

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
15C: PRIOR AUTHORIZATION OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIOSN

Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: **ANNUAL REVIEW OF SKIN CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KEYTRUDA QLEX™ (PEMBROLIZUMAB/BERAHYALURONIDASE ALFA-PMPH) AND OPDIVO QVANTIG™ (NIVOLUMAB/HYALURONIDASE-NVHY)**

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF SKIN CANCER MEDICATIONS
16C: PRIOR AUTHORIZATION OF SKIN CANCER MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF SKIN CANCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 17: **ANNUAL REVIEW OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE IMAAVY™ (NIPOCALIMAB-AAHU)**

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
17C: PRIOR AUTHORIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
17D: MARKET NEWS AND UPDATES
17E: IMAAVY™ (NIPOCALIMAB-AAHU) PRODUCT SUMMARY
17F: COST COMPARISONS
17G: COLLEGE OF PHARMACY RECOMMENDATIONS
17H: UTILIZATION DETAILS OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 18: **30-DAY NOTICE TO PRIOR AUTHORIZE ALYGLO™ [IMMUNE GLOBULIN (IG) INTRAVENOUS (IV), HUMAN-STWK], ASCENIV™ (IGIV, HUMAN-SLRA), CUVITRU® (IG SUBCUTANEOUS (SC), HUMAN), GAMMAGARD LIQUID® (IG INFUSION, HUMAN), GAMMAGARD S/D® (IGIV, HUMAN), GAMMAPLEX® (IGIV, HUMAN), HIZENTRA® (IGSC, HUMAN), PANZYGA® (IGIV, HUMAN-IFAS), PRIVIGEN® (IGIV, HUMAN), AND XEMBIFY® (IGSC, HUMAN-KLHW)**

18A: INTRODUCTIONS
18B: COST COMPARISONS
18C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 19: **ANNUAL REVIEW OF THROMBOCYTOPENIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DOPTELET® SPRINKLE (AVATROMBOPAG) AND WAYRILZ™ (RILZABRUTINIB)**

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF THROMBOCYTOPENIA MEDICATIONS
19C: PRIOR AUTHORIZATION OF THROMBOCYTOPENIA MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: WALYRILZ™ (RILZABRUTINIB) PRODUCT SUMMARY
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF THROMBOCYTOPENIA MEDICATIONS

Materials included in agenda packet; presented by Dr. O'Halloran

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 20: **ANNUAL REVIEW OF MUSCLE RELAXANT MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ATMEKSI® (METHOCARBAMOL ORAL SUSPENSION), METAXALONE 640MG TABLET, AND TANLOR® (METHOCARBAMOL 1,000MG TABLET)**

20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF MUSCLE RELAXANT MEDICATIONS
20C: PRIOR AUTHORIZATION OF MUSCLE RELAXANT MEDICATIONS
20D: MARKET NEWS AND UPDATES
20E: PRODUCT SUMMARIES
20F: CARISOPRODOL PRODUCTS COST COMPARISON
20G: COLLEGE OF PHARMACY RECOMMENDATIONS
20H: UTILIZATION DETAILS OF MUSCLE RELAXANT MEDICATIONS

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 21: **30-DAY NOTICE TO PRIOR AUTHORIZE ANDEMBRY® (GARADACIMAB-GXII), DAWNZERA™ (DONIDALORSEN), AND EKTERLY® (SEBETRALSTAT) AND CREATE A PRODUCT BASED PRIOR AUTHORIZATION (PBPA) CATEGORY FOR THE HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS**

21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: MARKET NEWS AND UPDATES
21C: PRODUCT SUMMARIES
21D: ESTIMATION OF SAVINGS
21E: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 22: **ANNUAL REVIEW OF ANTIDEPRESSANTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ESCITALOPRAM 15MG CAPSULE AND RALDESY™ (TRAZODONE ORAL SOLUTION)**

22A: CURRENT PRIOR AUTHORIZATION CRITERIA
22B: UTILIZATION OF ANTIDEPRESSANTS
22C: PRIOR AUTHORIZATION OF ANTIDEPRESSANTS
22D: MARKET NEWS AND UPDATES
22E: COST COMPARISONS
22F: COLLEGE OF PHARMACY RECOMMENDATIONS
22G: UTILIZATION DETAILS OF ANTIDEPRESSANTS

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 23: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES**
Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**
NO LIVE DUR MEETING IS SCHEDULED FOR JANUARY 2026. JANUARY 2026 WILL BE A PACKET ONLY MEETING.

24A: ADIPOSITY-BASED CHRONIC DISEASE (ABCD) MEDICATIONS
24B: ANTIHYPERLIPIDEMICS
24C: ANTIHYPERTENSIVE MEDICATIONS
24D: GASTROINTESTINAL (GI) CANCER MEDICATIONS
24E: NON-MALIGNANT SOLID TUMOR MEDICATIONS
24F: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)
24G: OPHTHALMIC ANTIBIOTIC MEDICATIONS

*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 25: **ADJOURNMENT**
The meeting was adjourned at 5:57pm.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: December 12, 2025

To: Terry Cothran, D.Ph.
Pharmacy Director
Oklahoma Health Care Authority

From: Michyla Adams, Pharm.D.
Drug Utilization Review (DUR) Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting on December 10, 2025

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Academic Detailing (AD) Program Update

NO ACTION REQUIRED.

Recommendation 3: SoonerCare Maintenance Drug List

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following additions to the maintenance drug list based on net costs (changes shown in red):

- Alzheimer's Medications
- Anticonvulsants
- Antidepressants/Anxiolytics
- Antihistamines
- Antihypertensive Medications
- Antipsychotic Medications
- Anti-Ulcer Medications
- Bladder Control Medications

- Benign Prostatic Hyperplasia (BPH) Medications
- Cardiovascular Medications
- Chronic Obstructive Pulmonary Disease (COPD) Medications
- Diabetes Medications
- Fluoride Preparations
- Glaucoma Medications
- Hyperlipidemia Medications
- Non-Controlled Attention-Deficit/Hyperactivity Disorder (ADHD) Medications
- Osteoporosis Medications
- Parkinson's Medications
- Preeclampsia Prevention
- Smoking Cessation
- Thyroid Medications

Recommendation 4: Vote to Prior Authorize Brinsupri™ (Brensocatib)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Brinsupri™ (brensocatib) with the following criteria (shown in red):

Brinsupri™ (Brensocatib) Approval Criteria:

1. An FDA approved diagnosis of non-cystic fibrosis bronchiectasis (NCFB). Diagnosis must be confirmed by both of the following:
   a. Chest computed tomography (CT) scan; and
   b. Clinical history consistent with NCFB (e.g., cough, chronic sputum production, and/or recurrent respiratory infections); and
2. Member must be 12 years of age or older; and
3. Member must not have cystic fibrosis; and
4. Member must have a history of pulmonary exacerbation(s) (e.g., required treatment with antibiotics and/or required hospitalization or emergency room visit) in the last 12 months according to member's age:
   a. Members 18 years of age or older: ≥2 exacerbations; or
   b. Members 12-17 years of age: ≥1 exacerbation; and
5. Prescriber must verify that any underlying cause of NCFB is adequately treated, if applicable; and
6. Brinsupri™ must be prescribed by, or in consultation with, a pulmonary or infectious disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary or infectious disease specialist); and
7. Initial approvals will be for the duration of 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Brinsupri™ as demonstrated by a decrease in NCFB

symptoms and/or exacerbations. Subsequent approvals will be for 1 year.

Recommendation 5: Vote to Prior Authorize Bildyos® (Denosumab-nxxp), Bilprevda® (Denosumab-nxxp), Bomyntra® (Denosumab-bnht), Conexxence® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), and Stoboclo® (Denosumab-bmwo) and Update the Approval Criteria for the Bone Density Regulators

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Osteoporosis Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following PBPA Tier chart and additional criteria):

1. The prior authorization of Bildyos® (denosumab-nxxp), Conexxence® (denosumab-bnht), and Stoboclo® (denosumab-bmwo) with placement into the Special PA Tier with additional criteria similar to Prolia®; and
2. Designating Jubbonti® (denosumab-bbdz) at parity with Prolia® (denosumab) as the preferred osteoporosis-indicated denosumab products based on net costs.

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax®)	alendronate + vitamin D tabs (Fosamax® + D)	abaloparatide inj (Tymlos®)
calcium + vitamin D†	risedronate tabs (Actonel®)	alendronate effervescent tabs (Binosto®)
ibandronate tabs (Boniva®)		alendronate soln (Fosamax®)
zoledronic acid inj (Reclast®)		denosumab inj (Prolia®)
		denosumab-bbdz inj (Jubbonti®)
		denosumab-bmwo inj (Stoboclo®)
		denosumab-bnht inj (Conexxence®)
		denosumab-nxxp inj (Bildyos®)
		ibandronate inj (Boniva® IV)
		risedronate 30mg tabs (Actonel®)
		risedronate DR tabs (Atelvia®)
		romosozumab-aqqg (Evenity®)
		teriparatide inj (Forteo®) – **Brand Preferred**

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
		teriparatide inj (Bonsity®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†OTC calcium + vitamin D must be used at recommended doses in conjunction with Tier-1 bisphosphonates for trial to be accepted unless member has a recent laboratory result showing adequate vitamin D or member is unable to tolerate calcium. OTC calcium + vitamin D are only covered for members with osteoporosis who are being treated with a bisphosphonate.
¥Unique criteria applies to medications in the Special PA Tier.
DR = delayed-release; inj = injection; PA = prior authorization; soln = solution; tabs = tablets

Bildyos® (Denosumab-nxxp), Boniva® [Ibandronate Intravenous (IV) Solution], Conexxence® (Denosumab-bnht), Jubbonti® (Denosumab-bbdz), ~~and~~ Prolia® (Denosumab), and Stoboclo® (Denosumab-bmwo) Approval Criteria:

1. A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or
2. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and
3. For Bildyos®, Conexxence®, ~~Jubbonti®,~~ and Stoboclo® a patient-specific, clinically significant reason why the member cannot use Jubbonti® or Prolia® must be provided.
    a. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

The College of Pharmacy also recommends the prior authorization of Bilprevda® (denosumab-nxxp), Bomyntra® (denosumab-bnht), and Osenvelt® (denosumab-bmwo) with criteria similar to Xgeva® (denosumab) and to designate Wyost® (denosumab-bbdz) as a preferred oncology-indicated denosumab product along with Xgeva® based on net costs (changes shown in red):

Bilprevda® (Denosumab-nxxp), Bomyntra® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), Wyost® (Denosumab-bbdz), and Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or
    b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
        i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or

c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
    i. Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of ~~Xgeva®~~ therapy; and

2. For Bilprevda®, Bomyntra®, and Osenvelt® ~~Wyost® (denosumab-bbdz),~~ a patient-specific, clinically significant reason why the member cannot use Wyost® or Xgeva® must be provided.
    a. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.
3. These products will be covered as a medical benefit only.

Recommendation 6: Vote to Prior Authorize Forzinity™ (Elamipretide)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Forzinity™ (elamipretide) with the following criteria (shown in red):

Forzinity™ (Elamipretide) Approval Criteria:

1. An FDA approved diagnosis of Barth syndrome; and
    a. Diagnosis must be confirmed by genetic testing identifying a hemizygous pathogenic variant in the *TAFAZZIN* gene (results of genetic testing must be submitted); and
2. Member's current weight must be provided and must be ≥30kg; and
3. Member's current estimated glomerular filtration rate (eGFR) must be provided and:
    a. Requested dose must be appropriate for the member's eGFR, per package labeling; and
    b. Member must not be on dialysis; and
4. Must be prescribed by, or in consultation with, a specialist with expertise in the treatment of Barth syndrome (or an advanced care practitioner with a supervising physician who is a specialist with expertise in the treatment of Barth syndrome); and
5. Prescriber must confirm the member and/or caregiver will be trained on the proper administration and storage of Forzinity™ prior to starting treatment; and
6. Initial approvals will be for a duration of 6 months. After 6 months of treatment, subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by an improvement in muscle strength, fatigue, or other clinical symptoms of the disease; and
7. A quantity limit of 14mL per 28 days will apply.

Recommendation 7: Vote to Prior Authorize Rhapsido® (Remibrutinib)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Rhapsido® (remibrutinib) with the following criteria (shown in red):

Rhapsido® (Remibrutinib) Approval Criteria:

1. An FDA approved diagnosis of chronic spontaneous urticaria (CSU); and
2. Member must be 18 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Member must have an Urticaria Activity Score (UAS) ≥16; and
5. Rhapsido® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Member must have a documented trial of (or have a contraindication or documented intolerance to) all of the following therapies:
    a. Second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
    b. Xolair® (omalizumab) for at least 12 weeks at recommended dosing; and
7. Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

Recommendation 8: Vote to Prior Authorize Harliku™ (Nitisinone), Orfadin® (Nitisinone), Nityr® (Nitisinone), and Sephience™ (Sepiapterin) and Update the Approval Criteria for the Amino Acid Disorder Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Harliku™ (nitisinone), Nityr® (nitisinone), and Orfadin® (nitisinone) with the following criteria (shown in red):

Harliku™ (Nitisinone), Nityr® (Nitisinone), and Orfadin® (Nitisinone) Approval Criteria [Alkaptonuria (AKU) Diagnosis]:

1. An indication to reduce urine homogentisic acid (HGA) in patients with alkaptonuria (AKU); and
    a. The diagnosis of AKU must be confirmed by 1 of the following (results of the selected test must be submitted with the request):

i. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the homogentisate 1,2-dioxygenase (HGD) gene; or
ii. Urine test for HGA showing >0.4 grams of HGA excreted in 24 hours; and

2. Nitisinone must be prescribed by, or in consultation with, a geneticist, rheumatologist, or specialist with expertise in the treatment of AKU; and
3. The prescriber must confirm the member will receive a baseline ophthalmologic examination prior to initiating nitisinone treatment; and
4. The prescriber must confirm the member has been counseled to report any unexplained ocular, neurologic, or other symptoms to their health care provider; and
5. Use of Harliku™ will require a documented failed trial of both generic nitisinone 2mg capsules and Nityr® (nitisinone) 2mg tablets and clinical justification as to why Harliku™ would be expected to confer a different response since it contains the same active ingredient (nitisinone); and
6. A quantity limit of 30 tablets for 30 days will apply; and
7. Initial approvals will be for the duration of 6 months; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
   a. Verification from the prescriber of continued response to therapy (i.e., decrease in urine HGA levels, improvement in joint pain, decrease in visible ochronosis).

Nityr® (Nitisinone) and Orfadin® (Nitisinone) Approval Criteria [Hereditary Tyrosinemia (HT-1) Diagnosis]:

1. An FDA approved diagnosis of HT-1; and
   a. The diagnosis of HT-1 must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
      i. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the fumarylacetoacetase hydrolase (FAH) gene; or
      ii. Elevated succinylacetone concentrations in the blood or urine; and
2. Documentation of active management with a tyrosine and phenylalanine restricted diet; and
3. Nitisinone must be prescribed by, or in consultation with, a geneticist or specialist with expertise in the treatment of HT-1; and
4. The prescriber must verify the member will receive appropriate ophthalmologic examinations; and
5. The prescriber must confirm the member has been counseled to report any unexplained ocular, neurologic, or other symptoms to their health care provider; and

6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
7. Initial approvals will be for the duration of 6 months; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
    a. Documentation of active management with a tyrosine and phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., decrease in plasma and/or urine succinylacetone concentration).

The College of Pharmacy recommends the prior authorization of Sephience™ (sepiapterin) with the following criteria (shown in red):

Sephience™ (Sepiapterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria (PKU); and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Sephience must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
5. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Member must meet 1 of the following (documentation must be provided):
    a. A 3-month trial with sapropterin with inadequate response, defined as blood phenylalanine ≥360micromol/L, despite consistent use in combination with dietary phenylalanine restriction; or
    b. Member is a non-responder to sapropterin defined as ≤30% decrease in phenylalanine after 30 days of sapropterin therapy in combination with dietary phenylalanine restriction; or
    c. A diagnosis of classic PKU (blood phenylalanine ≥1,200micromol/L at diagnosis or 2 null mutations in *trans*); or
    d. A patient specific, clinically significant reason why the member cannot use generic Kuvan® (sapropterin) must be provided; and
7. Initial approvals will be for 2 weeks. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and
    a. Members younger than 2 years of age will be approved for a longer dosage titration per the package labeling up to the maximum daily dosage of 60mg/kg/day. After which time, the prescriber must

verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; or
   b. If the member was initiated at 60mg/kg/day, then no additional approvals will be granted after a trial period of 2 weeks if the member did not respond to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
   a. Documentation of active management with a phenylalanine restricted diet; and
   b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

The College of Pharmacy also recommends updating the current approval criteria for the sapropterin products and Palynziq® (pegvaliase-pqpz) based on the new FDA approvals, guideline updates, and clinical practice (changes shown in red):

Javygtor™ (Sapropterin), ~~and~~ Kuvan® (Sapropterin), and Zelvysia™ (Sapropterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria (PKU); and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Member must not have 2 null mutations in *trans*; and
4. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
5. Sapropterin must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
6. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
7. Use of Javygtor™ (sapropterin) or Zelvysia™ (sapropterin) will require a patient specific, clinically significant reason why other generic formulations of sapropterin cannot be used; and
8. Initial approvals will be for the duration of 30 days. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
   a. If the member was initiated at 10mg/kg/day dose, then a subsequent trial of 20mg/kg/day for a duration of 30 days can be approved, after which time the prescriber must verify the member

responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; or

b. If the member was initiated at 20mg/kg/day dose, then no additional approvals will be granted after a trial period of 30 days if the member did not respond to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and

9. Subsequent approvals will be for the duration of 1 year; and
10. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved indication to reduce blood phenylalanine concentrations in members with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations >600micromol/L on existing management; and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Palynziq® must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
5. Concomitant use with Kuvan® (sapropterin) or Sephience™ (sepiapterin) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
8. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
9. ~~Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Members should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L. Slower dose titrations may be approved based on member's response and tolerability; and~~

a. ~~If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; and~~
b. ~~If after at least 16 weeks with the 40mg dose, member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 60mg once daily dosing for an additional 16 weeks of treatment; or~~
c. ~~If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, subsequent approvals will be for the duration of 1 year; and~~

10. Initial approvals will be for 1 year to allow for initial titration and maintenance treatment. Reauthorization may be granted if the following information is provided (documentation must be submitted):
    a. Member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline; or
    b. Member has achieved a blood phenylalanine concentration ≤600micromol/L; or
    c. Member is currently in the titration/maintenance phase of treatment, and the dose is being titrated up to the maximum daily dose of 60mg once daily. Slower dose titrations may be approved based on member's response and tolerability; and
11. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L after at least 16 weeks of continuous treatment with the maximum dosage of 60mg once daily will not be approved for subsequent approvals; and
12. Dose titrations up to the maximum daily dose of 60mg once daily will be permitted to allow members to achieve a blood phenylalanine level ≤360micromol/L based on the current treatment guideline goal for blood phenylalanine level; and
13. Subsequent approvals will be for the duration of 1 year; and
14. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

Recommendation 9: Vote to Prior Authorize Anzupgo® (Delgocitinib 2% Cream) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Anzupgo® (delgocitinib 2% cream) with the following criteria (shown in red):

Anzupgo® (Delgocitinib 2% Cream) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe chronic hand eczema (CHE) meeting 1 of the following:
   a. Hand eczema has persisted for >3 months; or
   b. Hand eczema has returned twice or more within the last 12 months; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
4. Prescriber must attest that the member has been counseled regarding standard non-medicated skin care, including but not limited to:
   a. Frequent use of emollients/moisturizers; and
   b. Washing hands in lukewarm (not hot) water; and
   c. Avoidance of known and relevant irritants and allergens where possible; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
   b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
6. Concurrent use with other Janus kinase (JAK) inhibitors or potent immunosuppressants will not generally be approved; and
7. Member must be counseled to apply Anzupgo® only to the hands and wrists. Anzupgo® will not be approved for application to any other area; and
8. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
9. A quantity limit of 60 grams per 30 days will apply.

The College of Pharmacy also recommends updating the Nemluvio® (nemolizumab-ilto) and Opzelura® (ruxolitinib 1.5% cream) approval criteria based on recent FDA approvals and DUR Board recommendations from the November 2025 DUR Board meeting (changes shown in red):

Nemluvio® (Nemolizumab-ilto) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies; and
2. Member must be 12 years of age or older; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member must agree to continue using a topical corticosteroid and/or a topical calcineurin inhibitor in combination with Nemluvio® until the disease has sufficiently improved; and
5. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
6. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and
7. Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
8. Requests for concurrent use of Nemluvio® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Nemluvio® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the initial dosing for the duration of 16 weeks; and
10. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
    a. A dosage of 30mg every 8 weeks will be approved for reauthorization; or
    b. If a dosage of 30mg every 4 weeks is requested for reauthorization, additional patient-specific information will be required to support the need for continuing the every 4 week dosing regimen.

Opzelura® (Ruxolitinib 1.5% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved indication for short-term and non-continuous treatment of mild-to-moderate atopic dermatitis; and

2. Member must be ~~12~~ 2 years of age or older; and
3. Member must not be immunocompromised; and
4. Member must have a body surface area (BSA) involvement ≤20%; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with ~~all~~ 2 of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); ~~and~~ or
   b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; ~~and~~ or
   c. Eucrisa® (crisaborole); and
6. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and
7. Prescriber must verify female members are not breastfeeding; and
8. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the Opzelura® pregnancy registry; and
9. Approvals will be for a maximum duration of 8 weeks of treatment; and
10. Reauthorization may be considered if member has a recent TCS, TCI, or Eucrisa® trial (or a contraindication or documented intolerance); and
    a. Additionally, the prescriber must document the member had a positive response to and tolerated previous treatment with Opzelura®; and
11. Subsequent approvals will only be considered once each 90-day period to ensure appropriate short-term and non-continuous utilization.

Next, the College of Pharmacy recommends updating the Zoryve® (roflumilast) approval criteria based on recent FDA approvals and DUR Board recommendations from the November 2025 DUR Board meeting (changes shown in red):

Zoryve® (Roflumilast 0.15% or 0.05% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of mild-to-moderate atopic dermatitis; and
2. ~~Member must be 6 years of age or older; and~~
3. Requested product must be FDA approved for the member's age; and
   a. 0.15% Cream: Member must be 6 years of age or older; or
   b. 0.05% Cream: Member must be 2 to 5 years of age; and
4. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
   b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and

c. Eucrisa® (crisaborole); and
5. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Cream or 0.3% Foam) Approval Criteria [Plaque Psoriasis Diagnosis]:

1. An FDA approved diagnosis of plaque psoriasis; and
2. ~~Member must be 6 years of age or older; and~~
3. Requested product must be FDA approved for the member's age; and
   a. 0.3% Cream: Member must be 6 years of age or older; or
   b. 0.3% Foam: Member must be 12 years of age or older; and
4. Member must have a body surface (BSA) involvement of ≤20% (or ≤25% if both the scalp and body are being treated); and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. ~~Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and~~
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
   a. An ultra-high to high potency topical corticosteroid (TCS); or
   b. A generic topical calcipotriene product; or
   c. A topical tazarotene product; and
8. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
9. A quantity limit of 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Foam) Approval Criteria [Seborrheic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of seborrheic dermatitis; and
2. Prescriber must confirm member's condition is moderate or severe; and
3. Member must be 9 years of age or older; and
4. Member must have a body surface area (BSA) involvement of ≤20%; and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. ~~Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and~~
7. If the affected area is limited to the scalp, member must have documented trials within the last 6 months for a minimum of 2 weeks

that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
   a. Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione); and
   b. OTC coal tar shampoo; and
   c. Tier-1 prescription antifungal shampoo (e.g., ketoconazole 2% shampoo); and
   d. Tier-1 topical corticosteroid; and
8. If the affected area includes the face or body, member must have documented trials within the last 6 months for a minimum of at least 2 weeks that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
   a. Tier-1 topical antifungal (e.g., ketoconazole, ciclopirox); and
   b. Tier-1 topical corticosteroid; and
   c. Topical calcineurin inhibitor (e.g., pimecrolimus 1% cream, tacrolimus 0.1% ointment); and
9. Initial approvals will be for a duration of 8 weeks. After 8 weeks, the prescriber will need to provide clinical documentation that the member is improving on the medication and provide justification for continuation of therapy; and
10. A quantity limit of 60 grams per 30 days will apply.

Lastly, the College of Pharmacy recommends updating the Elidel® (pimecrolimus cream) and Protopic® (tacrolimus ointment) approval criteria based on DUR Board recommendations from the November 2025 DUR Board meeting (changes shown in red):

Elidel® (Pimecrolimus Cream) and Protopic® (Tacrolimus Ointment) Approval Criteria:

1. The first 90 days of a 12-month period will be covered without prior authorization; and
2. After the initial period, authorization may be granted with documentation of 1 trial with a Tier-1 topical corticosteroid at least 6 weeks in duration within the past 90 days; and
3. Therapy will be approved only once each 90-day period to ensure appropriate short-term and intermittent utilization as advised by the FDA; and
4. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas; and
5. Authorizations will be restricted to those members who are not immunocompromised; and
~~6. Members must meet all of the following criteria:~~
   ~~a. An FDA approved indication:~~
      ~~i. Elidel®: Short-term and intermittent treatment for mild-to-moderate atopic dermatitis (eczema); or~~

~~ii. Protopic®: Short-term and intermittent treatment for moderate-to-severe atopic dermatitis (eczema); and~~

~~b. Age restrictions:~~

~~i. Elidel® 1% is restricted to 2 years of age and older; and~~

~~ii. Protopic® 0.03% is restricted to 2 years of age and older; and~~

~~iii. Protopic® 0.1% is restricted to 15 years of age and older; or~~

7. Clinical exceptions for the trial requirement may be considered for the following:
   a. Documented adverse effect, drug interaction, or contraindication to Tier-1 topical corticosteroids; or
   b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids.~~; or~~

~~8. Clinical exceptions for the age restrictions (for members younger than the FDA approved age) may be considered for the following:~~

~~a. Prescribed by a dermatologist.~~

Recommendation 10: Vote to Prior Authorize Omlyclo® (Omalizumab-igec) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Omlyclo® (omalizumab-igec) with criteria similar to Xolair® (omalizumab) and recommends updating the approval criteria for the asthma diagnosis to reflect the Global Initiative for Asthma (GINA) guidelines, for the chronic idiopathic urticaria diagnosis to be consistent with the FDA approved label, and all other diagnoses based on clinical practice (changes shown in red):

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Asthma Diagnosis]:

1. Diagnosis of severe persistent asthma [as per Global Initiative for Asthma (GINA) ~~National Asthma Education and Prevention Program (NAEPP)~~ guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least 1 perennial aeroallergen (positive perennial aeroallergens must be listed on the prior authorization request); and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and
5. Member's weight must be between 20kg and 150kg; and
6. Member must have failed a medium-to-high-dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
7. Prescribed ~~Xolair®~~ dose must be an FDA approved regimen per package labeling; and

8. For authorization ~~Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
9. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage ~~of Xolair®~~; and
10. ~~Xolair®~~ Must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
11. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
12. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
13. Initial approvals will be for the duration of 6 months ~~after which time compliance will be evaluated for continued approval.~~ Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Chronic ~~Idiopathic~~ Spontaneous Urticaria (~~CIU~~ CSU) Diagnosis]:

1. An FDA approved diagnosis of ~~CIU~~ CSU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. ~~Other potential causes of urticaria must be ruled out; and~~
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. For authorization ~~of Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and

7. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage ~~of Xolair®~~; and
8. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
9. A trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
10. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
11. Initial dosing will only be approved for 150mg every 4 weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every 4 weeks; and
12. ~~Initial approvals will be for the duration of 3 months at which time compliance will be evaluated for continued approval.~~
13. Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Immunoglobulin E (IgE)-Mediated Food Allergy Diagnosis]:

1. An FDA approved diagnosis of IgE-mediated food allergy for the reduction of allergic reactions; and
2. Member must be 1 year of age or older; and
3. Member must have a diagnosis of peanut, milk, egg, wheat, cashew, hazelnut, or walnut allergy confirmed by a positive skin test, positive in vitro test for food-specific IgE, or positive clinician-supervised oral food challenge; and
4. Prescriber must confirm member will use the requested product ~~Xolair®~~ with an allergen-avoidant diet; and

5. Member must have a pretreatment serum IgE level between 30 and 1,850 IU/mL; and
6. Member's weight must be between 10kg and 150kg; and
7. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescribed ~~Xolair®~~ dose must be an FDA approved regimen per package labeling; and
9. For authorization ~~of Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
10. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of ~~Xolair®~~; and
11. ~~Xolair®~~ Must be prescribed by an allergist or immunologist or the member must have been evaluated by an allergist or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
12. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
13. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to therapy. Additionally, compliance will be evaluated for continued approval.

Omlyclo® (Omalizumab-igec Injection) and Xolair® (Omalizumab Injection) Approval Criteria [Nasal Polyps Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and

5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/ pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
6. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
7. Member must have a pretreatment serum IgE level between 30 and 1,500 IU/mL; and
8. Member's weight must be between 31kg and 150kg; and
9. Prescribed ~~Xolair®~~ dose must be an FDA approved regimen per package labeling; and
10. For authorization ~~of Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
11. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage ~~of Xolair®~~; and
12. ~~Xolair®~~ Must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
13. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
14. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Next, the College of Pharmacy recommends the following changes to the Dupixent® (dupilumab), Nucala (mepolizumab), and Tezspire® (tezepelumab-ekko) approval criteria based on the new FDA approvals and to be consistent with the current guidelines (changes shown in red):

Dupixent® (Dupilumab Injection) Approval Criteria [Bullous Pemphigoid (BP) Diagnosis]:

1. An FDA approved diagnosis of BP; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that all other potential causes and/or diagnoses with a similar presentation to BP have been ruled out; and
4. Member must have both of the following:
    a. Bullous Pemphigoid Disease Area Index (BPDAI) activity score ≥24; and
    b. Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥4; and
5. Dupixent® must be prescribed by a dermatologist, or the member must have been evaluated by a dermatologist for BP within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist); and
6. Member must be using Dupixent® in combination with a tapering course of oral corticosteroids as outlined in the package labeling (or have a contraindication or documented intolerance); and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; or
    b. Oral corticosteroids; or
    c. Immunosuppressive agents (e.g., methotrexate, azathioprine, mycophenolate, cyclophosphamide); or
    d. Oral antibiotic agents (e.g., doxycycline, dapsone); and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Spontaneous Urticaria (CSU) Diagnosis]:

1. An FDA approved diagnosis of CSU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Member must have an Urticaria Activity Score (UAS) ≥16; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or

an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Member must have a documented trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
7. A patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use. (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

Dupixent® (Dupilumab injection) Approval Criteria [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member ~~has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and~~ is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2, COPD Assessment Test (CAT) ≥10]; and
4. Member must have a blood eosinophil count of ≥300 cells/mcL (can apply to either a recent level or a historical level prior to treatment); and
5. Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and
6. Member is inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
8. Dupixent® must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization

may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and

10. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab injection) Approval Criteria [Eosinophilic Esophagitis (EoE) Diagnosis]:

1. An FDA approved diagnosis of eosinophilic esophagitis (EoE) defined as:
   a. The presence of clinical symptoms of EoE ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
   b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf) in the esophagus]; and
2. Member must be 1 years of age or older and weigh ≥15kg; and
3. Dupixent® must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a gastroenterologist, allergist, or immunologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. Member must have documented trials for a minimum of 8 weeks that resulted in failure with 1 ~~both~~ of the following therapies (or have a contraindication or documented intolerance):
   a. One high-dose proton pump inhibitor; or ~~and~~
   b. One swallowed respiratory corticosteroid (e.g., budesonide); and
5. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
7. A quantity limit of 8mL (4 syringes) every 28 days will apply.

Nucala (Mepolizumab) Approval Criteria [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2, COPD Assessment Test (CAT) ≥10]; and
4. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or a historical level prior to treatment); and
5. Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or

≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and
6. Member is inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated; and
7. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Tezspire® (Tezepelumab-ekko) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in members with inadequately controlled CRSwNP; and
2. Member must be 12 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Tezspire® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/

congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Tezspire® in a health care facility, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or
10. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and
11. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Next the College of Pharmacy recommends updating the Cinqair® (resilizumab), Dupixent® (dupilumab), Fasenra® (benralizumab), Nucala (mepolizumab), and Tezspire® (tezepelumab-ekko) criteria to be consistent with the other asthma-indicated monoclonal antibodies (changes shown in red):

Cinqair® (Reslizumab) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment of members with severe asthma with an eosinophilic phenotype; and
2. Member must be 18 years of age or older; and
3. Member must have a blood eosinophil count ≥400cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and

7. Cinqair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
8. Cinqair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
10. Member's weight should be provided on prior authorization requests. Weights should have been taken within the last 4 weeks to provide accurate weight-based dosing.

Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in members with inadequately controlled CRSwNP; and
2. Member must be 12 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Dupixent® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and

10. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
11. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 2 syringes every 28 days will apply.

Dupixent® (Dupilumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma or Oral Corticosteroid-Dependent Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with moderate-to-severe eosinophilic phenotype asthma or oral corticosteroid-dependent asthma; and
2. Member must be 6 years of age or older; and
3. Member must meet 1 of the following:
    a. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); or
    b. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
4. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
7. Dupixent® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
9. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab) Approval Criteria [Prurigo Nodularis (PN) Diagnosis]:

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have a Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist for PN within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritus have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) diagnosis]:

1. An FDA approved indication for the treatment of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
   a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months; or
   b. Member must have refractory disease within the last 6 months following induction of standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and

5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent equal to or greater than 7.5mg/day) for a minimum of 4 weeks duration; and
6. Fasenra® must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Fasenra® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra; and
9. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant, and prescriber must verify the member is responding to Fasenra® as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dose regimen from baseline. Subsequent approvals will be for 1 year.

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and

6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Fasenra® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra; and
9. Fasenra must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. For members who require weight-based dosing, the member's recent weight, taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate dose according to package labeling; and
11. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled CRSwNP; and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Nucala must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care

practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/ pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
11. Requests for concurrent use of Nucala with other biologic medications will be reviewed on a case-by-case basis and will require patient specific information to support the concurrent use; and
12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved diagnosis of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
    a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months; or
    b. Member must have refractory disease within the last 6 months following induction of a standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥7.5mg/day) for a minimum of 4 weeks duration; and

6. Nucala must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dosing from baseline. Subsequent approvals will be for 1 year.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and

7. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Hypereosinophilic Syndrome (HES) Diagnosis]:

1. An FDA approved diagnosis of HES for ≥6 months without an identifiable non-hematologic secondary cause; and
2. Member must be 12 years of age or older; and
3. Member must have a past history of at least 2 confirmed HES flares [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of cytotoxic or immunosuppressive therapy, or hospitalization] within the past 12 months; and
4. Member must have a baseline blood eosinophil count of ≥1,000 cells/mcL in the last 4 weeks prior to initiating Nucala; and
5. Diagnosis of FIP1L1-PDGFRα kinase-positive HES will not be approved; and
6. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥10mg/day) for a minimum of 4 weeks duration or member is unable to tolerate corticosteroid therapy due to significant side effects from corticosteroid therapy; and
7. Nucala must be prescribed by a hematologist or a specialist with expertise in treatment of HES (or an advanced care practitioner with a supervising physician who is a hematologist or a specialist with expertise in treatment of HES); and
8. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or

9. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
10. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by fewer HES flares from baseline or a decrease in daily OCS dosing from baseline. Subsequent approvals will be for 1 year.

Tezspire® (Tezepelumab-ekko) Approval Criteria [Severe Asthma Diagnosis]:

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. For authorization of Tezspire® in a health care facility, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or
7. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and
8. Tezspire® must be prescribed by a pulmonologist or pulmonary specialist, or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months. ~~after which time compliance will be evaluated for continued approval~~ Reauthorization may be granted for the duration of 1 year, if the prescriber documents

the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and

10. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of umeclidinium/vilanterol (unbranded Anoro® Ellipta®) and removing the prior authorization from brand name Anoro® Ellipta® (umeclidinium/vilanterol) and designating it as brand preferred based on net costs, the following changes to the Ohtuvayre® (ensifentrine) approval criteria to be consistent with the current guidelines, and removing the prior authorization from Daliresp® (roflumilast) based on net costs (changes shown in red):

Umeclidinium/Vilanterol (Unbranded Anoro® Ellipta®) ~~Anoro® Ellipta® (Umeclidinium/Vilanterol)~~, Bevespi Aerosphere® (Glycopyrrolate/ Formoterol Fumarate), Duaklir® Pressair® (Aclidinium Bromide/Formoterol Fumarate), and Stiolto® Respimat® (Tiotropium/Olodaterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components or brand name Anoro® Ellipta® must be provided; and
4. Anoro® Ellipta® is brand preferred. Requests for unbranded umeclidinium/vilanterol will require a patient-specific, clinically significant reason why the member cannot use brand name Anoro® Ellipta®, which is available without prior authorization.

Ohtuvayre® (Ensifentrine) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and
3. Member ~~has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and~~ is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2, COPD Assessment Test (CAT) ≥10]; and
4. Member is inadequately controlled on dual or triple combination long-acting bronchodilator therapy (must have ≥3 claims for long-acting bronchodilators in the previous 6 months); and
5. Member must not be taking Daliresp® (roflumilast) concurrently with Ohtuvayre™; and
6. A quantity limit of 60 ampules (150mL) per 30 days will apply.

~~**Daliresp® (Roflumilast) Approval Criteria:**~~

~~1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) with history of chronic bronchitis; and~~
~~2. Forced expiratory volume (FEV) ≤50% of predicted; and~~
~~3. Member is inadequately controlled on long-acting bronchodilator therapy (must have 3 or more claims for long-acting bronchodilators in the previous 6 months).~~

Finally, the College of Pharmacy recommends the following changes to the Asthma and COPD Maintenance Medications Product Based Prior Authorization (PBPA) categories based on net costs (changes noted in red in the following PBPA Tier charts):

1. Moving Striverdi® Respimat® (olodaterol inhalation spray) from Tier-2 to Tier-1; and
2. Moving Tudorza® PressAir® (aclidinium inhalation powder) from Tier-1 to Tier-2; and
3. Making Arnuity® Ellipta® (fluticasone furoate) brand preferred.

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
Long-Acting Beta$_2$ Agonists* (LABA)	
olodaterol inhalation spray (Striverdi® Respimat®)	arformoterol nebulizer solution (Brovana®)
salmeterol inhalation powder (Serevent®)	formoterol nebulizer solution (Perforomist®)
	formoterol nebulizer solution kit
	~~**olodaterol inhalation spray (Striverdi® Respimat®)**~~
Long-Acting Muscarinic Antagonists (LAMA)	
~~**aclidinium inhalation powder (Tudorza® PressAir®)**~~	**aclidinium inhalation powder (Tudorza® PressAir®)**
tiotropium inhalation powder (Spiriva® HandiHaler®) – **Brand Preferred**	revefenacin inhalation solution (Yupelri®)
tiotropium soft mist inhaler (Spiriva® Respimat®)	
umeclidinium inhalation powder (Incruse® Ellipta®)	

*Tier-1 combination products that contain a long-acting beta$_2$ agonist (LABA) qualify for the LABA trial requirement.
Tier-1 medications do not require prior authorization.
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (QVAR® RediHaler®)	budesonide/formoterol (Symbicort Aerosphere®)
budesonide (Pulmicort Flexhaler®)	ciclesonide (Alvesco®)

budesonide/formoterol (Symbicort®)β – **Brand Preferred**	fluticasone propionate (Flovent®)
fluticasone furoate (Arnuity® Ellipta®) – **Brand Preferred**	fluticasone furoate/vilanterol (Breo® Ellipta®) – **Brand Preferred**
fluticasone propionate/salmeterol (Advair®)	fluticasone propionate/salmeterol (AirDuo RespiClick®)
mometasone furoate (Asmanex®)	mometasone furoate/formoterol 50mcg/5mcg (Dulera®)
mometasone furoate/formoterol (Dulera®)◊	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria apply to each Tier-2 product.
βDoes not include Breyna®; authorization of Breyna® requires a reason why the member cannot use the brand formulation (Symbicort®).
◊Includes all strengths other than Dulera® 50mcg/5mcg.

Recommendation 11: Vote to Prior Authorize Boruzu® (Bortezomib) and Lynozyfic™ (Linvoseltamab-gcpt) and Update the Approval Criteria for the Multiple Myeloma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Boruzu® (bortezomib) and Lynozyfic™ (linvoseltamab-gcpt) with the following criteria (shown in red):

Boruzu® (Bortezomib) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use generic Velcade® (bortezomib), which is available without a prior authorization, must be provided.

Lynozyfic™ (Linvoseltamab-gcpt) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; and
3. Member must be 18 years of age or older; and
4. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Next, the College of Pharmacy recommends adding new approval criteria for Blenrep (belantamab mafodotin-blmf) based on the recent FDA approval (new criteria shown in red):

Blenrep (Belantamab Mafodotin-blmf) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member must be 18 years of age or older; and
3. Used in combination with bortezomib and dexamethasone; and
4. Member has received at least 2 prior lines of therapy, including a proteasome inhibitor and immunomodulatory agent; and
5. Prescriber must verify the member will receive eye exams, including visual acuity and slit lamp ophthalmic examinations, at baseline, prior to each dose and promptly for any new or worsening symptoms; and
6. Prescriber must comply with the risk evaluation and mitigation strategy (REMS) requirements.

Additionally, the College of Pharmacy recommends updating the approval criteria for Abecma® (idecabtagene vicleucel) and Carvykti® (ciltacabtagene autoleucel) to be consistent with recent FDA label updates (changes shown in red):

Abecma® (Idecabtagene Vicleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥2 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma.
2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

Carvykti® (Ciltacabtagene Autoleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥1 prior line of therapy, including an immunomodulatory agent and a proteasome inhibitor; and
        i. Member must be refractory to lenalidomide; and
        ii. Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating the approval criteria for Darzalex® (daratumumab), Darzalex Faspro® (daratumumab/ hyaluronidase-fihj), Ninlaro® (ixazomib), Sarclisa® (isatuximab-irfc), Talvey® (talquetamab-tgvs), Tecvayli® (teclistamab-cqyv), and Xpovio® (selinexor) based on National Comprehensive Cancer Network (NCCN) recommendations (changes shown in red):

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Light Chain Amyloidosis Diagnosis]:

1. Relapsed/refractory light chain amyloidosis ~~as a single agent~~; ~~or~~ and
    a. Used as a single agent; or
    b. Used in combination with venetoclax for t(11;14) translocation; or
2. Newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone.

~~**Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Multiple Myeloma Diagnosis]:**~~

~~1. Diagnosis of multiple myeloma; and~~
~~2. Used in 1 of the following settings:~~
    ~~a. In combination with lenalidomide and dexamethasone as primary therapy in members who are ineligible for autologous stem cell~~

~~transplant (ASCT) or in members who have received at least 1 prior therapy; or~~

~~b. In combination with bortezomib, melphalan, and prednisone as primary therapy in members who are ineligible for ASCT; or~~

~~c. In combination with bortezomib, thalidomide, and dexamethasone or bortezomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for ASCT; or~~

~~d. After at least 1 prior therapy, in combination with 1 of the following:~~

~~i. Dexamethasone and bortezomib; or~~

~~ii. Carfilzomib and dexamethasone; or~~

~~iii. Dexamethasone and lenalidomide; or~~

~~iv. Cyclophosphamide, bortezomib, and dexamethasone; or~~

~~v. Pomalidomide and dexamethasone* [*previous therapy for this combination must include lenalidomide and a proteasome inhibitor (PI)]; or~~

~~vi. Selinexor and dexamethasone; or~~

~~e. In combination with lenalidomide and dexamethasone for members who are ineligible for ASCT or with cyclophosphamide, bortezomib, and dexamethasone as primary therapy or for disease relapse after 6 months following primary induction therapy with the same regimen; or~~

~~f. As a single agent in members who have received ≥3 prior therapies, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.~~

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
2. Used in 1 of the following settings:
   a. As primary therapy in members who are ineligible for autologous stem cell transplant (ASCT) and used in combination with:
      i. Lenalidomide and dexamethasone; or
      ii. Bortezomib, melphalan, and prednisone; or
   b. As primary therapy in members who are eligible for ASCT and used in combination with:
      i. Bortezomib and thalidomide or lenalidomide and dexamethasone; or
      ii. Carfilzomib, lenalidomide, and dexamethasone; or
   c. As maintenance therapy for response or stable disease following hematopoietic stem cell transplant (HCT) or primary myeloma therapy; and
      i. Used as a single agent; or
      ii. Used in combination with lenalidomide; or
   d. For disease relapse after 6 months following primary induction therapy with the same regimen and used in combination with:
      i. Lenalidomide and dexamethasone; or

ii. Cyclophosphamide, bortezomib, and dexamethasone; or

e. After at least 1 prior therapy, in combination with 1 of the following:
   i. Bortezomib and dexamethasone; or
   ii. Carfilzomib and dexamethasone; or
   iii. Lenalidomide and dexamethasone; or
   iv. Pomalidomide and dexamethasone (if previous therapy for this combination included lenalidomide and a proteasome inhibitor); or
   v. Cyclophosphamide, bortezomib, and dexamethasone; or
   vi. Selinexor and dexamethasone; or
   vii. Venetoclax and dexamethasone for patients with t(11:14) translocation; or

f. Used as a single-agent in members who have received ≥3 prior therapies, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Smoldering Myeloma Diagnosis]:

1. Diagnosis of high-risk smoldering myeloma (asymptomatic); and
2. Used a single agent.

Ninlaro® (Ixazomib) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of symptomatic multiple myeloma; and
2. Used in 1 of the following settings:
   a. As primary therapy; or
   b. Following disease relapse after 6 months following primary induction therapy with the same regimen, used in combination with 1 of the following regimens:
      i. Lenalidomide and dexamethasone; or
      ii. Cyclophosphamide and dexamethasone for transplant candidates only; or
      iii. Pomalidomide and dexamethasone if member has failed ≥2 prior therapies and demonstrated disease progression within 60 days; or
   c. As a single agent for maintenance therapy following response to primary myeloma therapy in transplant candidates or following hematopoietic stem cell transplant.

~~3. As a single-agent for the maintenance treatment of disease.~~

Sarclisa® (Isatuximab-irfc) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
   a. ~~Used in the first line setting~~ As primary therapy; and
      i. Used in combination with bortezomib, lenalidomide, and dexamethasone; ~~and~~ or
      ii. Used in combination with carfilzomib, lenalidomide, and dexamethasone for transplant eligible members; or

iii. Used in combination with lenalidomide and dexamethasone for transplant-deferred or when transplant is not indicated; or

~~b. Member is considered ineligible for autologous stem cell transplantation; or~~

2. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
   a. Used in 1 of the following settings:
      i. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
      ii. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

Talvey® (Talquetamab-tgvs) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Must meet 1 of the following:
   a. Used as a single agent in those who have ~~Member has~~ received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; ~~and~~ or
   b. Used in combination with teclistamab-cgyv in those who have received at least 3 prior lines of therapy; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Tecvayli® (Teclistamab-cqyv) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Must meet 1 of the following:
   a. Used as a single agent in those who have ~~Member has~~ received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; ~~and~~ or
   b. Used in combination with talquetamab-tgvs in those who have received at least 3 prior lines of therapy; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Xpovio® (Selinexor) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
2. Used in 1 of the following settings:
   a. In combination with dexamethasone in members who have received ≥4 prior therapies including refractory disease to ≥2 proteasome inhibitors (PIs), ≥2 immunomodulatory agents, and an anti-CD38 monoclonal antibody; or

b. Used in combination with bortezomib and dexamethasone in members who have failed at least 1 prior therapy; or
c. Used in combination with daratumumab or daratumumab/hyaluronidase and dexamethasone in members who have failed at least 1 prior therapy.

Recommendation 12: Fiscal Year 2025 Annual Review of Skysona® (Elivaldogene Autotemcel)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Skysona® (elivaldogene autotemcel) prior authorization criteria based on the FDA label updates (changes shown in red):

Skysona® (Elivaldogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of early, active cerebral adrenoleukodystrophy (CALD) in male members 4 to 17 years of age; and
2. Diagnosis must be confirmed by all of the following:
   a. Molecular genetic testing confirming a mutation in the *ABCD1* gene (results of genetic testing must be submitted); and
      i. Members must not have a full deletion of the *ABCD1* gene; and
   b. Lab results indicating elevated very long-chain fatty acids (VLCFAs); and
   c. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating the following:
      i. Loes score between 0.5 and 9 on the 34-point scale; and
      ii. Gadolinium enhancement (GdE+) on MRI of demyelinating lesions; and
   d. Neurological Function Score (NFS) of ≤1; and
3. Skysona® must be prescribed by a neurologist, endocrinologist, or hematologist/oncologist with expertise in the treatment of CALD and the administration of Skysona®; and
4. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
5. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
6. Member must not be taking statins, Lorenzo's oil, or dietary regimens used to lower VLCFA levels; and
7. Member must not have an immediate family member with known or suspected familial cancer syndrome (FCS); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to the package labeling; and

9. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Skysona®); and
10. Members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona®; and
11. Prescriber must verify members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
12. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Skysona®; and
13. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at least every 3 months ~~month 6 and month 12~~ and through assessments for evidence for clonal expansion or predominance at least twice in the first year after treatment with Skysona®, then ~~at least~~ annually thereafter for at least 15 years, ~~and with integration site analysis at months 6, 12,~~ and as warranted; and
14. Skysona® must be administered at a Skysona® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Skysona® dose from receipt to storage to administration; and
15. Approvals will be for 1 dose per member per lifetime.

Recommendation 13: Fiscal Year 2025 Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Keytruda Qlex™ (Pembrolizumab/Berahyaluronidase alfa-pmph) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 14: Fiscal Year 2025 Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Imaavy™ (Nipocalimab-aahu)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 15: 30-Day Notice to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Cuvitru® (IG Subcutaneous (SC), Human), Gammagard Liquid® (IG Infusion, Human), Gammagard S/D® (IGIV, Human), Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Panzyga® (IGIV, Human-ifas), Privigen® (IGIV, Human), and Xembify® (IGSC, Human – klhw)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 16: Fiscal Year 2025 Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 17: Fiscal Year 2025 Annual Review of Muscle Relaxant Medications and 30-Day Notice to Prior Authorize Atmeksi® (Methocarbamol Oral Suspension), Metaxalone 640mg Tablet, and Tanlor® (Methocarbamol 1,000mg Tablet)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 18: 30-Day Notice to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the Hereditary Angioedema (HAE) Medications

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 19: Fiscal Year 2025 Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 20: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 21: Future Business

NO ACTION REQUIRED.

- No live DUR Board meeting is scheduled for January 2026. January 2026 will be a packet-only meeting.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: January 16, 2026

To: Terry Cothran, D.Ph.
Pharmacy Director
Oklahoma Health Care Authority

From: Michyla Adams, Pharm.D.
Drug Utilization Review (DUR) Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Packet Meeting on January 14, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Appropriate Use of Riluzole in the SoonerCare Population

NO ACTION REQUIRED.

Recommendation 3: Fiscal Year 2025 Annual Review of Adiposity-Based Chronic Disease (ABCD) Medications and 30-day Notice to Prior Authorize Zepbound® (Tirzepatide)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 4: Fiscal Year 2025 Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Redemplo® (Plozasiran)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 5: Fiscal Year 2025 Annual Review of Antihypertensive Medications and 30-day Notice to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ (Hydrochlorothiazide Oral Suspension), Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution), and Univasc® (Moexipril)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 6: Fiscal Year 2025 Annual Review of Bowel Preparation Medications and 30-day Notice to Prior Authorize MoviPrep® (Polyethylene Glycol 3350 (PEG 3350)/Sodium Sulfate/ Sodium Chloride/Potassium Chloride/Sodium Ascorbate/Ascorbic Acid for Oral Solution)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 7: Fiscal Year 2025 Annual Review of Gastrointestinal (GI) Cancer Medications

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 8: Fiscal Year 2025 Annual Review of Non-Malignant Solid Tumor Medications and 30-day Notice to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 9: Fiscal Year 2025 Annual Review of Systemic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and 30-day Notice to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 10: Fiscal Year 2025 Annual Review of Ophthalmic Antibiotic Medications and 30-day Notice to Prior Authorize Levofloxacin Ophthalmic Solution

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 11: Fiscal Year 2025 Annual Review of Vasomotor Symptom (VMS) Medications and 30-day Notice to Prior Authorize EstroGel® (Estradiol 0.06% Gel) and Lynkuet® (Elinzanetant)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 12: 30-Day Notice to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas) and Xembify® (IGSC, Human)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY 2026.

Recommendation 13: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

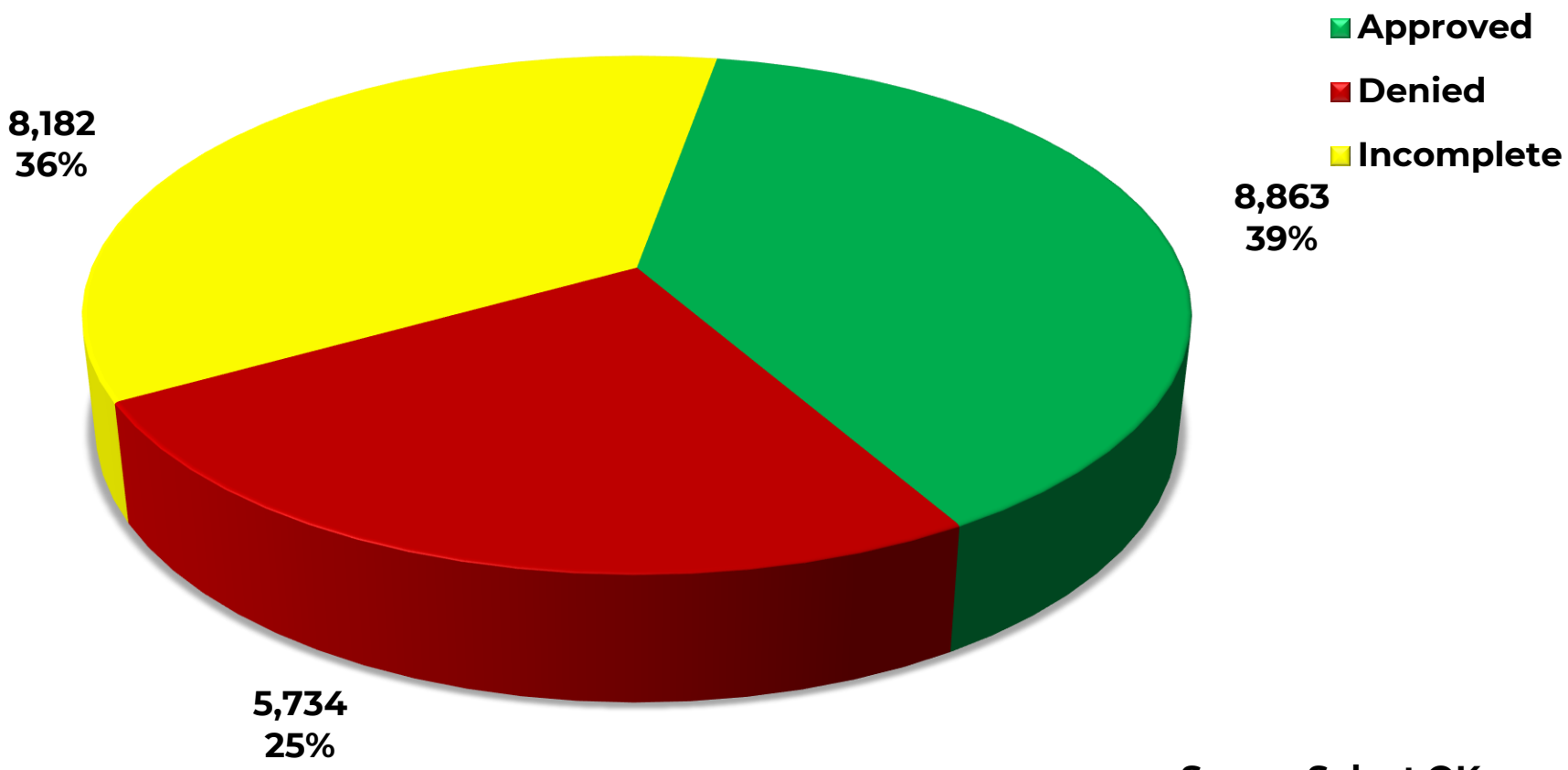
NO ACTION REQUIRED.

Recommendation 14: Future Business

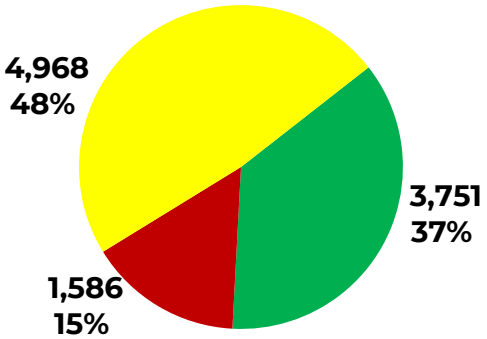
NO ACTION REQUIRED.

Appendix B

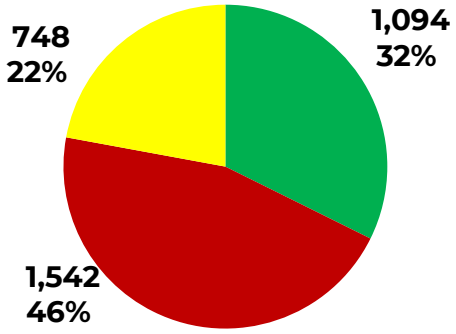
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JANUARY 2026



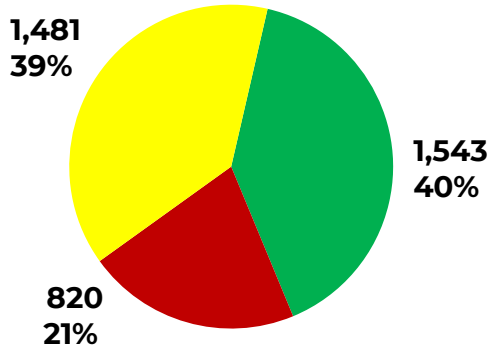
SoonerCare FFS



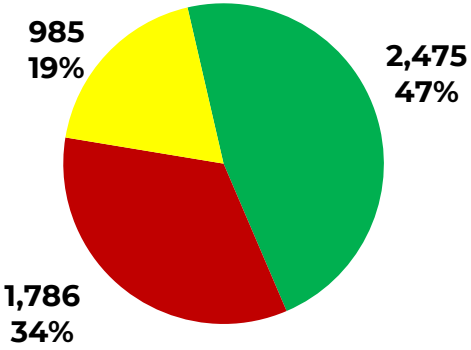
SoonerSelect Aetna



SoonerSelect Humana

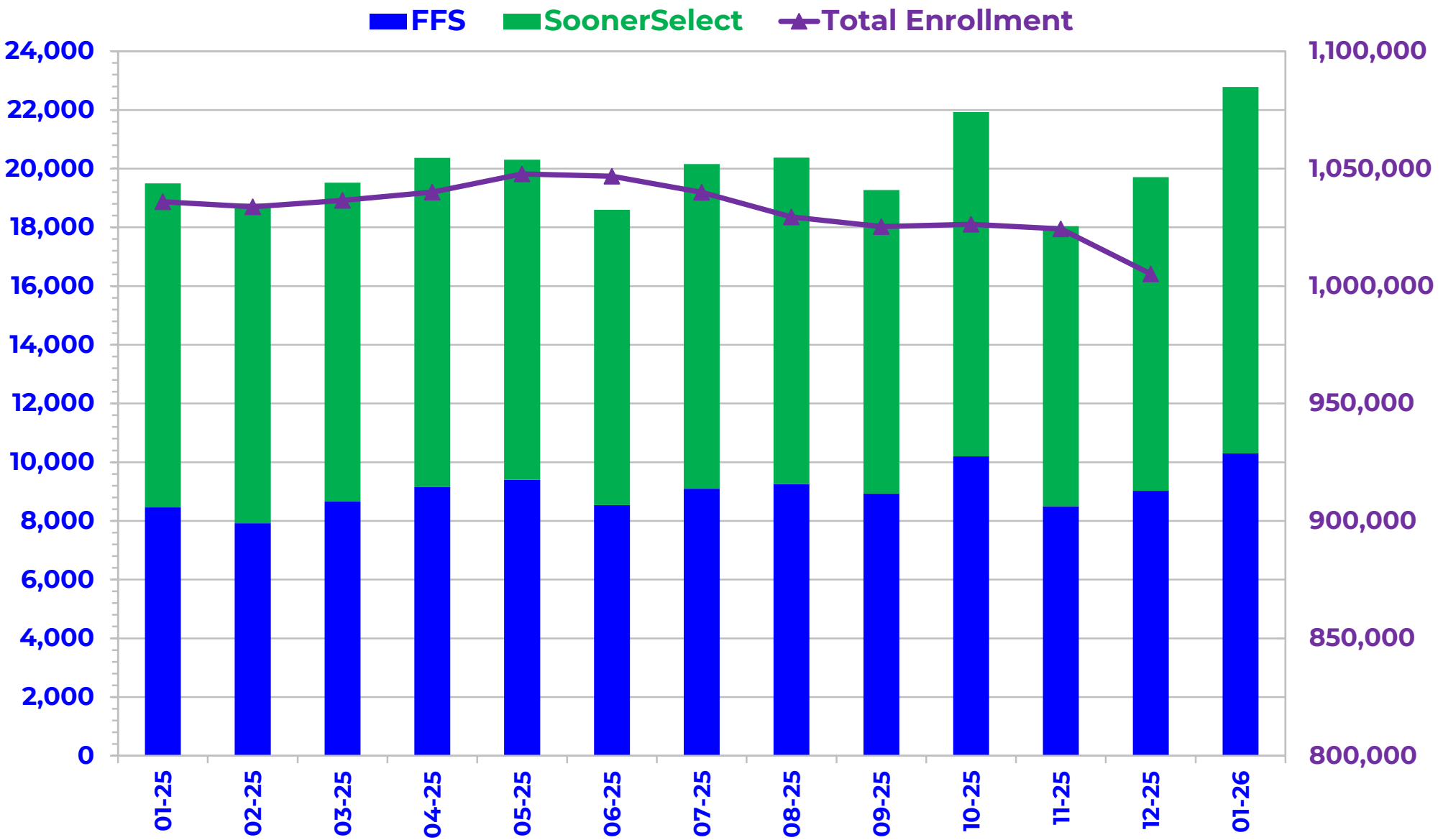


SoonerSelect OK Complete Health



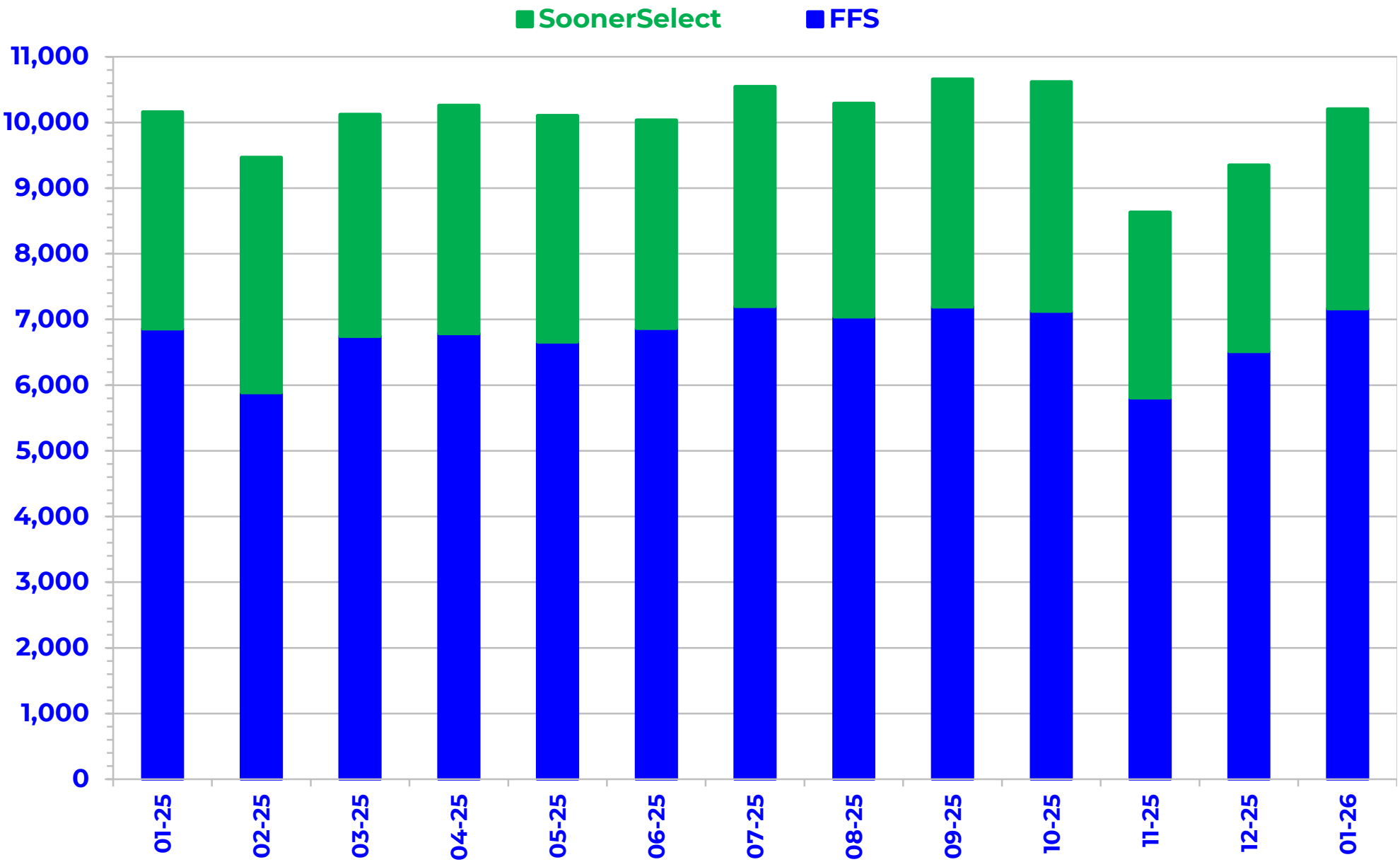
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: JANUARY 2025 – JANUARY 2026



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JANUARY 2025 – JANUARY 2026



SoonerCare FFS Prior Authorization Activity

1/1/2026 Through 1/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	1	1	2	176
Alternative Medicines	2	0	1	1	0
Amphetamines	874	470	70	334	356
Analgesics - Anti-Inflammatory	203	83	23	97	354
Analgesics - Nonnarcotic	9	0	1	8	0
Analgesics - Opioid	363	127	45	191	125
Androgens - Anabolic	77	12	22	43	344
Anorectal and Related Products	8	0	2	6	0
Antacids	1	1	0	0	360
Anthelmintics	20	3	3	14	11
Anti-infective Agents - Misc.	23	5	4	14	18
Anti-Obesity Agents	221	19	124	78	42
Antianginal Agents	1	0	0	1	0
Antianxiety Agents	42	4	2	36	154
Antiasthmatic and Bronchodilator Agents	618	114	106	398	489
Antibiotics	34	14	2	18	239
Anticoagulants	27	5	3	19	328
Anticonvulsants	275	121	14	140	374
Antidepressants	314	76	43	195	395
Antidiabetics	1,469	419	283	767	379
Antidotes and Specific Antagonists	1	0	1	0	0
Antiemetics	25	2	5	18	193
Antifungals	17	4	4	9	176
Antihistamines	35	6	11	18	317
Antihyperlipidemics	84	19	17	48	409
Antihypertensives	19	5	1	13	945
Antimalarials	1	1	0	0	358
Antineoplastics and Adjunctive Therapies	251	167	14	70	196
Antiparkinson and Related Therapy Agents	9	1	1	7	1,084
Antipsychotics/Antimanic Agents	376	147	26	203	373
Antivirals	14	5	2	7	63
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	273	183	12	78	969
Beta Blockers	19	6	1	12	790
Calcium Channel Blockers	15	4	1	10	907
Cardiotonics	2	0	0	2	0
Cardiovascular Agents - Misc.	122	59	12	51	426
Chemicals	1	0	0	1	0
Contraceptives	33	16	3	14	432
Corticosteroids	8	3	1	4	165
Cough/Cold/Allergy	2	0	2	0	0
Dermatologicals	496	138	128	230	212
Diagnostic Products	47	13	3	31	223
Dietary Products/Dietary Management Products	1	1	0	0	361
Digestive Aids	9	8	0	1	356
Diuretics	13	8	1	4	357
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	6	1	0	5	360
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	182	82	26	74	258
Estrogens	13	3	3	7	359

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents - Misc.	368	97	76	195	244
Genitourinary Agents - Misc.	4	0	3	1	0
Gout Agents	15	4	4	7	495
Hematological Agents - Misc.	26	8	0	18	360
Hematopoietic Agents	32	17	6	9	137
Histamine H3-receptor Antagonist/Inverse Agonists	5	3	0	2	136
Hypnotics/Sedatives/Sleep Disorder Agents	61	5	9	47	210
Laxatives	28	10	3	15	190
Medical Devices and Supplies	309	38	79	192	291
Migraine Products	414	109	101	204	252
Minerals and Electrolytes	14	4	3	7	185
Miscellaneous Therapeutic Classes	47	14	5	28	278
Mouth/Throat/Dental Agents	3	1	0	2	360
Multivitamins	7	5	0	2	359
Musculoskeletal Therapy Agents	49	7	9	33	269
Nasal Agents - Systemic and Topical	4	0	0	4	0
Neuromuscular Agents	79	35	29	15	356
Ophthalmic Agents	52	16	7	29	460
Other*	53	19	3	31	199
Otic Agents	24	8	2	14	23
Passive Immunizing and Treatment Agents	4	0	0	4	0
Progestins	4	0	1	3	0
Psychotherapeutic and Neurological Agents - Misc.	240	79	43	118	243
Respiratory Agents - Misc.	34	19	2	13	312
Stimulants - Misc.	255	115	14	126	343
Thyroid Agents	7	3	0	4	1,089
Ulcer Drugs/Antispasmodics/Anticholinergics	132	14	25	93	713
Urinary Antispasmodics	58	6	8	44	475
Vaginal and Related Products	3	0	1	2	0
Vitamins	49	5	33	11	213
Total	**9,039**	**2,997**	**1,490**	**4,552**	
Overrides					
Brand	50	23	2	25	368
Compound	18	15	1	2	38
Cumulative Early Refill	1	1	0	0	360
Dosage Change	145	129	1	15	16
High Dose	3	2	1	0	181
IHS-Brand	1	1	0	0	360
Ingredient Duplication	3	1	0	2	176
Lost/Broken Rx	37	31	3	3	32
MAT Override	8	6	0	2	233
NDC vs Age	169	106	15	48	492
NDC vs Sex	13	13	0	0	357
Nursing Home Issue	68	60	2	6	12
Opioid MME Limit	149	18	12	119	128
Opioid Quantity	23	7	6	10	147
Other	54	43	5	6	40
Prescriber Temp Unlock	1	0	0	1	0
Quantity vs Days Supply	437	257	27	153	355
STBS/STBSM	17	5	6	6	74
Step Therapy Exception	18	3	11	4	389

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Stolen	10	6	4	0	30
Third Brand Request	41	27	0	14	14
Overrides Total	**1,266**	**754**	**96**	**416**	
Total Regular PAs + Overrides	**10,305**	**3,751**	**1,586**	**4,968**	

Denial Reasons	
Unable to verify required trials.	4,247
Does not meet established criteria.	1,621
Lack required information to process request.	704
Other PA Activity	
Duplicate Requests	1,268
Letters	50,107
No Process	3
Helpdesk Initiated Prior Authorizations	405
PAs Missing Information	367
Pharmacotherapy	65
Changes to Existing PAs	659

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

SoonerSelect Aetna Prior Authorization Activity

1/1/2026 Through 1/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	284	170	104	10	361
Analgesics - Anti-Inflammatory	92	56	21	15	341
Analgesics - Nonnarcotic	8	1	6	1	365
Analgesics - Opioid	105	46	32	27	188
Androgens - Anabolic	62	6	52	4	365
Anorectal and Related Products	4	0	4	0	0
Anthelmintics	5	5	0	0	19
Antianxiety Agents	45	9	7	29	270
Antiasthmatic and Bronchodilator Agents	140	32	79	29	312
Antibiotics	10	1	4	5	365
Anticoagulants	7	0	0	7	0
Anticonvulsants	64	20	14	30	322
Antidepressants	205	48	73	84	566
Antidiabetics	497	133	268	96	324
Antidiarrheal/Probiotic Agents	1	1	0	0	90
Antidotes and Specific Antagonists	1	1	0	0	365
Antiemetics	12	2	4	6	186
Antifungals	2	1	1	0	90
Antihistamines	8	3	3	2	609
Antihyperlipidemics	31	3	12	16	181
Antihypertensives	16	0	2	14	0
Anti-Infective Agents - Misc.	7	3	2	2	35
Antimalarials	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	25	14	1	10	304
Anti-Obesity Agents	157	4	147	6	30
Antiparkinson and Related Therapy Agents	8	0	0	8	0
Antipsychotics/Antimanic Agents	163	42	70	51	346
Antivirals	2	0	1	1	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	71	55	14	2	780
Beta Blockers	21	0	1	20	0
Calcium Channel Blockers	11	0	2	9	0
Cardiovascular Agents - Misc.	33	13	12	8	316
Contraceptives	17	4	13	0	365
Corticosteroids	12	7	3	2	253
Cough/Cold/Allergy	3	0	0	3	0
Dermatologicals	289	118	121	50	245
Diagnostic Products	32	15	12	5	545
Digestive Aids	3	3	0	0	181
Diuretics	14	1	3	10	14
Endocrine and Metabolic Agents - Misc.	38	17	17	4	214
Estrogens	8	8	0	0	897
Gastrointestinal Agents - Misc.	87	32	46	9	249
Genitourinary Agents - Misc.	1	1	0	0	181
Gout Agents	6	2	0	4	365
Hematological Agents - Misc.	2	0	1	1	0
Hematopoietic Agents	34	8	24	2	307
Histamine H3-Receptor Antagonist/Inverse Agonists	2	2	0	0	186
Hypnotics/Sedatives/Sleep Disorder Agents	39	4	19	16	242

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Laxatives	12	1	7	4	365
Local Anesthetics-Parenteral	2	2	0	0	0
Medical Devices and Supplies	62	18	28	16	636
Migraine Products	191	62	119	10	220
Minerals and Electrolytes	14	1	1	12	365
Miscellaneous Therapeutic Classes	16	9	6	1	365
Musculoskeletal Therapy Agents	45	7	17	21	185
Nasal Agents - Systemic and Topical	24	1	11	12	365
Neuromuscular Agents	7	6	0	1	257
Ophthalmic Agents	27	6	14	7	254
Other	4	0	0	4	0
Otic Agents	9	0	9	0	0
Passive Immunizing and Treatment Agents	1	0	0	1	0
Progestins	3	3	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	23	7	15	1	186
Respiratory Agents - Misc.	3	2	1	0	273
Stimulants - Misc.	104	59	30	15	344
Thyroid Agents	3	0	2	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	75	11	25	39	345
Urinary Antispasmodics	18	3	11	4	365
Vaginal and Related Products	2	0	2	0	0
Vitamins	54	5	49	0	285
****Total**	**3,384**	**1,094**	**1,542**	**748**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Overrides					
Brand	2	2	0	0	228
Other	748	0	0	748	0
Quantity Level Limit	26	26	0	0	258
Step Therapy Met	1	1	0	0	30
Overrides Total	**777**	**29**	**0**	**748**	

Denial Reason	
Benefit	108
Experimental/Investigational	110
Lack Required Infomation to Process Request	88
Medical Necessity	1,233
Other	3
Other PA Activity	
Duplicate Requests	13
Letters	4,187
No Process	321
Changes to existing PAs	0
PAs missing info	12

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Humana Prior Authorization Activity

1/1/2026 Through 1/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	13	0	1	12	0
Analgesics - Anti-Inflammatory	64	52	2	10	341
Analgesics - Nonnarcotic	1	0	0	1	0
Analgesics - Opioid	77	26	20	31	269
Androgens - Anabolic	60	15	30	15	223
Anorectal and Related Products	6	1	0	5	61
Antacids	2	1	0	1	365
Anthelmintics	4	2	0	2	365
Antianxiety Agents	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	143	49	55	39	258
Antibiotics	10	1	1	8	365
Anticoagulants	10	1	5	4	41
Anticonvulsants	28	15	2	11	347
Antidepressants	68	33	12	23	277
Antidiabetics	312	99	128	85	217
Antiemetics	10	1	0	9	365
Antifungals	1	1	0	0	365
Antihistamines	2	0	0	2	0
Antihyperlipidemics	18	5	6	7	227
Antihypertensives	1	0	0	1	0
Anti-Infective Agents - Misc.	4	0	0	4	0
Antimalarials	4	0	0	4	0
Antineoplastics and Adjunctive Therapies	74	38	0	36	216
Anti-Obesity Agents	194	26	61	107	81
Antiparkinson and Related Therapy Agents	4	2	1	1	731
Antipsychotics/Antimanic Agents	9	3	0	6	548
Antivirals	5	2	1	2	150
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	13	10	2	1	562
Calcium Channel Blockers	1	0	0	1	0
Cardiovascular Agents - Misc.	31	10	4	17	446
Contraceptives	62	40	10	12	286
Corticosteroids	5	1	1	3	365
Dermatologicals	193	101	20	72	229
Diagnostic Products	25	14	6	5	322
Digestive Aids	1	0	0	1	0
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	2	0	0	183
Endocrine and Metabolic Agents - Misc.	46	29	3	14	239
Estrogens	3	0	0	3	0
Gastrointestinal Agents - Misc.	95	38	31	26	216
Gout Agents	7	2	0	5	152
Hematological Agents - Misc.	6	4	0	2	365
Hematopoietic Agents	10	4	1	5	365
Hypnotics/Sedatives/Sleep Disorder Agents	9	2	1	6	244
Laxatives	1	1	0	0	365
Medical Devices and Supplies	35	19	2	14	961
Migraine Products	152	79	51	22	214
Minerals and Electrolytes	1	0	0	1	0
Miscellaneous Therapeutic Classes	12	9	0	3	286

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Multivitamins	3	2	0	1	365
Musculoskeletal Therapy Agents	26	12	8	6	365
Neuromuscular Agents	30	16	1	13	266
Nutrients	1	1	0	0	365
Ophthalmic Agents	28	2	5	21	193
Other	7	0	0	7	0
Otic Agents	1	0	0	1	0
Passive Immunizing and Treatment Agents	3	0	0	3	0
Progestins	3	2	0	1	365
Psychotherapeutic and Neurological Agents - Misc.	49	29	3	17	264
Respiratory Agents - Misc.	6	4	0	2	297
Stimulants - Misc.	26	12	4	10	350
Thyroid Agents	1	0	0	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	17	4	0	13	264
Urinary Antispasmodics	11	0	8	3	0
Vaginal and Related Products	3	0	0	3	0
Vitamins	49	3	0	46	25
Total	**2,099**	**825**	**486**	**788**	
Overrides					
High Dose	1	1	0	0	365
Ingredient Duplication	154	92	39	23	179
NDC vs Age	403	273	12	118	410
Opioid MME Limit	11	8	1	2	298
Opioid Quantity	7	7	0	0	365
Other	216	68	82	66	110
Quantity vs Days Supply	208	132	36	40	255
STBS/STBSM	482	15	100	367	11
Step Therapy Exception	263	122	64	77	172
Overrides Total	**1,745**	**718**	**334**	**693**	
Total Regular PAs + Overrides	**3,844**	**1,543**	**820**	**1,481**	
Denial Reasons					
Alternatives Not Met					268
Medical Necessity					552

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Oklahoma Complete Health Prior Authorization Activity

1/1/2026 Through 1/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	930	657	159	114	1,093
Analgesics - Anti-Inflammatory	92	44	34	14	1,014
Analgesics - Nonnarcotic	9	0	5	4	0
Analgesics - Opioid	337	123	151	63	298
Androgens - Anabolic	72	14	46	12	1,095
Anorectal and Related Products	4	0	2	2	0
Anorexiants Non-Amphetamine	5	0	1	4	0
Anthelmintics	7	1	3	3	365
Antianxiety Agents	27	4	15	8	720
Antiasthmatic and Bronchodilator Agents	293	90	147	56	772
Antibiotics	21	9	3	9	261
Anticoagulants	6	4	2	0	594
Anticonvulsants	74	19	38	17	764
Antidepressants	160	47	81	32	940
Antidiabetics	646	307	236	103	899
Antidiarrheal/Probiotic Agents	2	0	0	2	0
Antidotes and Specific Antagonists	1	0	1	0	0
Antiemetics	21	2	7	12	354
Antifungals	6	4	2	0	207
Antihistamines	11	3	6	2	1,095
Antihyperlipidemics	24	2	20	2	637
Antihypertensives	6	3	2	1	351
Anti-Infective Agents - Misc.	10	2	1	7	180
Antimyasthenic/Cholinergic Agents	1	0	1	0	0
Antineoplastics and Adjunctive Therapies	73	44	11	18	520
Anti-Obesity Agents	182	8	119	55	463
Antiparkinson and Related Therapy Agents	2	0	2	0	0
Antipsychotics/Antimanic Agents	177	73	62	42	957
Antivirals	4	2	0	2	561
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	204	141	43	20	1,080
Beta Blockers	12	8	2	2	352
Calcium Channel Blockers	11	8	1	2	506
Cardiovascular Agents - Misc.	54	20	12	22	977
Chemicals	1	0	0	1	0
Contraceptives	23	8	12	3	476
Corticosteroids	9	5	1	3	304
Dermatologicals	305	121	116	68	480
Diagnostic Products	23	12	6	5	1,035
Digestive Aids	2	1	0	1	1,096
Diuretics	1	0	0	1	0
Endocrine and Metabolic Agents - Misc.	46	14	23	9	1,015
Estrogens	3	2	1	0	723
Gastrointestinal Agents - Misc.	128	50	40	38	890
Genitourinary Agents - Misc.	3	0	3	0	0
Gout Agents	1	0	1	0	0
Hematological Agents - Misc.	5	3	2	0	351
Hematopoietic Agents	26	4	9	13	484
Hypnotics/Sedatives/Sleep Disorder Agents	38	9	18	11	266

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Laxatives	22	7	5	10	651
Medical Devices and Supplies	123	80	21	22	947
Migraine Products	162	68	75	19	675
Miscellaneous Therapeutic Classes	20	12	5	3	526
Multivitamins	4	3	1	0	1,095
Musculoskeletal Therapy Agents	30	6	13	11	231
Nasal Agents - Systemic And Topical	8	2	5	1	1,095
Neuromuscular Agents	19	9	5	5	237
Ophthalmic Agents	41	17	12	12	479
Other	16	4	1	11	431
Otic Agents	20	1	14	5	365
Passive Immunizing and Treatment Agents	4	2	0	2	261
Pharmaceutical Adjuvants	2	2	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	42	12	24	6	860
Respiratory Agents - Misc.	12	7	4	1	1,095
Stimulants - Misc.	439	326	59	54	1,123
Thyroid Agents	17	11	2	4	721
Ulcer Drugs/Antispasmodics/Anticholinergics	55	12	31	12	695
Urinary Antispasmodics	27	6	14	7	720
Vaccines	2	0	2	0	0
Vaginal and Related Products	1	0	1	0	0
Vasopressors	2	2	0	0	723
Vitamins	80	18	45	17	895
****Total**	**5,246**	**2,475**	**1,786**	**985**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Denial Reasons	
Medical Necessity	1,786

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

Appendix C

Academic Detailing Program Update

Oklahoma Health Care Authority
February 2026

Background[1,2,3]

The Academic Detailing (AD) program is an educational initiative combining standards of care with the most current peer-reviewed studies and presenting them in an unbiased, independent, evidence-based manner. AD programs link prescribers with an educator, resulting in improved patient health and cost outcomes. Historically, AD programs that focus specifically on prescribing patterns are shown to reduce inappropriate prescribing to a modest, but significant degree, with a median difference of up to 7%. While not specifically designed to be a tool of cost containment, traditionally AD programs save $2 for every dollar spent.

Since July 2015, under the direction of the Oklahoma Health Care Authority (OHCA), Pharmacy Management Consultants (PMC) has operated an AD program to improve implementation of published guidelines and standards of pediatric care. Continued funding for the PMC-AD pediatric program is through a Health Service Initiative (HSI) grant under the Children's Health Insurance Program (CHIP). As such, special care is taken to identify topics with particular relevance to the care of pediatric members. In June 2023, the Oklahoma State Department of Health (OSDH) initiated the PMC-AD adult program with continued funding from OSDH. The adult program addresses safety and harm reduction strategies related to opioid use. Current and previous areas of focus include treatment of acute and chronic conditions, preventive care, and specialized technical training related to the delivery of pharmacy services. In consultation with OHCA, PMC clinical pharmacists, data analysts, and pharmacy graduate students analyze prescription claims data to determine AD topics, identify providers who may benefit from individualized support from an AD pharmacist, and assess outcomes.

For each topic, the PMC-AD pharmacist prepares educational materials in consultation with the National Resource Center for Academic Detailing (NaRCAD) and offers the program to providers. Educational materials include the following:

- Clinical treatment guidelines
- Provider resources
- Patient and parent resources
- Diagnostic and treatment tools
- Topic-specific continuing medical education (CME) course listings

- Drug alerts and statements from the U.S. Food and Drug Administration (FDA)
- National quality measures [e.g., Healthcare Effectiveness Data and Information Set (HEDIS)]
- OHCA Product Based Prior Authorization (PBPA) or Criteria Based Prior Authorization (CBPA) coverage criteria

To date, AD services have been provided to nearly 1,300 health care providers and/or their administrative staff and paid claims for all pediatric members have been used to determine the degree to which guidelines and best practice recommendations are followed by providers. Future AD services will be delivered to providers whose SoonerCare members' fee-for-service paid claims demonstrate possible areas of incomplete guideline implementation. As previously reported, changes in prescribing patterns and associated improvements in health care utilization have led to cost savings to OHCA in the amount of $4,551,008 through December 2025. This amount is inclusive of all federal and supplemental rebates for the analysis periods following AD on the treatment of the following for pediatric SoonerCare members:

- Attention-deficit/hyperactivity disorder (ADHD)
- Use of second generation/atypical antipsychotic medications (SGAs)
- Upper respiratory infections (URIs)
- Persistent asthma
- Diabetes
- Co-prescribing naloxone with opioid medications
- Depression
- Co-prescribing benzodiazepines with opioid medications

Current Topic: Pediatric Obesity[4,5,6,7,8,9]

In 2023, the American Academy of Pediatrics (AAP) released the first iteration of the Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. The guideline recommends pediatric primary care providers (PCPs) screen all children from 2 to 18 years of age for overweight, obesity, and severe obesity at least once per year. Screening includes:

- Height
- Weight
- Calculation of body mass index (BMI)
- Assessment of BMI percentile using age- and sex-specific Centers for Disease Control and Prevention (CDC) growth charts

Children with overweight or obesity should be evaluated for comorbidities and any metabolic abnormalities (e.g., lipids, glucose). Children 10 years of age and older should be further evaluated for risk factors for type 2 diabetes and non-alcoholic fatty liver disease [now often classified as metabolic dysfunction-associated steatotic liver disease (MASLD) or metabolic

dysfunction-associated steatohepatitis (MASH)]. Children 3 years of age and older with overweight or obesity should have their blood pressure measured at each office visit. The AAP also recommends PCPs use motivational interviewing techniques to offer intensive health behavior and lifestyle treatments. As an adjunct to health behavior and lifestyle treatment, pharmacotherapy or bariatric surgery should be offered.

The AAP guideline adds to the existing recommendations from the American Psychological Association (APA), the Pediatric Endocrine Society (PES), and the United States Preventive Services Task Force (USPSTF). The 2018 APA guideline notably supports use of family-based multicomponent behavioral interventions with ≥26 hours of contact for children with overweight or obesity. The 2017 PES guideline provided treatment and screening recommendations similar to both AAP and APA. However, the PES guideline specifically recommended against the use of pharmacotherapy except in the context of a clinical trial. The most recent USPSTF recommendation in 2024 states that children 6 years of age or older with a high BMI should be referred for comprehensive behavioral interventions.

In order to assess implementation of the existing best practice recommendations, the Centers for Medicare and Medicaid Services (CMS) includes the Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescent (WCC-CH) measure as a component of the Child Core Set (CCS). The WCC measure was developed by the National Committee for Quality Assurance (NCQA) and has been a CCS measure since 2010. The measure served as the basis for identifying providers for the most recent AD topic, pediatric obesity.

Data from SoonerCare paid pharmacy claims and member diagnoses were used to identify providers who stood to benefit from receiving Obesity-AD services. Prescribing and diagnosis data for pediatric members were compared across the following criteria, with Obesity-AD offered to SoonerCare providers meeting 4 or more of the following criteria:

1. Increase of ≥50% in the number of members with a diagnosis of obesity from 2023 to 2024
2. Having more members with obesity than their same specialty peers (e.g., general practitioner, physician assistant)
3. Having ≥20 members in their practice with obesity (excluding specialty providers)
4. Having ≥50% of members with an obesity diagnosis and without an obesity care paid claim
5. Having received AD for lack of metabolic monitoring for pediatric members receiving antipsychotics medications

Obesity-AD services were delivered by the PMC-AD pharmacist. Providers in co-practice with identified providers and those who had previously received detailing for other topics were also eligible to receive AD services. In total, 47 providers received Obesity-AD services. Obesity-AD was delivered through in-person visits, phone calls, and Zoom meetings.

Results: Obesity-Related Care[10,11,12,13]

Paid medical claims were compared for providers with members having an obesity diagnosis during an 8-month pre-AD period and an 8-month post-AD period. During the pre-AD period, across Oklahoma Medicaid 15,443 pediatric members had a diagnosis of obesity. Of those, 2,821 members received obesity-related care which includes 1 or more of the following:

- Dietary counseling
- Nutritional counseling
- Behavioral counseling
- Exercise class
- Weight management class
- Medical nutrition
- Examination for participation in sport

During the pre-AD period, providers who were selected to receive Obesity-AD services cared for 612 members with obesity. Of those, 68 members received obesity-related care as described above. Overall, detailed providers improved their quality of care for pediatric members with obesity. During the post-AD period, detailed providers cared for 784 members with obesity. Of those, 231 received obesity-related care. During the same time period, non-detailed providers cared for 19,692 members with obesity. Of those, 6,220 members received obesity-related care. While the prevalence of obesity among pediatric members appears to be increasing, Obesity-AD represents an 18.35% improvement in obesity-related care. Non-detailed providers also improved their care for members with obesity. However, the non-detailed providers improved by 13.32%. The Obesity-AD outcomes for detailed providers are shown in Figure 1.

Figure 1: Changes in Obesity Academic Detailing Outcomes

AD Providers (N=47)				
	Pre-AD	**Post-AD**	**Change**	**% Change**
Prescribing Patterns*				
Obesity care claims (AD)	11.11%	29.46%	**18.35%**	**165.18%**
Obesity care claims (non-AD)	18.27%	31.59%	**13.32%**	**72.91%**

AD = Academic detailing; N = Number of providers
* Positive indicates improvement

Based on peer-reviewed literature, pediatric obesity interventions that include clinical obesity-related care are associated with an average BMI reduction of 2.34 units per child over 24 months. Most of this reduction occurs

within the first 6 to 8 months after the intervention begins. Predictive economic models indicate that these interventions generally do not produce net cost savings within short-term evaluation periods. However, pediatric obesity care has consistently been shown to be cost-effective in multi-year economic models, the specifics of which are beyond the scope of this review. Cost savings are generally projected to begin after approximately 3.6 years, at which point annual health care savings of about $113 per person are expected. Applied to the obesity-AD population, this corresponds to estimated future annual savings of $17,402 attributable to obesity-related care. Across all parameters, detailed providers either maintained or improved their care for pediatric members living with obesity.

Provider Satisfaction

Provider satisfaction continues to remain very high as measured by post-visit satisfaction surveys. Providers meeting comparison criteria and those in co-practice were given satisfaction surveys in order to determine their acceptance of the program and to predict the likelihood of participation in future AD topics. Participants in the detailing sessions were given an online survey with an anonymous link and survey results are shown in Figure 2. To date, only 21 providers have been excluded from the PMC-AD program due to an unwillingness to participate. Other reasons for exclusion of targeted providers included the following:

- No longer treating the targeted disease or medication class
- Retired, moved out of state, or inactive license
- No longer treating pediatric patients
- No longer treating SoonerCare members

Figure 2: AD Provider Satisfaction

The information provided was:	**% choosing agree or strongly agree**
Easily understood	96%
Clearly presented	97%
Evidence-based	97%
Based on the information, I intend to:	**% choosing agree or strongly agree**
Make practice changes as a result	85%
Recommend this program to colleagues	86%
Participate in future topics	92%

AD = academic detailing

Academic Meeting Presentation(s)

Since July 2016, the PMC-AD program leaders have been invited to present program outcomes and breakout sessions at the International Conference on Academic Detailing, the Academy of Managed Care Pharmacy (AMCP), and the American Drug Utilization Review Society (ADURS). Additionally, a poster presentation featuring ADHD-AD results was awarded a silver ribbon at the

Nexus 2017 meeting of AMCP. The primary PMC-AD pharmacist is also currently 1 of 11 national training facilitators for NaRCAD.

Summary

As a result of AD interventions, the currently available data shows medication costs, PA submissions, inappropriate prescribing, and health care utilization costs have all been improved substantially. Prescription data has been analyzed using rebated and non-rebated data, pre-and post-detailing patterns for individual providers, and federal fiscal year and calendar year comparisons. Each analysis shows improvements following delivery of AD services.

Providers report satisfaction with the program and intend to participate in future topics. The AD program is well received by providers and targeted providers have fulfilled their stated intentions to make practice changes as prompted by the AD sessions. Continued implementation and expansion of the PMC-AD program is expected to increase delivery of evidence-based health care and reduce health care costs to OHCA.

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Appendix D

Narrow Therapeutic Index (NTI) Drug List

Oklahoma Health Care Authority
February 2026

Introduction[1,2,3]

The U.S. Food and Drug Administration (FDA) defines narrow therapeutic index (NTI) drugs as drugs where small differences in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions. NTI drugs generally have the following characteristics:

- Little separation between therapeutic and toxic doses
- Sub-therapeutic concentration may lead to serious therapeutic failure
- Drugs that are subject to therapeutic drug monitoring based on pharmacokinetic (PK) or pharmacodynamic (PD) measures
- In clinical practice, doses are often adjusted in very small increments (<20%)

The FDA Office of Generic Drugs assesses brand/generic interchangeability standards for NTI drugs. NTI drugs analyzed for bioequivalence by the FDA include warfarin, lithium, digoxin, theophylline, tacrolimus, phenytoin, levothyroxine, and carbamazepine. Other groups, including Health Canada, also include cyclosporine and sirolimus in their NTI drug classification group.

The Oklahoma Health Care Authority (OHCA) policy and rules state the following regarding brand necessary certification (317:30-5-77):

> "For certain narrow therapeutic index drugs, a prior authorization will not be required. The DUR Board will select and maintain the list of narrow therapeutic index drugs."

The purpose of this report is to provide the Drug Utilization Review (DUR) Board with the current SoonerCare NTI drug list for review, which is to be maintained by the DUR Board. Medications included in the NTI list are set up to bypass brand/generic substitution requirements in the claims processing system. Action by the DUR Board is not required unless the DUR Board recommends changes to the current NTI drug list.

SoonerCare NTI Drug List

- Carbamazepine
- Clozapine
- Cyclosporine
- Desipramine
- Digoxin
- Esketamine
- Levothyroxine
- Lithium
- Nortriptyline
- Phenytoin
- Sirolimus
- Tacrolimus
- Theophylline
- Warfarin

Recommendations

The College of Pharmacy does not recommend any changes to the SoonerCare NTI Drug List at this time.

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Appendix E

Vote to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib) and Update the Approval Criteria for the Thrombocytopenia Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5,6]

New U.S. Food and Drug Administration (FDA) Approval(s)

- **July 2025:** The FDA approved Doptelet® (avatrombopag) tablets for an expanded indication for the treatment of thrombocytopenia in pediatric patients 6 years of age and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to previous treatment. Additionally, a new Doptelet® Sprinkle capsule formulation was approved for the same indication in pediatric patients 1 year to younger than 6 years of age. Doptelet® Sprinkle capsule is available as a 10mg capsule that should be opened and sprinkled onto a small amount of soft food or liquid. Doptelet® tablets and Doptelet® Sprinkle capsules are not substitutable on a mg-to-mg basis.
- **August 2025:** The FDA approved Wayrilz™ (rilzabrutinib) for the treatment of adults with persistent or chronic ITP who have had an insufficient response to a previous treatment. Wayrilz™ is the first Bruton's tyrosine kinase (BTK) inhibitor approved for ITP.

News:

- **May 2025:** In May 2025, it was announced that Camber Pharmaceuticals was launching the first AB-rated generic formulation of Promacta® (eltrombopag olamine) tablets and oral suspension. Since the launch, additional eltrombopag generics have become available from other manufacturers.
- **November 2025:** The FDA announced a Safety Communication after receiving postmarketing reports of neutralizing antibodies to ADAMTS13, including 1 death, in patients with congenital thrombotic thrombocytopenia purpura (cTTP) who have been treated with Adzynma (ADAMTS13, recombinant-krhn). The reported death in a pediatric patient with cTTP appears to be related to Adzynma. Prior to treatment with Adzynma, the patient had severe allergic reactions to fresh frozen plasma (FFP). The patient presented with neurologic symptoms which progressed, and the presence of neutralizing

antibodies to ADAMTS13 were identified approximately 10 months after starting prophylactic treatment with Adzynma. It is important to note that current assays are unable to distinguish neutralizing antibodies to recombinant ADAMTS13 from neutralizing antibodies to endogenous ADAMTS13. The *Prescribing Information* includes information on the potential risk of development of neutralizing antibodies following treatment with Adzynma under *Warnings and Precautions – Immunogenicity*. Neutralizing antibodies were not reported in the cTTP clinical trials, and the current labeling does not include information regarding postmarketing reports of neutralizing antibodies associated with serious, including fatal, outcomes. The FDA is investigating the risk of development of neutralizing antibodies with serious, including life-threatening or fatal, outcomes following treatment with Adzynma and is evaluating the need for further regulatory action.

Wayrilz™ (Rilzabrutinib) Product Summary[7,8]

Therapeutic Class: BTK inhibitor

Indication(s): Treatment of adults with persistent or chronic ITP who have had an insufficient response to a previous treatment

How Supplied: 400mg oral tablet

Dosing and Administration:

- The recommended dose is 400mg twice daily.
- Wayrilz™ should be swallowed whole and should not be cut, crushed, or chewed.
- Pregnancy status in females of reproductive potential should be verified prior to initiating Wayrilz™.

Efficacy: The safety and efficacy of Wayrilz™ were studied in the Phase 3 LUNA3 trial, a randomized, double-blind, placebo-controlled, parallel group trial that evaluated Wayrilz™ versus placebo in adult patients with persistent or chronic ITP who had an insufficient response to a previous treatment for 24 weeks.

- Key Inclusion Criteria:
  - 18 years of age or older
  - 2 platelet counts of $<30x10^9$/L at least 5 days apart and no single platelet count $>35x10^9$/L
  - Prior response to intravenous immunoglobulin (IVIG)/anti-Rh_0(D), immunoglobulin infusion (anti-D), or CS that was not sustained and a documented intolerance, insufficient response, or contraindication to any other ITP therapy
  - Stable concomitant CS and/or thrombopoietin receptor agonist (TPO-RA) were allowed. Adjustments in the doses of concomitant

ITP medications were permitted for associated safety concerns only. Rescue medication to raise platelet counts was allowed for platelets of <20x10^9/L or bleeding/wet purpura.

- Key Exclusion Criteria:
  - Secondary ITP
  - Pregnant or lactating females
  - Treatment with rituximab or splenectomy within 3 months
- Intervention(s): Patients were randomized 2:1 to Wayrilz™ 400mg or placebo twice daily and randomization was stratified by prior splenectomy and thrombocytopenia severity.
  - Patients received an initial 12 weeks of double-blind treatment and responders (platelet response of ≥50x10^9/L, or >30x10^9/L to <50x10^9/L and at least doubling from baseline) could continue double-blinded treatment through week 24.
  - Non-responders could either discontinue from the study or enter the 28-week open label period and were classified as non-responders for the primary endpoint analysis.
- Endpoint(s):
  - Primary Endpoint:
    - Durable platelet response during a 24-week double-blind period, defined as a weekly platelet count ≥50x10^9/L for ≥two-thirds of ≥8 non-missing weekly scheduled platelet measurements during the last 12 weeks of the double-blind period in the absence of rescue therapy, provided that ≥2 non-missing weekly scheduled platelet measurements were ≥50x10^9/L during the last 6 weeks of the double-blind period.
  - Key Secondary Endpoint:
    - Number of weeks with platelet count ≥50x10^9/L or >30x10^9/L to <50x10^9/L and at least doubling from baseline without rescue therapy
    - Number of weeks with platelet counts ≥30x10^9/L to <50x10^9/L and at least doubling from baseline without rescue therapy
    - Time to first platelet response ≥50x10^9/L or between 30x10^9/L and <50x10^9/L and at least doubled from baseline without rescue therapy
    - Proportion of patients needing rescue therapy
- Results:
  - Primary Endpoint:
    - Achieved by 23.3% of patients who received Wayrilz™ vs. 0% of patients who received placebo [treatment difference: 23.1%; 95% confidence interval (CI): 15.95%, 30.31%; P<0.0001]
  - Key Secondary Endpoints:

- The improved durability of achieving multiple platelet count thresholds was consistently longer for Wayrilz™ vs. placebo.
- The least squares mean number of weeks with platelet response was 6.46 weeks (P<0.0001) for Wayrilz™ in all patients and 8.83 weeks (P<0.0001) for responders.
- Median time to platelet response was 36 days in all patients with Wayrilz™ vs. never achieved with placebo (P<0.0001) and 15 days for responders.
- 33% of patients on Wayrilz™ required rescue therapy vs. 58% on placebo. Wayrilz™ significantly reduced the need for rescue therapy by 52% (P=0.0007) with a median time to rescue therapy that was never reached for Wayrilz™ vs. 56 days for placebo.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Wayrilz™ (rilzabrutinib) 400mg tab	**$291.67**	**$17,500.20***	**$210,002.40**
Nplate® (romiplostim) 500mcg vial	$5,524.00	$44,192.00ᵝ	$574,496.00
Promacta® (eltrombopag olamine) 75mg	$708.16	$21,244.80⁺	$254,937.60
Alvaiz® (eltrombopag choline) 54mg tab	$622.92	$18,687.60ᵅ	$224,251.20
eltrombopag olamine (generic) 75mg tab	$558.25£	$16,747.50⁺	$200,970.00
Doptelet® (avatrombopag) 20mg tab	$439.62	$26,377.20¥	$316,526.40
Tavalisse® (fostamatinib) 150mg tab	$266.00	$15,960.00€	$191,520.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
tab = tablet; Unit = tablet or vial
£Cost varies per NDC
*Cost per month based on the FDA max recommended dose of 400mg twice daily
ᵝCost per month based on the FDA max recommended dose 10mcg/kg weekly for an 80kg patient
⁺Cost per month based on the FDA max recommended dose of 75mg once daily
ᵅCost per month based on the FDA max recommended dose of 54mg once daily
¥Cost per month based on the FDA max recommended dose of 40mg once daily
€Cost per month based on the FDA max recommended dose of 150mg twice daily

Recommendations

The College of Pharmacy recommends the prior authorization of Wayrilz™ (rilzabrutinib) with the following criteria (shown in red):

Wayrilz™ (Rilzabrutinib) Approval Criteria:

1. An FDA approved diagnosis of persistent or chronic immune thrombocytopenia (ITP); and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of ITP; and
4. Previous insufficient response to at least 2 of the following treatments:

a. Corticosteroids; or
b. Immunoglobulins; or
c. Splenectomy; or
d. Thrombopoietin receptor agonists; or
e. Fostamatinib; or
f. Rituximab; and

5. Prescriber must attest that all other causes of thrombocytopenia, including malignancy and liver disease, have been ruled out; and
6. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Wayrilz™ and during treatment as clinically indicated; and
7. Prescriber must verify that the member will be monitored for signs and symptoms of infection while on Wayrilz™; and
8. Member must not be taking any of the following medications concomitantly with Wayrilz™:
   a. Moderate to strong CYP3A inhibitors (e.g., itraconazole, clarithromycin); and
   b. Moderate to strong CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin); and
   c. Proton pump inhibitors; and
9. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 1 week after the last dose; and
10. Female members must not be breastfeeding during treatment and for at least 1 week after discontinuation of treatment; and
11. A quantity limit of 60 tablets per 30 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Doptelet® Sprinkle (avatrombopag) and updating the Doptelet® approval criteria based on the recent FDA approval and clinical practice (changes shown in red):

Doptelet® (Avatrombopag) and Doptelet® Sprinkle (Avatrombopag) Approval Criteria [Persistent or Chronic Immune Thrombocytopenia (ITP) Diagnosis]:

1. An FDA approved indication for the treatment of 1 of the following:
   a. Thrombocytopenia in adult members with chronic ITP who have had an insufficient response to a previous treatment; ~~and~~ or
   b. Thrombocytopenia in pediatric members 1 year of age or older with persistent or chronic ITP who have had an insufficient response to a previous treatment; and
2. Member must be 1 ~~18~~ year~~s~~ of age or older; and

3. Previous insufficient response with at least 1 of the following treatments:
   a. Corticosteroids; or
   b. Immunoglobulins; or
   c. Splenectomy; and
4. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
5. Prescriber must verify the degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
6. Prescriber must verify platelet counts will be assessed as per package labeling:
   a. Initiation of treatment: Weekly until a stable platelet count ~~>~~ ≥50 x 10^9/L has been achieved, and then obtained monthly thereafter; and
   b. Change in formulation: Weekly until a stable platelet count and dose will be adjusted as needed before resuming monthly monitoring; and
   c. Discontinuation: Weekly for 4 weeks following discontinuation; and
7. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
~~8. Doptelet® must not be used in an attempt to normalize platelet counts; and~~
9. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
10. Prescriber must verify female member is not breastfeeding; and
11. An age restriction will apply for Doptelet® Sprinkle. The sprinkle capsule formulation may be approvable for members 1 to 5 years of age. Members 6 years of age and older must use the tablet formulation; and
12. For Doptelet® Sprinkle, prescriber must verify that the member and/or caregiver has been counseled on the proper preparation and administration of Doptelet® Sprinkle; and
13. A quantity limit of 60 tablets or sprinkle capsules per 30 days will apply.

Doptelet® (Avatrombopag) Approval Criteria [Thrombocytopenia in Chronic Liver Disease (CLD) Diagnosis]:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with CLD who are scheduled to undergo a procedure; and
2. Date of procedure must be listed on the prior authorization request; and
3. Prescriber must verify the member will have the procedure within 5 to 8 days after the member receives the last dose of Doptelet®; and

4. Member must have a baseline platelet count <50 x 10^9/L (recent baseline platelet count must be provided); and
5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and
~~6. Doptelet® must not be used in an attempt to normalize platelet counts; and~~
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Prescriber must verify female member is not breastfeeding; and
9. A quantity limit of 15 tablets per scheduled procedure will apply.

Finally, the College of Pharmacy recommends making Promacta® (eltrombopag) brand preferred based on net costs and recommends updating the Alvaiz® (eltrombopag) and Mulpleta® (lusutrombopag) approval criteria based on clinical practice (changes show in red):

Eltrombopag (Generic Promacta®) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 1 year of age or older; and
3. Promacta® is brand preferred. Requests for generic eltrombopag will require a patient-specific, clinically significant reason why the member cannot use the brand formulation, which is available without prior authorization.

Alvaiz® (Eltrombopag) Approval Criteria [Persistent or Chronic Immune Thrombocytopenia (ITP) Diagnosis]:

1. An FDA approved diagnosis of persistent or chronic ITP; and
2. Member must have a platelet count of <30 x 10^9/L; and
~~3. Alvaiz® must not be used in an attempt to normalize platelet counts; and~~
4. Member must be 6 years of age or older; and
5. Member must not have a recent diagnosis of myelodysplastic syndromes; and
6. Previous insufficient response to at least 1 of the following treatments:
    a. Corticosteroids; or
    b. Immunoglobulins; or
    c. Splenectomy; and
7. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
8. Prescriber must attest that all other causes of thrombocytopenia, including malignancy and liver disease, have been ruled out; and
9. Prescriber must verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and

10. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz®; and
11. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of ITP; and
12. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 54mg per day, as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 90 tablets per 30 days; or
    c. 36mg strength: 30 tablets per 30 days; or
    d. 54mg strength: 30 tablets per 30 days.

Mulpleta® (Lusutrombopag) Approval Criteria:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic liver disease (CLD) who are scheduled to undergo a procedure; and
2. Date of procedure must be listed on the prior authorization request; and
3. Prescriber must verify the member will have the procedure 2 to 8 days after the member receives the last dose of Mulpleta®; and
4. Member must have a baseline platelet count <50 x 10^9/L (recent baseline platelet count must be provided); and
5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and
6. ~~Mulpleta® must not be used in an attempt to normalize platelet counts; and~~
7. A quantity limit of 7 tablets per scheduled procedure will apply.

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Appendix F

Vote to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the Hereditary Angioedema (HAE) Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **June 2025:** The FDA approved Andembry® (garadacimab-gxii) injection for the prophylaxis of HAE attacks in adult and pediatric patients 12 years of age and older. Andembry® is intended for patient self-administration via subcutaneous (sub-Q) injection and is the first therapy indicated for the prophylaxis of HAE attacks that targets factor XIIa (FXIIa).
- **July 2025:** The FDA approved Ekterly® (sebetralstat), a plasma kallikrein inhibitor, as the first oral therapy indicated for the on-demand treatment of acute attacks of HAE in adult and pediatric patients 12 years of age and older.
- **August 2025:** The FDA approved Dawnzera™ (donidalorsen) as the first ribonucleic acid (RNA)-targeted therapy for the prophylaxis of HAE attacks in patients 12 years of age and older. Dawnzera™ targets plasma prekallikrein, which activates inflammatory mediators in the bradykinin pathway leading to acute HAE attacks. Dawnzera™ can be self-administered via sub-Q injection by a patient or caregiver.

Andembry® (Garadacimab-gxii) Product Summary[4,5]

Therapeutic Class: FXIIA inhibitor monoclonal antibody

Indication(s): Prophylaxis to prevent attacks of HAE in adult and pediatric patients 12 years of age and older

How Supplied: 200mg/1.2mL solution in a single-dose prefilled syringe or autoinjector

Dosing and Administration: Initial loading dose of 400mg (2 injections) administered sub-Q followed by a maintenance dose of 200mg sub-Q once monthly

Efficacy: Andembry® was evaluated in VANGUARD, a multicenter, randomized, double-blind, placebo-controlled, parallel-group trial.

- Key Inclusion Criteria:
  - Diagnosis of HAE Type 1 or 2
  - 12 years of age and older
  - At least 3 documented HAE attacks within the 3 months prior to screening or before commencing any prophylactic therapy before screening
  - Willing to discontinue current longer-term prophylactic treatments at least 2 weeks before the run-in period
- Key Exclusion Criteria:
  - Concomitant diagnosis of another form of angioedema
- Intervention(s):
  - Andembry® 400mg loading dose followed by 200mg once monthly vs. volume-matched placebo
- Primary Endpoint(s):
  - Number of HAE attacks per month during the 6-month treatment period
- Results:
  - Statistically significant lower mean number of HAE attacks per month in the Andembry® group [0.27; 95% confidence interval (CI): 0.05, 0.49] vs. placebo (2.01; 95% CI: 1.44, 2.57), which is a difference of -87% (95% CI: -96, -58; P<0.0001)

Dawnzera™ (Donidalorsen) Product Summary[6]

Therapeutic Class: Prekallikrein-directed antisense oligonucleotide

Indication(s): Prophylaxis to prevent attacks of HAE in adult and pediatric patients 12 years of age and older

How Supplied: 80mg/0.8mL solution in a single-dose autoinjector

Dosing and Administration: 80mg sub-Q every 4 weeks; a dosage of 80mg every 8 weeks may also be considered

Efficacy: Dawnzera™ was evaluated in OASIS-HAE, a multicenter, randomized, double-blind, placebo-controlled trial.

- Key Inclusion Criteria:
  - Diagnosis of HAE Type 1 or 2
  - 12 years of age and older
  - ≥2 investigator-confirmed HAE attacks during the 8-week run-in period
  - Willing to discontinue current longer-term prophylactic treatments prior to the trial

- Intervention(s):
  - Dawnzera™ 80mg once sub-Q every 4 weeks, Dawnzera™ 80mg sub-Q once every 8 weeks, or matching placebo
- Primary Endpoint(s):
  - Number of HAE attacks per 4 weeks from week 0 to week 24
- Results:
  - Statistically significantly lower mean number of HAE attacks every 4 weeks in the Dawnzera™ group dosed every 4 weeks (0.44; 95% CI: 0.27, 0.73; P<0.001) and Dawnzera group dosed every 8 weeks (1.02; 95% CI: 0.65, 1.49; P=0.004) vs. placebo (2.26; 95% CI: 1.66, 3.09)

Cost Comparison: HAE Prophylaxis Products

Product	Cost Per Year*
Andembry® (garadacimab-gxii) 200mg/1.2mL autoinjector	**$799,399.99**
Dawnzera™ (donidalorsen) 80mg/0.8mL autoinjector	**$747,006.00**
Takhzyro® (lanadelumab-flyo) 300mg/2mL prefilled syringe	$680,082.00
Cinryze® (C1 esterase inhibitor) 500 IU/5mL vial	$681,853.12
Haegarda® (C1 esterase inhibitor) 2,000 and 3,000 IU vials	$654,498.00
Orladeyo® (berotralstat) 150mg capsule	$623,415.60

Costs do not reflect rebated prices or net costs.
Costs based on Specialty Pharmaceutical Allowable Costs (SPAC) or Wholesale Acquisition Costs (WAC).
IU = international units
*Cost per day based on the FDA recommended dosing of Andembry® 400mg sub-Q loading dose followed by 200mg sub-Q once monthly, Dawnzera™ 80mg sub-Q every 4 weeks, Takhzyro® 300mg sub-Q every 2 weeks, Cinryze® 1,000 units intravenously (IV) twice weekly, Haegarda® 60 IU/kg sub-Q twice weekly (based on a 75kg member), and Orladeyo® 150mg orally daily.

Ekterly® (Sebetralstat) Product Summary[7,8]

Therapeutic Class: Plasma kallikrein inhibitor

Indication(s): Treatment of acute attacks of HAE in adult and pediatric patients 12 years of age and older

How Supplied: 300mg film-coated tablets

Dosing and Administration: 600mg (2 tablets) orally at the earliest recognition of HAE attack

- If response is inadequate or symptoms worsen or recur, a second dose of 600mg may be taken 3 hours after the first dose (maximum recommended daily dosage: 1,200mg)
- See package labeling for information about dose modification for concomitant use with CYP3A4 inhibitors or inducers or for patients with hepatic impairment

Efficacy: Ekterly® was evaluated in KONFIDENT, a multicenter, randomized, double-blind, placebo-controlled crossover clinical trial.

- Key Inclusion Criteria:
  - Diagnosis of HAE Type 1 or 2
  - 12 years of age and older
  - If receiving long-term prophylaxis, must be on a stable regimen and remain on that regimen for the duration of the trial
  - At least 2 documented HAE attacks within 3 months prior to screening or randomization
- Key Exclusion Criteria:
  - Concomitant diagnosis of another form of chronic angioedema
  - Clinically significant history of poor response to other on-demand therapies for HAE
  - Use of angiotensin-converting enzyme (ACE) inhibitors within 7 days prior to randomization
- Intervention(s):
  - 3-way crossover of Ekterly® 600mg vs. 300mg vs. placebo
  - A second dose could be administered after 3 hours
  - Participants were required to treat an HAE attack prior to crossover to the next treatment period
  - Laryngeal attacks determined to be severe by the participant were not treated in the trial
- Primary Endpoint(s):
  - Time-to-event analysis of time to symptom relief
- Results:
  - Statistically significant median faster time to the beginning of symptom relief with the 300mg dose (1.61 hours) and 600mg dose (1.79 hours) vs. placebo (6.72 hours) (P<0.001 and P=0.001 for the individual treatment doses, respectively)

Cost Comparison: HAE Treatment Products

Product	Cost Per Treatment Dose*
Ekterly® (sebetralstat) 300mg tablet	**$16,720.00**
Kalbitor® (ecallantide) 10mg/mL vial	$17,392.38
Ruconest® (C1 esterase inhibitor) 2,100 IU vial	$15,446.76
Berinert® (C1 esterase inhibitor) 500 IU vial	$11,379.00
Firazyr® (icatibant) 30mg/3mL prefilled syringe	$3,759.51
Sajazir™ (icatibant) 30mg/3mL prefilled syringe (branded generic)	$3,759.51

Costs do not reflect rebated prices or net costs. Costs based on Special Pharmaceutical Allowable Cost (SPAC) and Wholesale Acquisition Costs (WAC).
IU = international units
*Cost per treatment dose based on the FDA approved dose of Ekterly® 600mg orally, Kalbitor® 30mg sub-Q, Ruconest® 4,200 IU IV (maximum dose), Berinert® 1,500 IU IV (weight-based for 75kg member), Firazyr® 30mg sub-Q, and Sajazir™ 30mg sub-Q.

Estimation of Savings

The proposed PBPA category for the HAE medications is intended to add clarity to the current prior authorization (PA) criteria, which has previously been outlined in a numbered list format. The creation of the Tier structure will simplify the order of preferred products, which could lead to time savings for prescribers and PA reviewers. The arrangement of these medications into the Tier structure is based on an analysis of net costs, clinical practice, and clinical guideline recommendations, as applicable.

Differences in cost between utilization of a lower tiered product versus a higher tiered product as a result of the Tier structure represents cost savings. The following estimations are based on the proposed recommendations for placement of the products into a Tier structure and the costs listed in the Cost Comparison tables in the Product Summary sections, which do not represent rebated prices or net costs. For the HAE prophylaxis products, the cost difference between Andembry® (the highest cost option) and Orladeyo® (the lowest cost option) is $175,984.39 per member per year based on the FDA recommended dosing for each product. For the HAE treatment products, the cost difference between Kalbitor® (the highest cost option) and Firazyr® (the lowest cost option) is $13,632.87 per treatment dose.

Recommendations

The College of Pharmacy recommends establishing a PBPA category for the HAE prophylaxis products with additional criteria shown below in place of the current HAE medications prior authorization criteria and recommends the prior authorization of Andembry® (garadacimab-gxii) and Dawnzera™ (donidalorsen) with placement into the Special PA Tier of the HAE Prophylaxis Products PBPA category (changes shown in red):

Hereditary Angioedema (HAE) Prophylaxis Products			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Orladeyo® (berotralstat)	**Cinryze® (C1 esterase inhibitor)**	**Takhzyro® (lanadelumab-flyo)**	**Andembry® (garadacimab-gxii)**
	Haegarda® (C1 esterase inhibitor)		**Dawnzera™ (donidalorsen)**

PA = prior authorization

Initial Approval Criteria for All HAE Prophylaxis Products:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and

4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Prescriber must verify the member or caregiver has been trained by a health care professional on proper storage and administration of the prescribed product; and
7. For products requiring weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
8. Quantity limits will apply based on FDA-approved dosing.

HAE Prophylaxis Products Tier-2 Approval Criteria:

1. Initial Approval Criteria for All HAE Prophylaxis Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all Tier-1 products must be provided.

HAE Prophylaxis Products Tier-3 Approval Criteria:

1. Initial Approval Criteria for All HAE Prophylaxis Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all Tier-1 and Tier-2 products must be provided.

HAE Prophylaxis Products Special Prior Authorization (PA) Approval Criteria:

1. Initial Approval Criteria for All HAE Prophylaxis Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all other available lower-tiered HAE prophylaxis products must be provided.

Additionally, the College of Pharmacy recommends establishing a PBPA category for the HAE treatment products with the additional criteria shown below in place of the current HAE medications prior authorization criteria and recommends the prior authorization of Ekterly® (sebetralstat) with placement into the Special PA Tier of the HAE Treatment Products PBPA category (changes shown in red):

Hereditary Angioedema (HAE) Treatment Products		
Tier-1	**Tier-2**	**Special PA**
Firazyr® (icatibant)	**Berinert® (C1 esterase inhibitor)**	**Ekterly® (sebetralstat)**
	Sajazir™ (icatibant)	**Kalbitor® (ecallantide)**
		Ruconest® (C1 esterase inhibitor)

PA = prior authorization

Initial Approval Criteria for All HAE Treatment Products:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. Prior authorization requests for products administered via injection must indicate if the product is to be self-administered or to be administered by a health care provider; and
    a. For products approved for self-administration per FDA package labeling, the prescriber must verify the member or caregiver has been trained by a health care professional on proper storage and administration of the prescribed product; or
    b. For products not recommended for self-administration by FDA package labeling, the prescriber must verify the product will be administered by a health care provider; and
4. For products requiring weight-based dosing, the member's recent weight must be provided on the prior authorization request.

HAE Treatment Products Tier-2 Approval Criteria:

1. Initial Approval Criteria for All HAE Treatment Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all Tier-1 products must be provided.

HAE Treatment Products Special Prior Authorization (PA) Approval Criteria:

1. Initial Approval Criteria for All HAE Treatment Products must be met; and
2. A patient specific, clinically significant reason why the member cannot use all other available lower-tiered HAE treatment products must be provided.

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[6] Dawnzera™ (Donidalorsen) Prescribing Information. Ionis Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219407s000lbl.pdf. Last revised 08/2025. Last accessed 01/26/2026.

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[8] Riedl MA, Farkas H, Aygören-Pürsün E, et al. Oral Sebetralstat for On-Demand Treatment of Hereditary Angioedema Attacks. *N Eng J Med* 2024; 391: 32-43. doi: 10.1056/NEJMoa2314192.

Appendix G

Vote to Prior Authorize Atmeksi® (Methocarbamol Oral Suspension), Metaxalone 640mg Tablet, and Tanlor® (Methocarbamol 1,000mg Tablet) and Update the Approval Criteria for the Muscle Relaxant Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **July 2025:** The FDA approved Atmeksi® (methocarbamol oral suspension) as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions in patients 16 years of age and older.

News:

- **August 2024:** According to the FDA's National Drug Code (NDC) Directory, Tanlor® (methocarbamol 1,000mg tablet), a new strength of methocarbamol, began being marketed in August 2024. Additionally, a generic formulation of methocarbamol 1,000mg tablet began being marketed in February 2025.
- **February 2025:** According to the FDA's NDC Directory, metaxalone 640mg tablet, a new strength of metaxalone, began being marketed in February 2025.
- **June 2025:** Amneal, the manufacturer of Lyvispah® (baclofen oral granules) announced that they have discontinued promotion and distribution of Lyvispah® as of June 30, 2025. The product will only remain available at pharmacies until existing stock is depleted.
- **September 2025:** According to the FDA's NDC Directory, Zanaflex® (tizanidine 8mg capsule), a new strength of tizanidine, began being marketed in September 2025.

Atmeksi® (Methocarbamol Oral Suspension) Product Summary[4,5,6]

Therapeutic Class: Muscle relaxant

Indication(s): Adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions in patients 16 years of age and older

How Supplied: 750mg/5mL fruit flavored oral suspension in a 150mL bottle

Dosing and Administration:

- The initial recommended dose is 1,500mg (10mL) 4 times daily.
- The recommended maintenance dosage is 750mg (5mL) every 4 hours or 1,500mg (10mL) 3 times daily.
- For the first 48 to 72 hours of treatment, 6 grams per day are recommended. For severe conditions, 8 grams per day may be administered). Thereafter, the dosage can usually be reduced to approximately 4 grams per day.

Other Formulation(s) Available:

- Methocarbamol 500mg, 750mg tablets:
  - Atmeksi® and methocarbamol tablets have the same indication and recommended dosing.
  - Methocarbamol tablets may be crushed and mixed with food or liquid if needed.

Cost: Cost information for Atmeksi® is not yet available.

Tanlor® (Methocarbamol 1,000mg Tablet) Product Summary[7,8]

Therapeutic Class: Muscle relaxant

Indication(s): Adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions

How Supplied: 1,000mg oral tablet

Dosing and Administration:

- The initial recommended dosage is 1.5 tablets (1,500mg) 4 times daily.
- The recommended maintenance dosage is 1 tablet 4 times daily.
- For the first 48 to 72 hours of treatment, 6 grams per day are recommended. For severe conditions, 8 grams per day may be administered). Thereafter, the dosage can usually be reduced to approximately 4 grams per day.

Other Formulation(s) Available:

- Methocarbamol 500mg, 750mg tablets:
  - Tanlor® and methocarbamol tablets have the same indication and recommended dosing.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
Tanlor® (methocarbamol) 1,000mg tablet	**$23.50**	**$2,820.00**	**$33,840.00**
methocarbamol 1,000mg tablet (generic)	**$23.01**	**$2,761.20**	**$33,134.40**
methocarbamol 500mg tablet (generic)	$0.03	$7.20	$86.40
methocarbamol 750mg tablet (generic)	$0.04	$6.00	$72.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the maintenance dose of 4 grams per day (or 3.75 grams per day for the 750mg strength).

Metaxalone 640mg Tablet Product Summary[9,10,11]

Therapeutic Class: Muscle relaxant

Indication(s): Adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions in adult and pediatric patients 13 years of age and older

How Supplied: 640mg oral tablet

Dosing and Administration:

- The recommended dosage is 640mg orally, with or without food, 3 to 4 times a day.
- The maximum recommended daily dosage is 4 tablets or 2,560mg.
- Metaxalone 640mg tablets and Skelaxin® (metaxalone) 800mg tablets are not mutually substitutable on a mg-to-mg basis due to differences in pharmacokinetic profiles.
- See full *Prescribing Information* for details regarding switching between metaxalone products, when appropriate.

Other Formulation(s) Available:

- Metaxalone 400mg, 800mg tablets:
  - Metaxalone 640mg tablets have the same indication as the 400mg and 800mg tablets.
  - The recommended dosing for the 400mg and 800mg tablets is 800mg 3 to 4 times a day.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
metaxalone 640mg tablet	**$62.50**	**$7,500.00**	**$90,000.00**
metaxalone 400mg tablet (generic)	$2.84	$681.60	$8,179.20
metaxalone 800mg tablet (generic)	$0.50	$60.00	$720.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the maximum dose for each product, 2,560mg daily for the 640mg strength or 3,200mg daily for the 400mg and 800mg strengths.

Zanaflex® (Tizanidine 8mg Capsule) Product Summary[12,13,14]

Therapeutic Class: Central alpha-2-adrenergic agonist

Indication(s): Spasticity

How Supplied: 8mg oral capsule

Dosing and Administration:

- The recommended starting dose is 2mg orally every 6-8 hours, as needed, to a maximum of 3 doses in 24 hours.
- Dosage can be gradually increased every 1-4 days by 2-4mg at each dose based on clinical response and tolerability. The maximum daily dosage is 36mg. Single doses greater than 16mg have not been studied.

Other Formulation(s) Available:

- Tizanidine 2mg, 4mg tablets; Tizanidine 2mg, 4mg, 6mg capsules:
  - Tizanidine tablets and capsules (including the new 8mg strength) have the same indication and recommended dosing.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Zanaflex® (tizanidine) 8mg capsule	**$58.32**	**$6,998.40**	**$83,980.80**
tizanidine 6mg capsule (generic)	$0.13	$23.40	$280.80
tizanidine 4mg tablet (generic)	$0.03	$8.10	$97.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on usage up to the maximum daily dose of 36mg per day for each product (using 4 capsules daily for the 8mg strength).
Unit = each capsule or tablet

Cost Comparison: Carisoprodol Products

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
carisoprodol 250mg tablet (generic)	$0.45	$54.00	$648.00
carisoprodol 350mg tablet (generic)	$0.06	$7.20	$86.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the FDA approved dosing of 4 tablets daily for either strength.

Recommendations

The College of Pharmacy recommends the following additions and changes to the Muscle Relaxant Medications Product Based Prior Authorization (PBPA) Tier chart (changes shown in red in the following Tier chart and additional criteria:

1. Prior authorization and placement of Atmeksi® (methocarbamol oral suspension), metaxalone 640mg tablet, and Tanlor® (methocarbamol 1,000mg tablet) into the Special PA Tier based on net costs; and
2. Updating the approval criteria for Zanaflex® (tizanidine) capsules based on the approval of the new 8mg capsule and based on net costs; and
3. Updating the approval criteria for Fleqsuvy® (baclofen 25mg/mL oral suspension), Ozobax® (baclofen 5mg/5mL oral solution), and Ozobax® DS [baclofen double strength (DS) 10mg/5mL oral solution] based on the discontinuation of Lyvispah® (baclofen oral granules); and
4. Moving metaxalone 400mg tablet from Tier-2 to the Special PA Tier based on net cost; and
5. Updating the carisoprodol approval criteria based on net costs and for clarity.

Muscle Relaxant Medications		
Tier-1	**Tier-2**	**Special PA***
baclofen 10mg, 20mg (Lioresal®)	metaxalone **800mg tabs** (Skelaxin®)	baclofen 5mg, 15mg (Lioresal®)
chlorzoxazone 500mg (Parafon Forte®)		baclofen oral granules (Lyvispah®)
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 10mg/5mL oral soln (Ozobax DS®)
orphenadrine (Norflex®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
tizanidine tabs (Zanaflex®)		carisoprodol 250mg (Soma®)
		carisoprodol 350mg (Soma®)
		chlorzoxazone 250mg tabs
		chlorzoxazone 375mg, 750mg (Lorzone®)

Muscle Relaxant Medications		
Tier-1	**Tier-2**	**Special PA***
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		metaxalone 400mg tabs (Skelaxin®)
		metaxalone 640mg tabs
		methocarbamol 1,000mg tabs (Tanlor®)
		methocarbamol oral susp (Atmeksi®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		tizanidine caps (Zanaflex®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets.

Atmeksi® (Methocarbamol Oral Suspension) Approval Criteria:

1. An FDA approved indication as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions; and
2. Member must be 16 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 methocarbamol 500mg or 750mg oral tablets, even when tablets are crushed, must be provided.

Fleqsuvy® (Baclofen 25mg/mL Oral Suspension), Lyvispah® (Baclofen Oral Granules), Ozobax® (Baclofen 5mg/5mL Oral Solution), and Ozobax® DS [Baclofen Double Strength (DS) 10mg/5mL Oral Solution] Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. ~~Requests for Fleqsuvy®, Ozobax®, or Ozobax® DS will require a patient-specific, clinically significant reason why the member cannot use Lyvispah®; and~~
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Metaxalone 640mg Tablet and Skelaxin® (Metaxalone 400mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other appropriate lower-tiered products, including metaxalone 800mg tablets, must be provided; and
2. For metaxalone 400mg tablets, a patient-specific, clinically significant reason why the member cannot split an 800mg metaxalone tablet to achieve the requested dose must be provided.

~~**Soma® (Carisoprodol 250mg) Approval Criteria:**~~

~~1. Authorization requires detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and patient-specific reason(s) why member cannot be drowsy for even a short time period must be provided. Member must not have other sedating medications in current claims history; and~~
~~2. For a diagnosis of acute musculoskeletal pain, the approval will be for the duration of 14 days per 365-day period. Conditions requiring chronic use will not be approved.~~

Soma® (Carisoprodol 250mg or 350mg) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other appropriate lower-tiered products must be provided; and
~~2. Members may receive 3 months of carisoprodol 350mg per rolling 365 days without prior authorization; and~~
3. Requests for carisoprodol 250mg will require a patient-specific, clinically significant reason why the member cannot use carisoprodol 350mg; and
~~4. After the member has received the 3 months, an additional approval for 1 month may be granted to allow titration or change to a Tier-1 muscle relaxant. This additional 1-month approval will be granted 1 time only. Further authorizations will not be granted; or~~
5. Requests will be approved for a maximum duration of 3 months; or
    a. Clinical exceptions may be made for members with the following diagnoses and approvals will be granted for the duration of 1 year: multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or cancer pain; and
6. A quantity limit of 120 tablets per 30 days will apply.

Tanlor® (Methocarbamol 1,000mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using methocarbamol 500mg or 750mg tablets to achieve the requested dose, must be provided.

Zanaflex® (Tizanidine) Capsules Approval Criteria:

1. Tizanidine tablets must be tried prior to consideration of the capsules.
2. The capsules may be considered for approval only if there is supporting information as to why the member cannot take the tablets; and
3. For Zanaflex® 8mg capsule, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic tizanidine 2mg, 4mg, or 6mg capsules to achieve the requested dose must be provided.

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Appendix H

Vote to Prior Authorize Imaavy™ (Nipocalimab-aahu) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **March 2025:** The FDA approved an expanded indication for Soliris® (eculizumab) to include pediatric patients 6 years of age and older with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. This is the first FDA approved treatment for pediatric patients with gMG. The approval was based on a 26-week single arm trial evaluating the safety of Soliris® in 11 pediatric patients with gMG 12 to 17 years of age, which showed similar adverse effects to those observed in adults.
- **March 2025:** The FDA approved Fabhalta® (iptacopan) for the treatment of adults with C3 glomerulopathy (C3G), to reduce proteinuria. This is the third FDA approved indication for Fabhalta®. The safety and efficacy of Fabhalta® in C3G were studied in the APPEAR-C3G trial, which was a randomized, double-blind, placebo-controlled trial in 74 adult patients with C3G. Patients were included if they had biopsy proven native kidney C3G, urine protein-to-creatinine ratio (UPCR) ≥1g/g, and an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2. Patients were randomized 1:1 to receive Fabhalta® or placebo for 6 months. The primary efficacy endpoint was the log-transformed ratio to baseline in 24-hour UPCR at 6 months. The results showed a 35% reduction in 24-hour UPCR from baseline in the Fabhalta® group compared to the placebo (P=0.0028).
- **April 2025:** The FDA approved Uplizna® (inebilizumab-cdon) for immunoglobulin G4-related disease (IgG4-RD). This is the second FDA approved indication for Uplizna®, which was previously approved in June 2020 for neuromyelitis optica spectrum disorder (NMOSD). The approval in IgG4-RD was based on the MITIGATE trial, which was a randomized, double-blind, multi-center, 52-week placebo-controlled trial that enrolled 135 adult patients with newly diagnosed or recurrent IgG4-RD that required glucocorticoid treatment at screening and confirmed history of organ involvement at any time during the course of disease. The primary endpoint was time to first treated and

adjudicated IgG4-RD flare. The time to the first flare was statistically significantly longer in the Uplizna® treated group versus placebo and Uplizna® reduced the risk of flare by 87% compared to placebo (hazard ratio: 0.13; P<0.0001). In the Uplizna® group 7 out of 68 patients experienced a flare compared to 40 out 67 patients in the placebo group.

- **April 2025:** The FDA approved a prefilled syringe of Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) that can be self-administered via subcutaneous (sub-Q) injection after a patient or caregiver receives proper training. Previously, Vyvgart® Hytrulo was only available in a single-dose vial that was required to be administered by a health care professional using a winged infusion set.
- **April 2025:** The FDA approved Imaavy™ (nipocalimab-aahu), a neonatal Fc receptor blocker, for the treatment of gMG in adult and pediatric patients 12 years of age and older with anti-AChR and anti-muscle-specific tyrosine kinase (MuSK) antibody positive gMG.
- **July 2025:** The FDA approved Empaveli® (pegcetacoplan) for the treatment of C3G and primary immune complex membranoproliferative glomerulonephritis (IC-MPGN) in patients 12 years of age and older, to reduce proteinuria. The safety and efficacy of Empaveli® for this indication was studied in the Phase 3 VALIANT trial, which showed a 68% reduction in proteinuria (P<0.0001). The results were consistent for both adults and pediatric patients with C3G and IC-MPGN and in patients with C3G who were post-transplant with disease recurrence.
- **December 2025:** The FDA approved Uplizna® (inebilizumab-cdon) for gMG in adults who are anti-AChR and anti-MuSK positive. This is the third indication for Uplizna®, which was previously approved for NMOSD and IgG4-RD. The approval in gMG was supported by the Myasthenia Gravis Inebilizumab Trial (MINT), which demonstrated a 1.9-point difference in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score compared with placebo (-4.2 vs. -2.2; P<0.0001).

Imaavy™ (Nipocalimab-aahu) Product Summary[12]

Therapeutic Class: Neonatal Fc receptor blocker

Indication(s): Treatment of gMG in adult and pediatric patients 12 years of age and older who are anti-AChR or anti-MuSK antibody positive

How Supplied:

- 300mg/1.62mL (185mg/mL) in a single-dose vial (SDV) for injection
- 1,200mg/6.5mL (185mg/mL) in a SDV for injection

Dosing and Administration:

- The recommended initial dose should be 30mg/kg once via intravenous (IV) infusion over at least 30 minutes. Two weeks after the initial dose, a maintenance dose of 15mg/kg should be administered via IV infusion over at least 15 minutes and continue every 2 weeks thereafter.
- See full *Prescribing Information* for instructions on dosage, preparation, and administration.
- Patients should be evaluated for the need to administer age-appropriate vaccines according to immunization guidelines before initiation of Imaavy™.
- Imaavy™ should be administered via IV infusion only.

Efficacy: The safety and efficacy of Imaavy™ were studied in a 24-week, multicenter, randomized, double-blind, placebo-controlled trial in 196 patients with gMG.

- Key Inclusion Criteria:
  - Diagnosis of gMG who met the following criteria:
    - Myasthenia Gravis (MG) Found of American (MGFA) Clinical Classification Class II to IV
    - MG-ADL total score of at least 6
    - On stable dose of standard of care MG therapy prior to baseline that included acetylcholinesterase (AChE) inhibitors or immunosuppressive therapies (ISTs), either in combination or alone
- Intervention: Patients were randomized 1:1 to receive Imaavy™ or placebo
- Primary Outcome: Comparison of the mean change from baseline to week 24 between treatment groups in the MG-ADL total score
- Results: The least squares mean change from baseline to week 24 in MG-ADL total scores was -4.7 in the Imaavy™-treated group compared to -3.3 in the placebo group [treatment difference: -1.5; 95% confidence interval (CI): -2.4, -0.5, P=0.002].

Cost Comparison: Eculizumab Products

Medication	Cost Per mL	Cost Per Dose	Cost Per Year*
Soliris® (eculizumab) 300mg/30mL	$217.43	$26,091.60	$678,381.60
Bkemv® (eculizumab-aeeb) 300mg/30mL	$195.69	$23,482.80	$610,552.80
Epysqli® (eculizumab-aagh) 300mg/30mL	$152.20	$18,264.00	$474,864.00

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
*Cost per year based on the FDA approved maintenance dose of 1,200mg every 2 weeks for gMG.

Cost Comparison: Neonatal Fc Receptor Blockers

Medication	Cost Per mL	Cost Per Year
Imaavy® (nipocalimab-aahu) 1,200mg/6.5mL	**$1,920.00**	**$324,480.00[α]**
Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,000mg/5mL prefilled syringe	$3,346.40	$468,496.00[±]
Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,008mg/5.6mL	$2,930.40	$459,486.72[Δ]
Vyvgart® (efgartigimod alfa-fcab) 400mg/20mL	$315.71	$353,595.20[¥]
Rystiggo® (rozanolixizumab-noli) 560mg/4mL	$3,155.37	$378,644.40[λ]

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
[α]Cost based on an 80kg patient receiving an IV maintenance dose of 1,200mg every 2 weeks.
[±]Cost based on a fixed dose of 1,000mg/5mL with 4 infusion per cycle (7 cycles per year).
[Δ]Cost based on a fixed dose of 1,008mg/5.6mL with 4 infusions per cycle (7 cycles per year).
[¥]Cost based on an 80kg patient receiving an 800mg dose with 4 infusions per cycle (7 cycles per year).
[λ]Cost based on an 80kg patient receiving 560mg weekly for 6 infusions per cycle (5 cycles per year).
Please note: For Rystiggo®, Vyvgart®, and Vyvgart® Hytrulo the number of treatment cycles could vary per year based on clinical response.

Cost Comparison: C3G Therapies

Medication	Cost Per Unit	Cost Per Year
Fabhalta® (iptacopan) 200mg capsule	$799.31	$575,503.20[α]
Empaveli® (pegcetacoplan) 1,080mg/20mL	$255.10	$530,608.00[β]

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Unit = capsule or mL
[α]Cost based on the FDA approved dose of 200mg twice daily.
[β]Cost based on the FDA approved dose of 1,080mg twice weekly.

Recommendations

The College of Pharmacy recommends updating the prior authorization criteria for the eculizumab products based on the FDA approved age expansion for gMG and based on net costs (changes shown in red):

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS;
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and

5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or ~~Epysqli®~~ Soliris®, a patient-specific, clinically significant reason why the member cannot use ~~Soliris®~~ Epysqli® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement inhibitor used to treat aHUS; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 6 years of age and older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must meet 1 of the following:
   a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
   b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and
7. Bkemv™, Epysqli®, Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. For use of Bkemv™ or ~~Epysqli®~~ Soliris®, in patients 18 years of age or older, a patient-specific, clinically significant reason why the member cannot use ~~Soliris®~~ Epysqli® must be provided. Biosimilars and/or

reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and

~~11. Use of Bkemv™, Epysqli®, or Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and~~

12. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with a neonatal Fc receptor blocker or another complement inhibitor used to treat gMG; and
13. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or ~~Epysqli®~~ Soliris®, a patient-specific, clinically significant reason why the member cannot use ~~Soliris®~~ Epysqli® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement protein C5 inhibitor, complement protein C3 inhibitor, or complement factor B inhibitor used to treat PNH; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

The College of Pharmacy recommends the addition of prior authorization criteria for Fabhalta® (iptacopan) for a diagnosis of C3G and for Uplizna® (inebilizumab-cdon) for a diagnosis of IgG4-RD and gMG based on the new FDA approved indications with the following criteria (shown in red):

Fabhalta® (Iptacopan) Approval Criteria [Complement 3 Glomerulopathy (C3G) Diagnosis]:

1. An FDA approved indication to reduce proteinuria in adults with C3G; and
2. The diagnosis of C3G must be confirmed by a kidney biopsy (can refer to a recent or historical biopsy); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must have a urine protein-to-creatinine (UPCR) ratio ≥1.0g/g; and
6. Member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
7. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Fabhalta® in combination with another complement protein C3 inhibitor used to treat C3G; and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Immunoglobulin G4-Related Disease (IgG4-RD) Diagnosis]:

1. An FDA approved diagnosis of IgG4-RD which meets the classification criteria for IgG4-RD by the 2019 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR); and
2. Member must be 18 years of age or older; and
3. Member must have a confirmed history of organ involvement; and
4. Uplizna® must be prescribed by, or in consultation with, a gastroenterologist, rheumatologist, or a specialist with expertise in the treatment of IgG4-RD; and
5. Member must have previously been treated with glucocorticoid therapy or have a patient specific, clinically significant reason why glucocorticoid therapy is not appropriate; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and

8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify the member has not received any live-attenuated or live vaccines within 4 weeks prior to the initiation of therapy and that member will not receive any live-attenuated or live vaccines during treatment with Uplizna® or after discontinuation until B-cell repletion; and
15. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
16. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and

7. Uplizna® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Uplizna® in combination with a complement inhibitor or with a neonatal Fc receptor blocker used to treat gMG; and
9. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
10. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
11. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
12. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
13. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
14. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
15. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
16. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
17. Prescriber must verify the member has not received any live-attenuated or live vaccines within 4 weeks prior to the initiation of therapy and that member will not receive any live-attenuated or live vaccines during treatment with Uplizna® or after discontinuation until B-cell repletion; and
18. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
19. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy recommends updating the approval criteria for Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) based on the FDA approval of the prefilled syringe (changes shown in red):

Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Approval Criteria [Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Diagnosis]:

1. An FDA approved diagnosis of CIDP; and
2. Member must be 18 years of age or older; and
3. Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Member must have previously failed treatment with intravenous immunoglobulin (IVIG) or a patient specific, clinically significant reason why the member cannot use IVIG must be provided; and
5. For member self-administration or caregiver administration of the prefilled syringe, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Vyvgart® Hytrulo prefilled syringe; and
6. Initial approvals will be for 12 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Vyvgart® (Efgartigimod Alfa-fcab) and Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥5; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Vyvgart® or Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Vyvgart® or Vyvgart® Hytrulo in combination with a complement inhibitor or with another neonatal Fc receptor blocker used to treat gMG; and
9. For member self-administration or caregiver administration of Vyvgart® Hytrulo prefilled syringe, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Vyvgart® Hytrulo prefilled syringe; and
10. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization

requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

The College of Pharmacy also recommends the prior authorization of Imaavy® (nipocalimab-aahu) with the following criteria (shown in red):

Imaavy™ (Nipocalimab-aahu) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 12 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Imaavy™ must be prescribed by, or in consultation with, a neurologist, or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Imaavy in combination with a complement inhibitor or with another neonatal Fc receptor blocker used to treat gMG; and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
10. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

The College of Pharmacy recommends the addition of prior authorization criteria for Empaveli® (pegcetacoplan) based on the new FDA approved diagnosis with the following criteria (shown in red):

Empaveli® (Pegcetacoplan) Approval Criteria [Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) Diagnosis]:

1. An FDA approved diagnosis to reduce proteinuria in members with C3G or primary IC-MPGN; and
2. The diagnosis of C3G or IC-MPGN must be confirmed by a kidney biopsy (can refer to a recent or historical biopsy); and
3. Member must be 12 years of age or older and weigh at least 30kg; and

4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must have a urine protein-to-creatinine (UPCR) ratio ≥1.0g/g; and
6. Member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
7. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Empaveli®; and
9. Member must not be receiving Empaveli® in combination with another complement inhibitor used to treat C3G; and
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends updating the immunoglobulin A nephropathy (IgAN) criteria for Fabhalta® and the neuromyelitis optica spectrum disorder (NMOSD) criteria for Uplizna® (inebilizumab-cdon) to be consistent with clinical practice (changes shown in red):

Fabhalta® (Iptacopan) Approval Criteria [Immunoglobulin A Nephropathy (IgAN) Diagnosis]:

1. An FDA approved indication to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and

7. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and
5. Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify the member has not received any live-attenuated or live vaccines ~~vaccinations~~ within 4 weeks prior to

initiation of therapy and member will not receive any live-attenuated or live vaccines during treatment with Uplizna® or after discontinuation until B-cell repletion; and

15. Member must not be receiving Uplizna® in combination with other immunomodulators to treat NMOSD; and
16. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

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Appendix I

Vote to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution) and Update the Approval Criteria for the Antidepressants

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5,6,7]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **November 2024:** The FDA approved a New Drug Application (NDA) for Raldesy™ (trazodone oral solution) for the treatment of major depressive disorder (MDD) in adults. The efficacy of Raldesy™ is based on studies for the trazodone oral tablets. Raldesy™ is available as a 10mg/mL oral solution in 150mL and 300mL bottles.
- **January 2025:** The FDA approved a supplemental New Drug Application (sNDA) for Spravato® (esketamine) for the treatment of treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant. Previously, Spravato® was only approved for TRD in conjunction with an oral antidepressant. The approval is supported by results from a randomized, double-blind, placebo-controlled trial assessing the efficacy and safety of Spravato® 56mg and Spravato® 84mg as monotherapy versus placebo. Spravato® 56mg and 84mg as monotherapy showed a rapid and superior improvement in the Montgomery-Asberg Depression Rating Scale (MADRS) total score with a reduction of -11.4 [treatment difference: -5.1; 95% confidence interval (CI): -7.9, -2.3] and -13.0 (treatment difference: -6.8; 95% CI: -9.5, -4.1), respectively, vs. a reduction of -6.3 for placebo at day 28.
- **August 2025:** The FDA approved an NDA for a new capsule formulation of escitalopram in a 15mg strength for the treatment of MDD in adults younger than 65 years of age and pediatric patients 12 years of age and older and for generalized anxiety disorder in adults younger than 65 years of age. The escitalopram 15mg capsule is not indicated for patients 65 years of age and older or those with hepatic impairment as the recommended dose for these patients is 10mg per day.

Guideline Update(s):

- **American College of Obstetrics and Gynecology (ACOG):** ACOG released revised guidance on the use of brexanolone and zuranolone in the postpartum period for depression that has onset in the third trimester or within 4 weeks postpartum as a focused update to the

Treatment and Management of Mental Health Conditions During Pregnancy and Postpartum. Some notable updates include:

- ACOG recommends the consideration of zuranolone in the postpartum period for severe depression that has an onset in the third trimester or within 4 weeks postpartum. The decision to use zuranolone should balance the benefits alongside the challenges specific to initiating and managing the medication.
- If zuranolone is not effective or if symptoms reoccur after completing a clinical course of treatment, repeating the medication course is not indicated and other approaches to perinatal depression management should be considered.
- A Phase 1 open-label study that assessed zuranolone transfer to human milk in 15 healthy, nonpregnant, lactating adults showed a day 5 relative infant dose (RID) of 30mg being 0.357% and a simulated RID of 50mg estimating to be <1%. This is below the <10% threshold that is generally considered compatible with human milk feeding. Pumping and discarding human milk through 1-week past treatment completion may be considered due to the absence of direct clinical safety data; however, this option should be weighed against the option of continued breastfeeding through shared decision making given that the RID is generally considered compatible with human milk feeding.

Cost Comparison: Escitalopram Products

Product	Cost Per Unit	Cost Per Month*	Cost Per Year*
escitalopram 15mg capsule	**$5.67**	**$170.10**	**$2,041.20**
escitalopram 5mg tablet (generic)	$0.04	$3.60	$43.20
escitalopram 10mg tablet (generic)	$0.03	$1.35	$16.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule or tablet
*Cost per month based on a dose of 15mg once daily

Cost Comparison: Trazodone Products

Product	Cost Per Unit	Cost Per Month*	Cost Per Year
Raldesy™ (trazodone oral soln) 10mg/mL 150mL bottle	**$2.46**	**$2,214.00**	**$26,568.00**
Raldesy™ (trazodone oral soln) 10mg/mL 300mL bottle	**$1.62**	**$1,458.00**	**$17,496.00**
trazodone 300mg tablet (generic)	$0.58	$17.40	$208.80
trazodone 150mg tablet (generic)	$0.09	$5.40	$64.80
trazodone 100mg tablet (generic)	$0.05	$4.50	$54.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
soln = solution; Unit = mL or tablet
*Cost per month based on a dose of 300mg per day

Recommendations

The College of Pharmacy recommends the following changes to the Antidepressants Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier chart and additional criteria):

1. Prior authorization of Raldesy™ (trazodone oral solution) and escitalopram 15mg capsule and placement into the Special PA Tier with the following additional criteria; and
2. Updating the Drizalma Sprinkle™ and Irenka™ approval criteria to encompass all FDA approved diagnoses; and
3. Updating the Spravato® (esketamine) approval criteria for the TRD diagnosis based on the new FDA approval; and
4. Updating the Zurzuvae® (zuranolone) approval criteria to be consistent with the current ACOG guideline recommendations.

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps
escitalopram tabs & soln (Lexapro®)			citalopram 20mg/10mL soln (UDC)
fluoxetine caps & soln (Prozac®)			**escitalopram 15mg caps**
fluvoxamine (Luvox®)			escitalopram 10mg/10mL soln (UDC)
paroxetine (Paxil®)			fluoxetine 20mg/5mL soln (UDC)
sertraline tabs & soln (Zoloft®)			fluoxetine tabs

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
			fluoxetine DR (Prozac® Weekly™)
			fluvoxamine CR (Luvox CR®)
			paroxetine CR (Paxil CR®)
			sertraline 150mg & 200mg caps
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine succinate ER (Pristiq®)	desvenlafaxine ER	bupropion ER (Forfivo XL®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	duloxetine (Drizalma Sprinkle™)
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine 40mg (Irenka™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	trazodone 300mg tabs (Desyrel®)
venlafaxine ER caps (Effexor XR®)			**trazodone oral soln (Raldesy™)**
venlafaxine IR tabs (Effexor®)			venlafaxine besylate ER 112.5mg tablets
venlafaxine 37.5mg. 75mg & 150mg ER tabs (Effexor XR®)			venlafaxine ER 225mg tabs (Effexor XR®)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity®)
			esketamine nasal spray (Spravato®)
			gepirone (Exxua™)
			zuranolone (Zurzuvae®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets

Escitalopram Capsule Approval Criteria:

1. An FDA approved indication; and
2. Member must have initiated treatment with escitalopram tablets for dose titration; and
3. A patient-specific, clinically significant reason why the member cannot use escitalopram tablets, including splitting an escitalopram 10mg tablet to achieve a 15mg dose, must be provided; and
4. Escitalopram capsules will not be approved for members 65 years of age or older or for members with hepatic impairment; and
5. A quantity limit of 30 capsules per 30 days will apply.

Drizalma Sprinkle™ (Duloxetine Capsule) Approval Criteria ~~[Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]~~:

1. An FDA approved diagnosis ~~of diabetic peripheral neuropathy or chronic musculoskeletal pain~~; and
2. For non-depression related diagnoses, a patient-specific, clinically significant reason why the member cannot use generic duloxetine 20mg, 30mg, or 60mg capsules, which are available without prior authorization, in place of Drizalma Sprinkle™ must be provided; and
3. For depression-related diagnoses, a patient-specific, clinically significant reason why the member cannot use all other available lower tiered medications, including generic duloxetine 20mg, 30mg, or 60mg capsules, must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply.

Irenka™ (Duloxetine 40mg Capsule) Approval Criteria ~~[Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]~~:

1. An FDA approved diagnosis ~~of diabetic peripheral neuropathy or chronic musculoskeletal pain~~; and
2. A patient-specific, clinically significant reason why the member cannot use 2 duloxetine 20mg capsules in place of Irenka™ 40mg capsules must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply; and

Raldesy™ (Trazodone Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use the tablet formulation must be provided; and
4. Requests for the 150mL package size will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size; and
5. The following quantity limits will apply:
    a. 150mL package size: 450mL per 30 days; or
    b. 300mL package size: 1,200mL per 30 days.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Treatment-Resistant Depression Diagnosis]:

1. An FDA approved diagnosis of treatment-resistant depression in adults; and
2. Member must be 18 years of age or older; and
~~3. Spravato® must be used in conjunction with an oral antidepressant; and~~
4. Member must have had an inadequate response to at least 2 different antidepressants from different classes at least 4 weeks in duration each and titrated to recommended dosing during the current depressive episode, unless contraindicated or clinically significant adverse effects; and
5. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
6. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with package labeling; and
7. Member must not have any contraindications to therapy [e.g., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
8. Member must not have severe hepatic impairment (Child Pugh C); and
9. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
10. Prescriber must verify female member is not breastfeeding; and
11. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
12. Member must be enrolled in the Spravato® REMS program; and
13. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
14. Initial approvals will be for the duration of the induction phase. For continued authorization, prescriber must verify member demonstrated an adequate response during the induction phase ~~and verify member is using Spravato® in combination with an oral antidepressant~~; and
15. A quantity limit of 4 kits per 28 days will apply for maintenance dosing.

Zurzuvae® (Zuranolone) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe postpartum depression (PPD); and
2. Member must be ≤12 months postpartum and the date of delivery must be provided; and
3. Member must be a female 18 years of age or older; and
4. Prescriber must verify the following:

a. Member has been counseled on the proper administration of Zurzuvae® including taking with a fat-containing meal; and
b. Member has been counseled on the central nervous system (CNS) depression effects of Zurzuvae® and the member agrees not to drive or engage in other potentially hazardous activities until at least 12 hours after administration; and
c. Member is not currently pregnant and will use effective contraception while receiving treatment and for 7 days after the last dose of Zurzuvae®; and
~~d. Member is not breastfeeding or has agreed to temporarily hold breastfeeding during Zurzuvae® therapy and for 7 days after the last dose; or~~
~~e. If the member does not agree to cease breastfeeding, the following must be provided:~~
~~i. Prescriber attests that the benefits of Zurzuvae® therapy while breastfeeding outweigh the risks to the infant due to studies showing that Zurzuvae® is present in breastmilk; and~~
~~ii. Member has been counseled on the potential risks of CNS depression effects that may occur in the infant; and~~

5. Dosing and approval duration will be limited to the following:
   a. 50mg once daily for 14 days; or
   b. For members with severe hepatic impairment, moderate to severe renal impairment, or concomitant use with CYP3A4 inhibitors:
      i. 30mg once daily for 14 days; and
   c. If a dose reduction to 40mg once daily is required due to CNS depression effects, the prescriber should contact the specialty pharmacy that filled the member's initial Zurzuvae® prescription to obtain the 20mg capsules from the manufacturer for the remainder of the member's treatment course; and
6. Approvals will be for 1 treatment course.

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[3] Raldesy™ (Trazodone Oral Solution) Prescribing Information. Validus Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218637s003lbl.pdf. Last revised 06/2025. Last accessed 01/20/2026.
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[7] American College of Obstetricians and Gynecologists. Zuranolone and Brexanolone for the Treatment of Postpartum Depression. Clinical Practice Update. *Obstet Gynecol* 2025; 146. doi: 10.1097/AOG.0000000000006093.

Appendix J

Vote to Prior Authorize Keytruda Qlex™ (Pembrolizumab/Berahyaluronidase Alfa-pmph) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) and Update the Approval Criteria for the Skin Cancer Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **December 2024:** The FDA granted accelerated approval to Braftovi® (encorafenib) for a new indication, in combination with cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin), for patients with metastatic colorectal cancer (CRC) with a *BRAF V600E* mutation, as detected by an FDA-approved test.
- **December 2024:** The FDA approved Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy), a new subcutaneous (sub-Q) formulation of nivolumab, for the treatment of most of the same adult indications as the intravenous (IV) formulation of nivolumab, including indications for renal cell carcinoma (RCC), melanoma, non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck, urothelial carcinoma, CRC, hepatocellular carcinoma (HCC), esophageal cancer, gastric cancer, gastroesophageal junction (GEJ) cancer, and esophageal adenocarcinoma.
- **January 2025:** The FDA approved a label update for Yervoy® (ipilimumab) to change the recommended dose for adjuvant melanoma from 10mg/kg to 3mg/kg and to change the infusion time from 90 minutes to 30 minutes.
- **April 2025:** The FDA approved new indications for the combination use of Opdivo® (nivolumab) and Yervoy® (ipilimumab) for adult and pediatric patients 12 years of age and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) CRC.
- **April 2025:** The FDA approved new indications for the combination use of Opdivo® (nivolumab) and Yervoy® (ipilimumab) for the first-line treatment of adult patients with unresectable or metastatic HCC.
- **May 2025:** The FDA approved Zynyz® (retifanlimab-dlwr) for a new indication, in combination with carboplatin and paclitaxel, for the first-line treatment of adults with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC). The FDA also

approved retifanlimab-dlwr, as a single agent, for adults with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy.

- **May 2025:** The FDA approved updated labels for Keytruda® (pembrolizumab), Opdivo® (nivolumab), Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy), and Yervoy® (ipilimumab) for indications including gastric or GEJ adenocarcinoma, esophageal or GEJ carcinoma, and esophageal squamous cell carcinoma (ESCC) limiting the use for these indications to patients whose tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1. These changes are to reflect the population with a favorable risk-benefit assessment.
- **June 2025:** The FDA approved Keytruda® (pembrolizumab) for a new indication for the treatment of adults with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 with CPS ≥1 as determined by an FDA-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy with or without cisplatin after surgery, and then as a single agent.
- **September 2025:** The FDA approved Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph), a new sub-Q formulation of pembrolizumab, for the treatment of most of the same adult indications as the IV formulation of pembrolizumab, including adult indications for melanoma, NSCLC, mesothelioma, HNSCC, urothelial cancer, MSI-H or dMMR solid tumors, MSI-H or dMMR CRC, gastric cancer, esophageal cancer, cervical cancer, HCC, biliary tract cancer (BTC), Markel cell carcinoma (MCC), RCC, endometrial carcinoma, tumor mutational burden-high (TMB-H) solid tumors, cutaneous squamous cell carcinoma (cSCC), and triple-negative breast cancer (TNBC). Additionally, Keytruda Qlex™ has pediatric indications for patients 12 years of age and older with melanoma, MSI-H or dMMR solid tumors, MCC, and TMB-H solid tumors.
- **October 2025:** The FDA approved Libtayo® (cemiplimab-rwlc) for a new indication for the adjuvant treatment of adult patients with cSCC at high risk of recurrence after surgery and radiation.
- **November 2025:** The FDA approved Keytruda® (pembrolizumab) and Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph) for a new indication, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment of adult patients with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for BTC allow for the use of pembrolizumab in combination with carboplatin and gemcitabine for the treatment of locally advanced or metastatic BTC.
- The NCCN guidelines for basal cell carcinoma (BCC) allow for the use of sonidegib for locally advanced BCC that has recurred following surgery or radiation or if surgery or radiation is contraindicated.
- The NCCN guidelines for colon and rectal cancer allow for the use of nivolumab as a single agent or in combination with ipilimumab for unresectable or metastatic disease that has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb].
- The NCCN guidelines for esophageal and esophagogastric junction cancers allow for the use of nivolumab as induction therapy in combination with fluoropyrimidine- and platinum-based chemotherapy or in combination with ipilimumab.
- The NCCN guidelines for gastric cancer allow for the use of nivolumab for locally advanced, recurrent, or metastatic human epidermal receptor 2 (HER2) overexpression negative disease in patients that have a PD-L1/CPS score ≥1.
- The NCCN guidelines for HCC allow for the use of ipilimumab in combination with nivolumab in the first line setting for unresectable or metastatic disease.
- The NCCN guidelines for Hodgkin lymphoma allow for the use of:
    - Nivolumab in combination with involved-site radiation therapy (ISRT) for stage I-II (unfavorable) disease and with brentuximab and ISRT or as a single agent in patients that are not a candidate for an anthracycline and in combination with ifosfamide, carboplatin and etoposide (ICE) as second line or subsequent therapy.
- The NCCN guidelines for melanoma allow for the use of:
    - Nivolumab for stage III disease with clinically positive nodes in combination with ipilimumab or as a single agent in the neoadjuvant and adjuvant setting; and
    - Vemurafenib for unresectable or metastatic disease that is BRAF mutated in combination with cobimetinib and atezolizumab.
- The NCCN guidelines for NSCLC allow for the use of ipilimumab in combination with nivolumab in patients that express PD-L1 score ≥1 for recurrent, advanced or metastatic disease and for the use of cemiplimab as continuation maintenance therapy following first-line therapy in combination with pemetrexed or as a single agent.
- The NCCN guidelines for ovarian cancer allow for the use of trametinib as a single agent for platinum-sensitive or platinum-resistant recurrent disease.

- The NCCN guidelines for thyroid carcinoma allow for the use of dabrafenib and trametinib following progression following prior treatment options and no satisfactory alternative treatment options.

Keytruda Qlex™ (Pembrolizumab/Berahyaluronidase Alfa-pmph) Product Summary[27]

Therapeutic Class: Combination of pembrolizumab, a programmed death receptor-1 (PD-1) blocking antibody, and berahyaluronidase alfa, an endoglycosidase

Indication(s):
- Indicated for most of the same adult indications as the IV formulation of pembrolizumab, including adult indications for melanoma, NSCLC, mesothelioma, HNSCC, urothelial cancer, MSI-H or dMMR solid tumors, MSI-H or dMMR CRC, gastric cancer, esophageal cancer, cervical cancer, HCC, BTC, MCC, RCC, endometrial carcinoma, TMB-H solid tumors, cSCC, and TNBC
- Additionally, Keytruda Qlex™ has pediatric indications for patients 12 years of age and older with melanoma, MSI-H or dMMR solid tumors, MCC, and TMB-H solid tumors.
- Please see full *Prescribing Information* for a complete list of indications.

How Supplied:
- 395mg pembrolizumab/4,800 units berahyaluronidase alfa per 2.4mL solution in a single-dose vial (SDV)
- 790mg pembrolizumab/9,600 units berahyaluronidase alfa per 4.8mL solution in a single-dose vial (SDV)

Dosing and Administration:
- The recommended dosing varies by indication and whether it is used as monotherapy or in combination with other agents. When used as monotherapy, the recommended dosing is 395mg of pembrolizumab and 4,800 units of berahyaluronidase alfa every 3 weeks or 790mg of pembrolizumab and 9,600 units of berahyaluronidase alfa every 6 weeks. This should be continued until disease progression, unacceptable toxicity, or up to a maximum duration for the specific indication, as listed in the label.
- Keytruda Qlex™ is administered sub-Q into the thigh or abdomen over 1 minute (for the 395mg/4,800 unit dose) or over 2 minutes (for the 790mg/9,600 units dose).
- Keytruda Qlex™ must be administered by a health care professional.
- Please refer to the full *Prescribing Information* for indication-specific recommendations, including the dosing, duration of treatment, timing

of administration relative to other medications, and other administration details.

Cost: The Wholesale Acquisition Cost (WAC) of Keytruda Qlex™ is $12,031.36 for the 2.4mL SDV or $24,062.72 for the 4.8mL SDV. For a member receiving 395mg/4,800 units every 3 weeks or 790mg/9,600 units every 6 weeks, this would result in an estimated cost of $216,564.48 per year.

Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Product Summary[28]

Therapeutic Class: Combination of nivolumab, a PD-1 blocking antibody, and hyaluronidase, an endoglycosidase

Indication(s):

- Indicated for most of the same adult indications as the IV formulation of nivolumab, including indications for RCC, melanoma, NSCLC, squamous cell carcinoma of the head and neck, urothelial carcinoma, CRC, HCC, esophageal cancer, gastric cancer, GEJ cancer, and esophageal adenocarcinoma
- Please see full *Prescribing Information* for a complete list of indications.
  - **Limitation(s) of Use:** Opdivo Qvantig™ is not indicated in combination with ipilimumab for any indication.

How Supplied: Available in a SDV as follows:

- 600mg nivolumab/10,000 units hyaluronidase in a 5mL SDV
- 300mg nivolumab/5,000 units hyaluronidase in a 2.5mL SDV

Dosing and Administration:

- The recommended dosing varies by indication and whether it is used as monotherapy or in combination with other agents. When used as monotherapy, the recommended dosing is 600mg of nivolumab and 10,000 units of hyaluronidase every 2 weeks or 1,200mg of nivolumab and 20,000 units of hyaluronidase every 4 weeks. This should be continued until disease progression, unacceptable toxicity, or up to a maximum duration for the specific indication, as listed in the label.
- Opdivo Qvantig™ is administered sub-Q into the abdomen or thigh over 3-5 minutes.
- Opdivo Qvantig™ must be administered by a health care professional.
- Please refer to the full *Prescribing Information* for indication-specific recommendations, including the dosing, duration of treatment, timing of administration relative to other medications, and other administration details.

Cost: The Wholesale Acquisition Cost (WAC) of Opdivo Qvantig™ is $1,620.39 per mL. For a member receiving 600mg/10,000 units every 2 weeks or

1,200mg/20,000 units every 4 weeks, this would result in an estimated cost of $16,203.90 per month or $210,650.70 per year.

Recommendations

The College of Pharmacy recommends the prior authorization of Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph) with criteria similar to Keytruda® (pembrolizumab) and recommends additional updates based on recent FDA approvals, NCCN recommendations for pembrolizumab, and to be consistent with current FDA approved indications for pembrolizumab (changes and new criteria shown in red):

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic BTC; and
2. Used in combination with gemcitabine and cisplatin or carboplatin (if ineligible for cisplatin).

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer; and
    a. Tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥10; and
    b. Used in combination with chemotherapy; or
2. Diagnosis of early stage triple-negative breast cancer; and
    a. Disease is considered high-risk; and
    b. Used in combination with chemotherapy as neoadjuvant therapy and may be continued as a single agent as adjuvant treatment after surgery.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
    a. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
    b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
        i. Disease progression on or after chemotherapy; or
        ii. As first-line therapy in combination with chemotherapy, with or without bevacizumab; or
        iii. As second line or subsequent therapy as a single agent; or

2. Diagnosis of FIGO 2014 Stage III-IVA cervical cancer; and
    a. Used in combination with concomitant chemotherapy and radiation.

Keytruda® (Pembrolizumab) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. For adult members:
    a. Diagnosis of relapsed or refractory cHL and member does not have lymphocyte-predominant Hodgkin lymphoma; and
        i. Used as a single agent; or
        ~~ii. Exception: lymphocyte-predominant Hodgkin lymphoma; or~~
        iii. Used in second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin (GVD) or ifosfamide, carboplatin, and etoposide (ICE); or
3. For pediatric members:
    a. Used as a single agent; and
    b. Diagnosis of refractory cHL; or
    c. Relapsed disease after ≥2 therapies; or
    d. Decrease in cardiac function is observed.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of locally advanced, recurrent or metastatic disease; and
2. Not curable by radiation or surgery.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
    a. Member is not a candidate for curative surgery or radiation; and
    b. Used in 1 of the following settings:

i. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
ii. As a single agent for advanced endometrial cancer that is MSI-H or dMMR; or

3. Primary advanced (newly diagnosed stage III/IVA or stage IVB) or recurrent endometrial cancer; and
   a. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance pembrolizumab.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Esophageal or Gastroesophageal Junction (GEJ) Carcinoma Diagnosis]:

1. Diagnosis of locally advanced, recurrent, or metastatic esophageal or GEJ carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
   a. In combination with platinum- and fluoropyrimidine-based chemotherapy; or
4. For second-line or greater therapy:
   a. Following disease progression after 1 or more prior lines of systemic therapy; and
   b. Tumor must be squamous cell histology; and
   c. Used as a single agent; and
   d. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS ≥10).

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced, unresectable, or metastatic gastric or GEJ adenocarcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
   a. Human epidermal receptor 2 (HER2)-positive disease; and
      i. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and
      ii. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1; or
   b. HER2-negative disease; and
      i. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; and

ii. Tumor is positive for expression of PD-L1 with a CPS ≥1.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of head and neck cancer; and
2. Squamous cell histology; and
~~3. Used in first-line or recurrent setting; and~~
~~4. If used in the recurrent setting, member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].~~
5. Used in first-line or recurrent setting for resectable locally advanced disease; and
    a. As neoadjuvant and adjuvant addition to standard care (surgery and adjuvant radiotherapy with or without concomitant chemotherapy); and
    b. Tumor expresses PD-L1 [Combined Positive Score (CPS) ≥1]; and
    c. Request must be for Keytruda®. Keytruda Qlex™ may not be used in the neoadjuvant/adjuvant addition setting; or
6. Used in metastatic or unresectable disease, as first-line or subsequent-line therapy, in combination with chemotherapy; and
    a. Pembrolizumab was not previously used; and
    b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
7. As subsequent therapy as a single agent; and
    a. Disease is PD-L1 positive recurrent or metastatic disease; or
    b. Disease is tumor-mutational burden-high (TMB-H) tumors (≥10 mut/Mb); or
    c. Disease has progressed on or after prior platinum therapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of relapsed or progressive HCC; and
2. Member must have been previously treated with sorafenib; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Melanoma Diagnosis]:

1. Member meets 1 of the following:
    a. Adjuvant treatment of adult and pediatric members 12 years of age or older with stage 2B, 2C, or 3 melanoma following complete resection; or
    b. Diagnosis of unresectable or metastatic melanoma in adults; and
2. Used as a single agent; and

3. Member meets 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line therapy or subsequent therapy for disease progression if not previously used; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
5. For adjuvant treatment of melanoma, approvals will be for a maximum duration of 1 year.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of recurrent, locally advanced, or metastatic MCC; and
2. No history of prior systemic chemotherapy; and
3. Used as a single agent; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
5. Member must be 12 years of age or older; and
6. For use of Keytruda Qlex™, member must weigh ≥40kg.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma; and
2. Used as first-line therapy in adult members; and
3. Used in combination with pemetrexed and platinum chemotherapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Metastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression as follows:
    a. As a single agent, first-line: ≥1%; or
    b. First-line in combination: No expression required; or
    c. As a single agent, second-line: ≥1%; and
4. Member meets 1 of the following:
    a. Previously untreated, metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel; or
    b. Previously untreated, metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or

c. New diagnosis as first-line therapy (member has not received chemotherapy to treat disease) if:
    i. Tumor does not express sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations; or
d. Used as a single agent for disease progression on or after platinum-containing chemotherapy (i.e., cisplatin, carboplatin):
    i. Members with EGFR-mutation-positive tumors should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations* (*examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib);* and
    ii. Members with ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations (examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib).*

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumor (Tissue/Site-Agnostic) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. MSI-H or dMMR solid tumors that have progressed following prior treatment with no satisfactory alternative treatment options; and
3. For Keytruda®, member must be 6 months of age or older; or
    a. For Keytruda Qlex™, member must be 12 years of age or older and weigh ≥40kg.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of stage 3 NSCLC; and
    a. Ineligible for surgery or definitive chemoradiation; and
    b. Tumor proportion scores for PD-L1 expression ≥1%; and
    c. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; or
2. Diagnosis of stage 1B (T2a ≥4cm), stage 2, or stage 3A NSCLC; and
    a. Used as adjuvant treatment following resection and platinum-based chemotherapy; or
3. Diagnosis of resectable (tumors ≥4cm or node positive) NSCLC; and

a. Used as neoadjuvant treatment in combination with platinum-containing chemotherapy; and
b. Continued as a single agent as adjuvant treatment after surgery.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [~~Non-Muscle Invasive~~ Bladder Cancer ~~(NMIBC)~~ Diagnosis]:

1. For non-muscle invasive bladder cancer (NMIBC):
   a. Diagnosis of high-risk NMIBC; and
   b. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
   c. Member must be ineligible for or has elected not to undergo cystectomy; or
2. For muscle invasive bladder cancer (MIBC):
   a. Used as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment; and
   b. Used in combination with enfortumab vedotin; and
   c. Member is ineligible for cisplatin-containing chemotherapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of new or recurrent stage 4 clear-cell RCC; and
   a. Member has not received previous systemic therapy for advanced disease; and
   b. Must be used in combination with axitinib or lenvatinib; and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Progressed on or following a platinum-based regimen and at least 1 other regimen; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Tumor Mutational Burden-High (TMB-H) Solid Tumors Diagnosis]:

1. Diagnosis of unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors; and
2. Used following disease progression after prior treatment; and
3. No satisfactory alternative treatment options; and
4. For Keytruda®, member must be 6 months of age or older; or
    a. For Keytruda Qlex™, member must be 12 years of age or older and weigh ≥40kg.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Member must have 1 of the following:
    a. As a single agent for locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
    b. As a single agent within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
    c. As a single agent frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy or any platinum-containing chemotherapy; and
        i. Cisplatin ineligibility is defined as:
            1. Baseline creatinine clearance of <60mL/min; or
            2. ECOG performance status of 2; or
            3. Class III heart failure; or
            4. Grade 2 or greater peripheral neuropathy; or
            5. Grade 2 or greater hearing loss; or
    d. In combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Next, the College of Pharmacy recommends the prior authorization of Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy) with criteria similar to Opdivo® (nivolumab) and recommends additional updates based on recent FDA approvals and NCCN recommendations for nivolumab (changes and new criteria shown in red):

~~**Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:**~~

~~1. Member has had complete resection of melanoma; and~~
~~2. Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and~~
~~3. Member is 12 years of age or older for Opdivo®; and or~~
~~a. Member is 18 years of age or older for Opdivo Qvantig™; and~~
~~4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and~~
~~5. Used as a single agent; and~~
~~6. Opdivo Qvantig™ must not be used in combination with ipilimumab; and~~
~~7. Maximum approval duration of 1 year.~~
~~8. Dose as follows:~~
~~a. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or~~
~~b. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; and~~
~~c. Maximum duration of 1 year.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite-instability high (MSI-H), ~~or~~ mismatch repair deficient (dMMR), or has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]; and
3. Used as a single agent or in combination with ipilimumab; and
4. Member must be 12 years of age or older for Opdivo®; or
    a. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Cutaneous ~~Unresectable or Metastatic~~ Melanoma Diagnosis]:

1. Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and
    a. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
    b. Used as a single agent; and
    c. Maximum approval duration of 1 year; or
2. Diagnosis of stage 3 disease with clinically positive nodes; and
    a. Used as neoadjuvant therapy; and
    b. Used in combination with ipilimumab or as a single agent; and

c. Adjuvant nivolumab may be continued after therapeutic lymph node dissection (TLND) for 11 cycles; or

3. Diagnosis of unresectable or metastatic melanoma; and
   a. Used as a single agent or in combination with ipilimumab:
      i. As first-line therapy for untreated melanoma; or
      ii. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
      iii. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Member ~~is~~ must be 12 years of age or older for Opdivo®; ~~and~~ or
   a. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.
6. ~~Dose as follows:~~
   ~~a. Single agent:~~
      ~~i. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or~~
      ~~ii. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; or~~
   ~~b. In combination with ipilimumab:~~
      ~~i. Adult and pediatric patients ≥40kg: Nivolumab 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240mg every 2 weeks or 480mg every 4 weeks; or~~
      ~~ii. Pediatric patients <40kg: 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3mg/kg every 2 weeks or 6mg/kg every 4 weeks.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
   a. Used in the first-line setting; and
   b. Used in combination with 1 of the following:
      i. Fluoropyrimidine- and platinum-based chemotherapy; or
      ii. Ipilimumab; ~~or~~ and
   c. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1; or
2. Diagnosis of esophageal or GEJ cancer; and
   a. Used in 1 of the following settings:
      i. Member has received preoperative chemoradiation; and
         1. Member underwent R0 (complete) resection and has residual disease; and
         2. As a single agent; or

ii. As induction therapy in members who are medically fit and planned for esophagectomy; and
    1. Squamous cell histology; and
    2. Tumor is positive for expression of PD-L1 with a CPS ≥1 or tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR); and
    3. Used in combination with fluoropyrimidine- and platinum-based chemotherapy or used in combination with ipilimumab; or
3. Palliative therapy for members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; and
    a. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in first-line setting; and
            1. Used in combination with oxaliplatin and fluorouracil or capecitabine; and
            2. Adenocarcinoma pathology; ~~or~~ and
            3. Tumor is positive for expression of PD-L1 with a CPS ≥1; or
        ii. Used in the second-line or greater setting; and
            1. As a single agent; and
            2. Squamous cell pathology; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of locally advanced, recurrent, or metastatic human epidermal receptor 2 (HER2) negative disease; and
2. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1
3. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic head and neck cancer; and
2. Squamous cell histology; and
3. Member has received prior platinum-containing regimen (i.e., cisplatin, carboplatin); and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Member must be 18 years of age or older for Opdivo Qvantig™; and
6. Opdivo Qvantig™ must not be used in combination with ipilimumab.

~~7. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Member must have unresectable disease and is not a transplant candidate, metastatic disease, or extensive liver tumor burden; and
3. Must meet 1 of the following:
   a. Used as first-line systemic therapy, in combination with ipilimumab, if no previous anti-CTLA-4 combination therapy; or
   b. Used as subsequent therapy, as a single agent, if not previously treated with another checkpoint inhibitor as subsequent therapy; and
   ~~c. If used as first-line therapy, must be used as single agent; and~~
      ~~i. Ineligible for tyrosine kinase inhibitors or anti-angiogenic agents; or~~
   ~~d. If used as second-line or greater therapy, may be used as single agent or in combination with ipilimumab; and~~
      ~~i. Must not have failed other checkpoint inhibitors; and~~
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) Approval Criteria [Hodgkin Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma and member does not have lymphocyte-predominant Hodgkin lymphoma; and
   ~~a. Exception: lymphocyte-predominant Hodgkin lymphoma~~
2. Nivolumab must be used in 1 of the following settings:
   a. As a single-agent; or
   b. In combination with doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease or together with involved-site radiation therapy (ISRT) for state I-II (unfavorable) disease; or
   c. In combination with ISRT plus brentuximab vedotin or as a single agent for primary systemic therapy in members who are not a candidate for anthracyclines; or
   d. In combination with brentuximab vedotin or ifosfamide, carboplatin, and etoposide (ICE) as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
2. For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:
   a. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
   b. Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; ~~and~~ or
   ~~c. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and~~
   d. Used in combination with Yervoy® (ipilimumab) and expresses programmed death ligand 1 (PD-L1) ≥1%; or
3. For first-line therapy for resectable disease (>4cm or node positive), meeting the following:
   a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or
4. For resectable disease (tumors ≥4cm or node positive), meeting the following:
   a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy, followed by single-agent nivolumab as adjuvant treatment after surgery; and
   b. No known EGFR mutations or ALK rearrangements; or
5. For second-line therapy for metastatic disease, meeting the following:
   a. Tumor histology is 1 of the following:
      i. Adenocarcinoma; or
      ii. Squamous cell; or
      iii. Large cell; and
   b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
   d. Used as a single agent; and
   ~~e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.~~
6. Member must be 18 years of age or older for Opdivo Qvantig™; and
7. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
2. Used in 1 of the following settings:
   a. For nivolumab monotherapy:

i. Diagnosis of relapsed or surgically unresectable stage 4 disease; and
ii. Failed prior therapy with 1 of the following medications:
1. Sunitinib; or
2. Sorafenib; or
3. Pazopanib; or
4. Axitinib; or

b. For nivolumab use in combination with ipilimumab:
i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or

c. For nivolumab use in combination with cabozantinib:
i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and

3. Member must be 18 years of age or older for Opdivo Qvantig™; and
4. Opdivo Qvantig™ must not be used in combination with ipilimumab.
5. ~~Dose as follows:~~
~~a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or~~
~~b. In combination with ipilimumab: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks thereafter; or~~
~~c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks; nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.~~

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Must meet 1 of the following criteria:
a. Disease relapsed within 6 months of initial chemotherapy; or
b. Disease is progressive on initial chemotherapy; and
2. Used as a single agent; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and

a. Member has undergone radical resection; and
b. Disease is at high risk of recurrence; or

2. Diagnosis of metastatic or unresectable locally advanced disease; and
   a. Used as second-line or greater therapy; and
   b. Previous failure of a platinum-containing regimen; and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; or
3. Diagnosis of metastatic or unresectable urothelial carcinoma; and
   a. Used as first-line therapy; and
   b. In combination with cisplatin and gemcitabine; and
   c. Followed by maintenance treatment with nivolumab for a maximum duration of 24 months of therapy; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Next, the College of Pharmacy also recommends updating the approval criteria for Braftovi® (encorafenib) and Zynyz® (retifanlimab-dlwr) based on recent FDA approvals (new criteria and changes shown in red):

Braftovi® (Encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic colorectal cancer (CRC); and
   a. BRAF V600E mutation positive; and
   b. Used in combination with cetuximab or panitumumab; and
   c. Disease must have progressed following adjuvant therapy within 12 months; or
   d. Used following progression of any line of metastatic therapy; or
2. Diagnosis of metastatic CRC; and
   a. BRAF V600E mutation positive; and
   b. Used in combination with cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin).

Zynyz® (Retifanlimab-dlwr) Approval Criteria [Squamous Cell Carcinoma of the Anal Canal (SCAC) Diagnosis]:

1. Diagnosis of SCAC; and
2. Used as first-line treatment in combination with carboplatin and paclitaxel; and
   a. Inoperable locally recurrent or metastatic disease; and
   b. A maximum treatment duration of 12 months will apply; or
3. Used as a single agent; and
   a. Locally recurrent or metastatic disease; and
   b. Used as subsequent or second-line therapy if progression or intolerance to platinum-based chemotherapy; and
   c. Member has received no prior immunotherapy; and
   d. A maximum treatment duration of 24 months will apply; and

4. Member must be 18 years of age or older.

Next, the College of Pharmacy recommends updating the Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Odomzo® (sonidegib), Tafinlar® (dabrafenib), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) criteria based on recent FDA approvals and NCCN recommendations (changes and new criteria shown in red):

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cutaneous Squamous Cell Carcinoma (CSCC) Diagnosis]:

1. Diagnosis of metastatic or locally advanced CSCC; and
2. Member must meet 1 of the following:
    a. Disease is very-high risk; and
        i. Used as neoadjuvant treatment when surgery alone may be insufficient; or
        ii. Used as adjuvant treatment following surgery or radiation in patients at high risk of recurrence; or
    b. Disease is primary or recurrent; and
        i. Used for systemic therapy alone when curative surgery and curative radiation are not feasible; and
~~3. Member is not eligible for curative surgery or radiation; and~~
4. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab)~~, Opdivo (nivolumab), Yervoy (ipilimumab)~~].

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, unresectable, or metastatic NSCLC; and
2. Used in the first-line setting; and
3. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
4. Used in 1 of the following settings:
    a. Used as a single agent; and
        i. High programmed death ligand 1 (PD-L1) expression [tumor proportion score (TPS) ≥50%]; or
    b. Used in combination with platinum-based chemotherapy; and
        i. No requirement for PD-L1 expression; or
    c. Used as continuation maintenance therapy following first line therapy with cemiplimab; and
        i. Used in combination with pemetrexed; or
        ii. Used as a single agent.

Mekinist® (Trametinib) Approval Criteria [~~Anaplastic~~ Thyroid Cancer ~~(ATC)~~ Diagnosis]:

1. Diagnosis of ~~ATC~~ thyroid cancer; and
2. Locally advanced or metastatic disease; and

2. *BRAF* V600E mutation; and
~~3. No satisfactory locoregional treatment options.~~
4. Used following progression following prior treatment options and no satisfactory alternative treatment options; and
5. Used in combination with dabrafenib.

Mekinist® (Trametinib) Approval Criteria [Serous Ovarian Cancer Diagnosis]:

1. Diagnosis of persistent disease or recurrent low-grade serous carcinoma; and
2. Meets 1 of the following:
    a. Used in combination with dabrafenib; and
        i. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
        ii. Progression on primary, maintenance, or recurrence therapy; or
        iii. Stable or persistent disease (if not on maintenance therapy); or
        iv. Complete remission and relapse after completing chemotherapy; or
    b. Used as a single agent for platinum-sensitive or platinum-resistant recurrence.

Mekinist® (Trametinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must not have colorectal cancer; and
4. Member must be 1 year of age or older; and
5. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
6. Used in combination with dabrafenib.

Odomzo® (Sonidegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated.~~; or~~
~~2. Diagnosis of metastatic BCC.~~

Tafinlar® (Dabrafenib) Approval Criteria [~~Anaplastic~~ Thyroid Cancer ~~(ATC)~~ Diagnosis]:

1. Diagnosis of ~~ATC~~ thyroid cancer; and
2. Locally advanced or metastatic disease; and
3. *BRAF* V600E mutation; and
~~4. No satisfactory locoregional treatment options.~~

5. Used following progression following prior treatment options and no satisfactory alternative treatment options; and
6. Used in combination with trametinib.

Tafinlar® (Dabrafenib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must not have colorectal cancer; and
4. Member must be 1 year of age or older; and
5. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
6. Used in combination with trametinib.

~~**Yervoy® (Ipilimumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:**~~

~~1. Member has had complete resection of melanoma with lymphadenectomy; and~~
~~2. Member has stage 3 disease with regional nodes of >1mm and no in-transit metastasis; and~~
~~3. Used as a single agent; and~~
~~4. Maximum dose of 10mg/kg will apply.~~

Yervoy® (Ipilimumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
   a. Used in the first-line setting; and
   b. Used in combination with nivolumab; and
   c. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1 or tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR); or
2. Used as induction therapy in members who are medically fit and planned for esophagectomy; and
   a. Tumor is positive for expression of PD-L1 with a CPS ≥1 or tumor is MSI-H or dMMR; and
   b. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Must meet 1 of the following:
   a. Member must have unresectable disease and is not a transplant candidate; or
   b. Metastatic disease or extensive liver tumor burden; and
2. Must meet 1 of the following:
   a. Used in the first-line setting; or

b. Used as second-line or greater therapy in members with progression on or after prior therapy; and
3. Used in combination with nivolumab; and
4. Must not have failed other checkpoint inhibitors.

Yervoy® (Ipilimumab) Approval Criteria [Cutaneous Melanoma Diagnosis]:

1. Stage 3 cutaneous melanoma with regional nodes of >1mm and no in-transit metastasis; and
    a. Used as a single agent; or
2. As neoadjuvant therapy in combination with nivolumab as initial primary treatment for stage III cutaneous melanoma disease with clinically positive nodes; or
3. Unresectable or metastatic melanoma; and
    a. Used in combination with nivolumab as:
        i. First-line therapy; or
        ii. Second-line or subsequent therapy for disease progression if nivolumab was not previously used; or
    b. Used as a single agent for 1 of the following:
        i. First-line therapy as a single course of 4 treatments; or
        ii. Second-line or subsequent lines of therapy as a single course of 4 treatments; or
        iii. Retreatment, consisting of a 4-dose limit, for a member who had:
            1. No significant systemic toxicity during prior ipilimumab therapy; and
            2. Whose disease progressed after being stable >6 months following completion of a prior course of ipilimumab; and
            3. For whom no intervening therapy has been administered.

Yervoy® (Ipilimumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
    a. Used for first-line therapy ~~and must meet the following:~~; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Used in 1 of the following settings:
        i. Used in combination with nivolumab and member has programmed death ligand 1 (PD-L1) ≥1% expression; or
        ii. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy.~~; and~~
        iii. ~~Expresses programmed death ligand 1 (PD-L1) ≥1%.~~

~~**Yervoy® (Ipilimumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:**~~

~~1. Diagnosis of unresectable or metastatic melanoma; and~~
~~2. Used in combination with nivolumab as:~~
~~a. First-line therapy; or~~
~~b. Second-line or subsequent therapy for disease progression if nivolumab was not previously used; or~~
~~3. Used as a single agent for 1 of the following:~~
~~a. First-line therapy as a single course of 4 treatments; or~~
~~b. Second-line or subsequent lines of therapy as a single course of 4 treatments; or~~
~~c. Retreatment, consisting of a 4-dose limit, for a member who had:~~
~~i. No significant systemic toxicity during prior ipilimumab therapy; and~~
~~ii. Whose disease progressed after being stable >6 months following completion of a prior course of ipilimumab; and~~
~~iii. For whom no intervening therapy has been administered; and~~
~~4. Maximum dose of 3mg/kg will apply.~~

Zelboraf® (Vemurafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Vemurafenib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line or subsequent therapy; and
4. Used as a single agent or in combination with cobimetinib, or in combination with cobimetinib and atezolizumab.

[1] U.S. Food and Drug Administration (FDA). FDA Grants Accelerated Approval to Encorafenib with Cetuximab and mFOLFOX6 for Metastatic Colorectal Cancer with a BRAF V600E Mutation. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-encorafenib-cetuximab-and-mfolfox6-metastatic-colorectal-cancer-braf. Issued 12/20/2024. Last accessed 01/27/2026.
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[10] U.S. FDA. Yervoy® (Ipilimumab) Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/125377Orig1s136ltr.pdf. Issued 05/23/2025. Last accessed 01/27/2026.
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[12] U.S. FDA. FDA Approves Pembrolizumab and Berahyaluronidase Alfa-pmph for Subcutaneous Injection. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-and-berahyaluronidase-alfa-pmph-subcutaneous-injection. Issued 09/19/2025. Last accessed 01/27/2026.
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Appendix K

Vote to Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1]

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for hepatocellular carcinoma (HCC) allow for the use of tislelizumab-jsgr as first-line systemic therapy.

Recommendations

The College of Pharmacy recommends updating the Tevimbra® (tislelizumab-jsgr) approval criteria based on NCCN recommendations with the following criteria (shown in red):

Tevimbra® (Tislelizumab-jsgr) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Used in 1 of the following settings:
   a. Disease is liver-confined, unresectable, and member is ineligible for transplant; or
   b. Disease is extrahepatic/metastatic and member is ineligible for resection, transplant, or locoregional therapy; and
3. Used as first-line systemic therapy; and
4. As a single agent.

[1] National Comprehensive Cancer Network (NCCN). Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Last revised 10/22/2025. Last accessed 01/27/2026.

Appendix L

Vote to Prior Authorize Gomekli® (Mirdametinib), Papzimeos™ (Zopapogene Imadenovec-drba), and Romvimza™ (Vimseltinib) and Update the Approval Criteria for the Non-Malignant Solid Tumor Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **February 2025:** The FDA approved Gomekli® (mirdametinib) for the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas not amenable to complete resection.
- **February 2025:** The FDA approved Romvimza™ (vimseltinib) for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.
- **August 2025:** The FDA approved Papzimeos™ (zopapogene imadenovec-drba) for the treatment of adults with recurrent respiratory papillomatosis.
- **September 2025:** The FDA approved Koselugo® (selumetinib) for an age expansion for the treatment of pediatric patients 1 year of age and older with NF1 who have symptomatic, inoperable plexiform neurofibromas. Previously, Koselugo® was FDA approved for this indication in patients 2 years of age or older. Additionally, the FDA approved a new oral granule formulation of Koselugo® for use in patients who have difficulty swallowing whole capsules. The oral granules are available in 5mg and 7.5mg strengths and are contained within capsules that can be opened and mixed with a small amount of smooth yogurt or fruit puree containing apple, banana, pear, or strawberry prior to consuming.
- **November 2025:** The FDA approved Koselugo® (selumetinib) for a new indication for the treatment of adults with NF1 who have symptomatic, inoperable plexiform neurofibromas. Previously, Koselugo® was only FDA approved for pediatric patients with this indication.

Gomekli® (Mirdametinib) Product Summary[6]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult and pediatric patients 2 years of age and older with NF1 who have symptomatic plexiform neurofibromas not amenable to complete resection

How Supplied:
- Capsules: 1mg and 2mg
- Tablets for oral suspension: 1mg

Dosing and Administration:
- The recommended dose is 2mg/m^2 orally twice daily (approximately every 12 hours) with or without food for the first 21 days of each 28-day cycle.
- The maximum dose is 4mg twice daily.
- Treatment should be continued until disease progression or unacceptable toxicity.
- The capsules should be swallowed whole and should not be opened, broken, or chewed. The tablets can be swallowed whole or can be dispersed in drinking water and administered orally as a liquid.

Cost: The Wholesale Acquisition Cost (WAC) is $222.75 for each 1mg capsule/tablet or $445.50 for each 2mg capsule. For a member using the maximum recommended dose of 4mg twice daily for the first 21 days of each 28-day cycle, this would result in an estimated cost of $37,422 per 28-day cycle or $486,486 per year.

Papzimeos™ (Zopapogene Imadenovec-drba) Product Summary[7]

Therapeutic Class: Non-replicating adenoviral vector-based immunotherapy

Indication(s): Treatment of adults with recurrent respiratory papillomatosis

How Supplied: Single-dose vial (SDV) containing 5 x 10^{11} particle units (PU) in an extractable volume of 1mL of suspension

Dosing and Administration:
- The recommended dose is 5 x 10^{11} PU per injection administered by subcutaneous (sub-Q) injection 4 times over a 12-week interval.
- The second dose should be administered 2 weeks after dose 1, the 3rd dose should be administered 6 weeks after dose 1, and the 4th dose should be administered 12 weeks after dose 1.
- Prior to initial administration, a surgical debulking of visible papilloma should be performed to establish minimal residual disease.

- To maintain minimal residual disease during treatment with Papzimeos™, visible papilloma should be removed, if present, prior to the 3rd and 4th administration of Papzimeos™.

Cost: The WAC is $115,000 per SDV, resulting in an estimated cost of $460,000 for the recommended 4-dose treatment series.

Romvimza™ (Vimseltinib) Product Summary[8]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause worsening functional limitation or severe morbidity

How Supplied: 14mg, 20mg, and 30mg oral capsules

Dosing and Administration:

- The recommended dose is 30mg orally taken twice weekly, with or without food, with a minimum of 72 hours between doses; doses should be taken on the same days each week.
- Dose reductions to 20mg twice weekly or 14mg twice weekly may be needed due to adverse reactions.

Cost: The WAC is $3,462 for each 30mg capsule. For a member using the recommended dose of 30mg twice weekly, this would result in an estimated cost of $27,696 per 28 days or $360,048 per year.

Recommendations

The College of Pharmacy recommends the prior authorization of Gomekli® (mirdametinib), Papzimeos™ (zopapogene imadenovec-drba), and Romvimza™ (vimseltinib) with the following criteria (shown in red):

Gomekli® (Mirdametinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:

1. Diagnosis of NF1; and
2. Member must be 2 years of age or older; and
3. Member has symptomatic plexiform neurofibromas not amenable to complete resection; and
4. Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling.

Papzimeos™ (Zopapogene Imadenovec-drba) Approval Criteria [Recurrent Respiratory Papillomatosis Diagnosis]:

1. Diagnosis of recurrent respiratory papillomatosis; and
2. Member must be 18 years of age or older; and
3. Initial administration will follow surgical debulking of visible papilloma to maintain minimal residual disease; and
4. Visible papilloma will be removed, if present, prior to the third and fourth administration; and
5. Approvals will be for no more than 4 doses per member per lifetime.

Romvimza™ (Vimseltinib) Approval Criteria [Tenosynovial Giant Cell Tumor (TGCT) Diagnosis]:

1. Diagnosis of TGCT; and
2. Member is 18 years of age or older; and
3. Member is not a candidate for surgical resection.

Additionally, the College of Pharmacy recommends updating the Koselugo® (selumetinib) approval criteria based on recent FDA approvals with the following changes (shown in red):

Koselugo® (Selumetinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:

1. Diagnosis of NF1 with symptomatic, inoperable plexiform neurofibromas; and
2. Member must be ~~2 years~~ 1 year of age or older; and
3. Member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
4. For the 5mg and 7.5mg oral granule formulation, the request must indicate that the member is unable to swallow whole capsules.

[1] U.S. Food and Drug Administration (FDA). FDA Approves Mirdametinib for Adult and Pediatric Patients with Neurofibromatosis Type 1 Who Have Symptomatic Plexiform Neurofibromas Not Amenable to Complete Resection. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-mirdametinib-adult-and-pediatric-patients-neurofibromatosis-type-1-who-have-symptomatic. Issued 02/11/2025. Last accessed 01/27/2026.
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[3] U.S. FDA. FDA Approves First Immunotherapy for Recurrent Respiratory Papillomatosis. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-immunotherapy-recurrent-respiratory-papillomatosis. Issued 08/14/2025. Last accessed 01/27/2026.
[4] U.S. FDA. FDA Approves Selumetinib for Pediatric Patients 1 Year of Age and Older with Neurofibromatosis Type 1 with Symptomatic, Inoperable Plexiform Neurofibromas. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-selumetinib-pediatric-patients-1-year-age-and-older-neurofibromatosis-type-1. Issued 09/10/2025. Last accessed 01/27/2026.
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Appendix M

Vote to Prior Authorize Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam® (IGIV, Human), Panzyga® (IGIV, Human-ifas), and Xembify® (IGSC, Human)

Oklahoma Health Care Authority
February 2026

Cost Comparison: IGIV Products

Product	Cost Per Gram	Cost Per Dose*	Cost Per Year⁺
Asceniv™ (IGIV, human-slra) 10%	**$965.40**	**$38,616.00**	**$695,088.00**
Alyglo™ (IGIV, human-stwk) 10%	**$247.68**	**$9,907.20**	**$178,329.60**
Bivigam® (IGIV, human) 10%	**$159.29**	**$6,371.60**	**$114,688.80**
Panzyga® (IGIV, human-ifas) 10%	**$142.45**	**$5,698.00**	**$102,564.00**
Gammaplex® (IGIV, human) 10%	**$127.86**	**$5,114.40**	**$92,059.20**
Octagam® (IGIV, human) 5%	**$94.77**	**$3,790.80**	**$68,234.40**
Gammagard S/D® (IGIV, human) 10g vial	$157.78	$6,311.20	$113,601.60
Privigen® (IGIV, human) 10%	$100.56	$4,022.40	$72,403.20
Gammaked™ (IG inj, human) 10g/100mL	$98.15	$3,926.00	$70,668.00
Gamunex®-C (IG inj, human) 10g/100mL	$98.15	$3,926.00	$70,668.00
Gammagard Liquid® (IG inf, human) 10%	$94.58	$3,783.20	$68,097.60

Costs do not reflect rebated prices or net costs.
Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Allowable Costs (SPAC).
*Cost per dose is based on 500mg/kg, which is the midpoint of the FDA-approved dosing range of 400-600mg/kg for primary immunodeficiency (PI), rounded to the nearest 5g for a 75kg patient.
⁺Cost per year is based on IV administration every 3 weeks, which is the shortest interval recommended by the FDA for PI; the cost per year calculation assumes a stable dose (e.g., no titration based on individual patient response or IgG levels).
IGIV = immunoglobulin intravenous; inf = infusion; inj = injection

Cost Comparison: IGSC Products

Product	Cost Per Gram	Cost Per Dose*	Cost Per Year+
Xembify® (IGSC, human) 20%	**$197.40**	**$1,974.00**	**$102,648.00**
Cuvitru® (IGSC, human) 20%	**$172.62**	**$1,726.20**	**$89,762.40**
Hizentra® (IGSC, human) 20%	**$145.43**	**$1,454.30**	**$75,623.60**
HyQvia® (IG inf, human/recombinant human hyaluronidase) 10%	$183.30	$1,833.00	$95,316.00
Cutaquig® (IGSC, human) 16.5%	$146.76	$1,467.60	$76,315.20
Gammaked™ (IG inj, human) 10g/100mL	$98.15	$981.50	$51,038.00
Gamunex®-C (IG inj, human) 10g/100mL	$98.15	$981.50	$51,038.00
Gammagard Liquid® (IG inf, human) 10%	$94.58	$945.80	$49,181.60

Costs do not reflect rebated prices or net costs.
Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Allowable Costs (SPAC).
*Cost per dose is based on the FDA-approved starting dose of 150mg/kg for primary immunodeficiency (PI), rounded to the nearest 5mg, for a 75kg patient.
+Cost per year excludes loading doses and is based is SC administration weekly, which is a recommended initiating interval per the FDA; assumes a stable dose (e.g., no titration based on individual patient response or IgG levels).
IGSC = immunoglobulin subcutaneous; inf = infusion; inj = injection

Recommendations

The College of Pharmacy recommends the prior authorization of Alyglo™ (IGIV, human-stwk), Asceniv™ (IGIV, human-slra), Bivigam® (IGIV, human), Cuvitru® (IGSC, human), Gammaplex® (IGIV, human), Hizentra® (IGSC, human), Octagam® (IGIV, human), Panzyga® (IGIV, human-ifas), and Xembify® (IGSC, human) with the following criteria (shown in red):

Alyglo™ [Immune Globulin (IG) Intravenous (IV), Human-stwk], Asceniv™ (IGIV, Human-slra), Bivigam® (IGIV, Human), Cuvitru® [IG Subcutaneous (SC), Human], Gammaplex® (IGIV, Human), Hizentra® (IGSC, Human), Octagam (IGIV, Human), Panzyga® (IGIV, Human-ifas) and Xembify® (IGSC, Human) Approval Criteria:

1. Documentation of prior stabilization on the requested product with documented benefit from therapy (i.e., recent office notes) must be submitted with the request; or
2. For Alyglo™ and Asceniv™, a patient-specific clinically significant reason why the member cannot use all other available immunoglobulin therapy products must be provided; or
3. A patient-specific, clinically significant reason why the member cannot use all of the following, which are available without prior authorization, as appropriate for the requested route of administration:
    a. For intravenous (IV) administration:
        i. Gammagard Liquid® (IG infusion, human); and
        ii. Gammagard S/D® (IGIV, human); and
        iii. Gammaked™ (IG injection, human); and

iv. Gamunex®-C (IG injection, human); and
v. Privigen® (IGIV, human); and

b. For subcutaneous (SC) administration:
i. Cutaquig® (IGSC, human); and
ii. HyQvia® (IG infusion, human and recombinant human hyaluronidase); and
iii. Gammagard Liquid® (IG infusion, human); and
iv. Gammaked™ (IG injection, human); and
v. Gamunex®-C (IG injection, human); and

4. Member's recent weight (taken within the last 3 months) utilized for dosing calculations (e.g., actual body weight, ideal body weight, adjusted body weight) and intended dosing frequency must be provided on the prior authorization request in order to authorize the appropriate amount of product; and
5. Initial approvals will be for up to 6 months. Subsequent approval will be for the duration of up to 1 year if there is documentation of clinical effectiveness.

Appendix N

Vote to Prior Authorize Redemplo® (Plozasiran) and Update the Approval Criteria for the Antihyperlipidemics

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5,6,7,8,9,10]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **July 2025:** The FDA approved a label update for Leqvio® (inclisiran) which removed the requirement for Leqvio® to be used in combination with a statin. Leqvio® is now approved as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).
- **August 2025:** The FDA approved a label expansion for Repatha® (evolocumab) to include those at risk of major adverse cardiovascular (CV) events due to uncontrolled LDL-C. This removed the prior requirement that the patient had to have established CV disease.
- **September 2025:** The FDA approved an age expansion for Evkeeza® (evinacumab-dgnb) down to 1 year of age or older to treat homozygous familial hypercholesterolemia (HoFH). Previously, Evkeeza® was approved in patients 5 years of age or older. The efficacy of Evkeeza® was studied in 6 patients 1 year to younger than 5 years of age in an expanded access program, which showed a reduction in LDL-C.
- **October 2025:** The FDA approved a label expansion for Praluent® (alirocumab) to include those at risk of major adverse CV events due to uncontrolled LDL-C. This removed the prior requirement that the patient had to have established CV disease.
- **November 2025:** The FDA approved Redemplo® (plozasiran) as an adjunct to diet to reduce triglycerides (TG) in adults with familial chylomicronemia syndrome (FCS).
- **November 2025:** The FDA approved revisions to the indications in the Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe) *Prescribing Information* to clarify that bempedoic acid is indicated to reduce the risk of major adverse CV events, such as CV death, myocardial infarction, stroke, or coronary revascularization, in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin). Additionally, for the HeFH diagnosis, bempedoic acid should be used in combination with exercise along with diet.

Redemplo® (Plozasiran) Product Summary[11,12]

Therapeutic Class: Apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid (siRNA)

Indication(s): Adjunct to diet to reduce TG in adults with FCS

How Supplied: 25mg/0.5mL solution in a single-dose pre-filled syringe

Dosing and Administration:

- The recommended dosage of Redemplo® is 25mg injected subcutaneously (sub-Q) once every 3 months.
- Redemplo® should be injected sub-Q into the front of the thigh or abdomen. The outer area of the upper arm can be used as an injection site if a health care provider or caregiver administers the injection.

Efficacy: The efficacy of Redemplo® was studied in the PALISADE clinical trial, a randomized, placebo-controlled, double-blind trial in adult patients with genetically confirmed or clinically diagnosed FCS who were maintained on a low-fat diet (≤20 grams of fat per day).

- Key Inclusion Criteria:
  - 18 years of age or older
  - Fasting TGs ≥880mg/dL at screening
  - Diagnosis of severe hypertriglyceridemia that was resistant to standard lipid-lowering therapy
  - A documented history of a fasting TGs of >1,000mg/dL on ≥3 occasions
  - Genetically confirmed FCS or symptomatic persistent chylomicronemia
- Exclusion Criteria:
  - Uncontrolled diabetes
  - Use of corticosteroids or anabolic steroids
  - Chronic kidney disease
- Intervention(s): 75 eligible patients were randomly assigned in a 2:1:2:1 ratio to receive 25mg of Redemplo® or volume-matched placebo or to receive 50mg of Redemplo® or volume-matched placebo sub-Q every 3 months for 12 months.
- Primary Endpoint: The primary endpoint was the median percent change from baseline in the fasting TG level at 10 months.
- Results:
  - The median relative reduction from baseline in the fasting TG level was −80% in the 25mg Redemplo® group, −78% in the 50mg Redemplo® group, and −17% in the placebo group.
  - The median percent change in the fasting TG level in the Redemplo® group compared with placebo was −59% points [95%

confidence interval (CI): −90, −28; P<0.001] in the 25mg group and −53% points (95% CI: −83, –22; P<0.001) in the 50mg group.

Cost Comparison:

Medication	Cost Per Syringe	Cost Per Year
Redemplo® (plozasiran) 25mg/0.5mL injection	**$15,000**	**$60,000[α]**
Tryngolza® (olezarsen) 80mg/0.8mL injection	$49,584	$595,008[β]

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
[α]Cost based on the FDA approved dose of 25mg/0.5mL once every 3 months.
[β]Cost based on the FDA approved dose of 80mg/0.8mL once monthly.

Recommendations

The College of Pharmacy recommends the prior authorization of Redemplo® (plozasiran) with the following criteria and recommends updating the approval criteria for Tryngolza® (olezarsen) based on the FDA approval of Redemplo®, net cost, and clinical practice (shown in red):

Redemplo® (Plozasiran) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
    a. Fasting triglyceride levels ≥880mg/dL; and
    b. One of the following:
        i. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); or
        ii. Familial chylomicronemia score ≥10; or
        iii. North American familial chylomicronemia syndrome score ≥45; or
        iv. History of clinical signs and symptoms associated with FCS (i.e., pancreatitis and/or abdominal pain, eruptive xanthomas, lipemia retinalis, lipemic plasma) and a diagnosis of multifactorial chylomicronemia syndrome (MCS) has been ruled out; and
3. Member must be 18 years of age or older; and
4. Must be prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a specialist with expertise in the treatment of disorders related to severe hypertriglyceridemia; and
5. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Redemplo®; and

6. Member or caregiver will be trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Redemplo®; and
7. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Tryngolza® (Olezarsen) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
    a. Fasting triglyceride levels ≥880mg/dL; and
    b. One of the following:
        i. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); or
        ii. Familial chylomicronemia score ≥10; or
        iii. North American familial chylomicronemia syndrome score ≥45; or
        iv. History of clinical signs and symptoms associated with FCS (i.e., pancreatitis and/or abdominal pain, eruptive xanthomas, lipemia retinalis, lipemic plasma) and a diagnosis of multifactorial chylomicronemia syndrome (MCS) has been ruled out; and
3. Member must be 18 years of age or older; and
4. Must be prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a specialist with expertise in the treatment of disorders related to severe hypertriglyceridemia; and
5. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Tryngolza®; and
6. Member or caregiver ~~has been~~ will be trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tryngolza®; and
7. A patient specific, clinically significant reason why the member cannot use Redemplo® (plozasiran) must be provided; and
8. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a

positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the approval criteria for Evkeeza® (evinacumab-dgnb), Leqvio® (inclisiran), Nexletol® (bempedoic acid), Nexlizet® (bempedoic acid/ezetimibe), Praluent® (alirocumab), and Repatha® (evolocumab) based on the new FDA approved label expansions and clinical practice (changes shown in red):

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

1. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
    a. Documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
    b. An untreated LDL >500mg/dL and at least 1 of the following:
        i. Documented evidence of definite HeFH in both parents; or
        ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and
2. Member must be ~~5~~ 1 year~~s~~ of age or older; and
3. Documented trial of high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy at least 12 weeks in duration; and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Documented trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®) at least 12 weeks in duration; and
6. Member requires additional lowering of LDL-cholesterol (LDL-C) (baseline, current, and goal LDL-C levels must be provided); and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for 5 months after discontinuation of therapy; and

8. Initial approvals will be for the duration of 6-months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication as an adjunct to diet and exercise ~~statin therapy~~ for the treatment of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. Established atherosclerotic cardiovascular disease (ASCVD); and
        i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or
    c. Primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
2. Member must be 18 years of age or older; and
3. Documented trial of all of the following for at least 12 weeks in duration each:
    a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and
    b. Ezetimibe; and
    c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and

5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and
6. Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and
    a. Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and
        i. Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or
        ii. Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and
7. Initial approvals will be for the duration of 6 months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of this medication, and compliance will be checked at that time and every 6 months thereafter for continued approval.

Nexletol® (Bempedoic Acid) and Nexlizet® (Bempedoic Acid/Ezetimibe) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. As an adjunct to diet and exercise, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with heterozygous familial hypercholesterolemia (HeFH). HeFH must be confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. As an adjunct to diet and exercise, in combination with other LDL-C lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
    c. To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, and coronary revascularization)

in ~~those~~ adults at increased risk for these events who are unable to take recommended statin therapy; and ~~with 1 of the following:~~
    ~~i. High risk for a cardiovascular disease (CVD) event without established atherosclerotic CVD (ASCVD); or~~
    ~~ii. Established ASCVD; and~~
    iii. Supporting diagnoses/conditions/risk factors ~~and dates of occurrences must be submitted~~ signifying increased risk of major adverse CV events must be submitted; and
2. Member must be 18 years of age or older; and
3. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
    a. LDL-C levels should be included following at least 4 weeks of treatment; and
    b. Member must not be taking simvastatin at doses >20mg or pravastatin at doses >40mg due to drug interactions with Nexletol® and Nexlizet®; and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
6. A quantity limit of 30 tablets per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Praluent® (Alirocumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:

1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or

iii. Dutch Lipid Clinic Network Criteria score of >8; or

b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
   i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
   ii. An untreated LDL >500mg/dL and at least 1 of the following:
      1. Documented evidence of definite HeFH in both parents; or
      2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or

c. ~~As an adjunct to maximally tolerated statin therapy~~ To reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, and unstable angina requiring hospitalization) ~~coronary revascularization~~ in adults at increased risk for these events ~~with established cardiovascular disease (CVD)~~; and
   ~~i. Documentation of established CVD; and~~
   ii. Supporting diagnoses/conditions/risk factors ~~and date of occurrence~~ signifying ~~established CVD~~ increased risk of major adverse CV events must be submitted; or

d. Primary hyperlipidemia; and
   i. Member's untreated LDL-C level must be ≥190mg/dL; and
   ii. Current LDL-C level is ≥100mg/dL; and

2. For HeFH, member must be 8 years of age or older; and
3. For FDA approved indications other than HeFH, the member must be 18 years of age or older; and
4. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
   a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
   b. LDL-C levels should be included following at least 12 weeks of treatment; and
5. Members with statin intolerance must meet 1 of the following:
   a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or

c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and

6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
8. Prescriber must verify that member ~~has been~~ will be counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or pens per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Repatha® (Evolocumab)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
      i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. Both of the following:
         1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
         2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
      iii. Dutch Lipid Clinic Network Criteria score of >8; or
   b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
      i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
      ii. An untreated LDL >500mg/dL and at least 1 of the following:

1. Documented evidence of definite HeFH in both parents; or
2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or

c. ~~As an adjunct to maximally tolerated statin therapy~~ To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or ~~and~~ coronary revascularization) in adults at increased risk for these events ~~with established cardiovascular disease (CVD)~~; and
   i. ~~Documentation of established CVD; and~~
   ii. Supporting diagnoses/conditions/risk factors ~~and date of occurrence~~ signifying ~~established CVD~~ increased risk of major adverse CV events must be submitted; or

d. Primary hyperlipidemia; and
   i. Member's untreated LDL-C level must be ≥190mg/dL; and
   ii. Current LDL-C level is ≥100mg/dL; and

2. For HeFH or HoFH, member must be 10 years of age or older; and
3. For FDA approved indications other than HeFH or HoFH, the member must be 18 years of age or older; and
4. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
   a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
   b. LDL-C levels should be included following at least 12 weeks of treatment; and
5. Members with statin intolerance must meet 1 of the following:
   a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or
   c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
   d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and

8. Prescriber must verify that member ~~has been~~ will be counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or auto-injectors per 28 days will apply; and
10. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

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[1] Novartis. Novartis Twice-Yearly Leqvio® (Inclisiran) Receives FDA Approval for New Indication Enabling First-Line Use. Available online at: https://www.novartis.com/us-en/news/media-releases/novartis-twice-yearly-leqvio-inclisiran-receives-fda-approval-new-indication-enabling-first-line-use. Issued 07/31/2025. Last accessed 01/20/2026.
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Appendix O

Vote to Prior Authorize Coxanto® (Oxaprozin 300mg Capsule), Ibuprofen 300mg Tablet, Vyscoxa™ (Celecoxib Oral Suspension), and Xifyrm™ (Meloxicam Injection) and Update the Approval Criteria for the Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **October 2023:** The FDA approved Coxanto® (oxaprozin 300mg capsule) for the relief of signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), or juvenile rheumatoid arthritis (JRA). Coxanto® has not previously been a covered product through SoonerCare because the manufacturer was not participating with the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS); however, a new manufacturer began marketing Coxanto® in November 2025, and this manufacturer is participating with the MDRP.
- **June 2025:** The FDA approved Xifyrm™ (meloxicam injection) for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics.
- **July 2025:** The FDA approved Vyscoxa™ (celecoxib oral suspension) for adults with OA, RA, or ankylosing spondylitis (AS) or for pediatric patients 2 years of age and older with JRA.

News:

- **February 2025:** According to the FDA's National Drug Code (NDC) Directory, a new formulation of ibuprofen, available as a 300mg oral tablet, began being marketed in February 2025.

Coxanto® (Oxaprozin 300mg Capsule) Product Summary[5]

Therapeutic Class: NSAID

Indication(s): Relief of signs and symptoms of OA, RA, or JRA

How Supplied: 300mg oral capsule

Dosing and Administration:

- OA: 1,200mg [(4) 300mg capsules] orally once daily
- RA: 1,200mg [(4) 300mg capsules] orally once daily
- JRA: Recommended dose is based on body weight as follows:
  - 22-31kg: 600mg [(2) 300mg capsules] orally once daily
  - 32-54kg: 900mg [(3) 300mg capsules] orally once daily
  - ≥55kg: 1,200mg [(4) 300mg capsules] orally once daily
- The lowest effective dosage should be used for the shortest duration consistent with individual patient treatment goals.

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Coxanto® (oxaprozin) 300mg capsule	**$42.88**	**$5,145.60**	**$61,747.20**
oxaprozin 600mg tablet (generic)	$0.40	$24.00	$288.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on use of 1,200mg daily
Unit = Each capsule or tablet

Ibuprofen 300mg Tablet Product Summary[6]

Therapeutic Class: NSAID

Indication(s): Relief of the signs and symptoms of RA and OA, for relief of mild to moderate pain, and for the treatment of primary dysmenorrhea

How Supplied: 300mg oral tablets

Dosing and Administration:

- RA and OA: Suggested dosage is 1,200-3,200mg per day (in divided doses, 3-4 times daily)
- Mild to moderate pain or dysmenorrhea: 400mg every 4-6 hours as necessary

Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
ibuprofen 300mg tablet (generic)	**$13.19**	**$3,957.00**	**$47,484.00**
ibuprofen 400mg tablet (generic)	$0.04	$9.60	$115.20
ibuprofen 600mg tablet (generic)	$0.05	$7.50	$90.00
ibuprofen 800mg tablet (generic)	$0.06	$7.20	$86.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on use of up to 3,200mg daily

Vyscoxa™ (Celecoxib Oral Suspension) Product Summary[7]

Therapeutic Class: NSAID

Indication(s): Treatment of adults with OA, RA, or AS or for the treatment of JRA in pediatric patients 2 years of age and older

- **Limitation(s) of Use:** Vyscoxa™ must be administered on an empty stomach at least 2 hours before or 1 hour after food. Taking Vyscoxa™ with food results in plasma exposures of celecoxib up to 50% higher than intended. If patients cannot tolerate Vyscoxa™ in the fasted state, discontinue use of Vyscoxa™.

How Supplied: 10mg/mL unflavored oral suspension in a 473mL bottle

Dosing and Administration:

- OA: 200mg (20mL) once daily or 100mg (10mL) twice daily
- RA: 100mg (10mL) to 200mg (20mL) twice daily
- AS: 200mg (20mL) once daily single dose or 100mg (10mL) twice daily; if no effect is observed after 6 weeks, a trial of 200mg (20mL) twice daily may be of benefit
- JRA: 50mg (5mL) twice daily in patients 10kg to 25kg; 100mg (10mL) twice daily in patients >25kg
- Vyscoxa™ is not recommended at a single dose greater than 200mg (20mL). Single doses of the suspension greater than 200mg may result in celecoxib concentrations higher than intended. For patients who require a single dose over 200mg, a different celecoxib formulation should be used.

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Vyscoxa™ (celecoxib) 10mg/mL suspension	**$6.12**	**$7,344.00**	**$88,128.00**
celecoxib 200mg capsule (generic)	$0.07	$4.20	$50.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on use of 200mg twice daily
Unit = Each capsule or mL

Xifyrm™ (Meloxicam Injection) Product Summary[8]

Therapeutic Class: NSAID

Indication(s): For use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics

- **Limitation(s) of Use:** Because of delayed onset of analgesia, Xifyrm™ alone is not recommended for use when rapid onset of analgesia is required.

How Supplied: 30mg/mL single-dose vial (SDV)

Dosing and Administration:

- The recommended dose is 30mg once daily, administered by intravenous (IV) bolus injection over 15 seconds.
- Xifyrm™ should be used for the shortest duration consistent with individual patient treatment goals (clinical studies were for a maximum of 3 doses).
- The patient's analgesic response should be monitored and a short-acting, non-NSAID, immediate-release analgesic should be administered if analgesic response is inadequate.
- Patients must be well hydrated before Xifyrm™ administration to reduce the risk of renal toxicity.

Cost Comparison:

Product	Cost Per Unit	Cost Per Day*
Xifyrm™ (meloxicam) 30mg/mL vial	**$30.00**	**$30.00**
meloxicam 15mg tablet (generic)	$0.01	$0.01
meloxicam 7.5mg tablet (generic)	$0.01	$0.01

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on 30mg daily for Xifyrm™ and 1 tablet daily for meloxicam tablets.

Recommendations

The College of Pharmacy recommends the following changes to the NSAIDs Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Prior authorization and placement of Coxanto® (oxaprozin 300mg capsule), ibuprofen 300mg tablet, Vyscoxa™ (celecoxib oral suspension), and Xifyrm™ (meloxicam injection) into the Special PA Tier with the additional criteria listed below; and
2. Moving EC-Naprosyn® (naproxen) 375mg tablet from Tier-1 to Tier-2; and
3. Moving Feldene® (piroxicam) from Tier-2 to Tier-1 based on net cost.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) caps	diclofenac ER (Voltaren® XR)	celecoxib (Elyxyb®) oral solution
diclofenac potassium (Cataflam®)	diclofenac sodium/ misoprostol (Arthrotec®)	**celecoxib (Vyscoxa™) susp**
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac epolamine (generic Flector® Patch)
diclofenac sodium 1% (Voltaren® Gel)	diflunisal 500mg tabs	diclofenac potassium (Cambia®) powder pack
etodolac (Lodine®) tabs	etodolac ER (Lodine® XL)	diclofenac potassium (Lofena™) tabs
ibuprofen (Motrin®) **400mg, 600mg, & 800mg tabs**	flurbiprofen (Ansaid®)	diclofenac potassium (Zipsor®) caps
indomethacin (Indocin®) caps	indomethacin (Indocin® SR) ER caps	diclofenac sodium (Pennsaid®) topical drops
meloxicam (Mobic®)	mefenamic acid (Ponstel®)	diflunisal (Dolobid™) 250mg and 375mg tabs
nabumetone (Relafen®)	naproxen DR (EC-Naprosyn®) ~~**500mg tab**~~	fenoprofen (Nalfon®)
naproxen* (Naprosyn®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	ibuprofen (Caldolor®) inj
~~**naproxen DR (EC-Naprosyn®) 375mg tab**~~	oxaprozin (Daypro®) **600mg tabs**	**ibuprofen (Motrin®) 300mg tabs**
piroxicam (Feldene®)	~~**piroxicam (Feldene®)**~~	ibuprofen/acetaminophen (Combogesic® IV) inj+
sulindac (Clinoril®)		ibuprofen/famotidine (Duexis®)
		indomethacin (Indocin®) supp & susp
		ketoprofen (Orudis®) caps
		ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®) nasal spray
		meclofenamate (Meclomen®)
		meloxicam (Vivlodex®) caps
		meloxicam (Xifyrm™) inj+
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
		oxaprozin (Coxanto®) 300mg caps
		tolmetin (Tolectin®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
⁺Unique criteria applies.
caps = capsules; DR = delayed-release; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; supp = suppository; susp = suspension; tabs = tablets

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and
4. Additionally, use of Coxanto® (oxaprozin) 300mg capsule will require a patient-specific, clinically significant reason why the member cannot use generic oxaprozin 600mg tablets, which can be split to achieve the requested dose, must be provided; and
5. Additionally, use of Dolobid™ (diflunisal) 250mg or 375mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic diflunisal 500mg tablets; and
6. Additionally, use of Elyxyb® (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
7. Additionally, use of ibuprofen 300mg tablets will require a patient-specific, clinically significant reason why the member cannot use all Tier-1 strengths of ibuprofen tablets and all other lower-tiered NSAIDs; and
8. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products; and
9. Additionally, use of Vyscoxa™ (celecoxib oral suspension) will require a patient-specific, clinically significant reason why the member cannot use Tier-1 celecoxib capsules, which can be opened and sprinkled on applesauce for members with difficulties swallowing, must be provided.

Xifyrm™ (Meloxicam Injection) Approval Criteria:

1. An FDA approved diagnosis of management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics; and
2. Member must be 18 years of age or older; and
3. Member must be well hydrated before administration to reduce the risk of renal toxicity; and
4. Should be used for the shortest duration consistent with individual patient treatment goals; and
5. A patient-specific, clinically significant reason the member cannot use oral meloxicam tablets or other Tier-1 NSAID products must be provided; and
6. A quantity limit of 3 vials per 3 days will apply; and
7. For consideration of a longer duration of use, a patient-specific, clinically significant reason why the member cannot transition to an oral Tier-1 NSAID product must be provided, along with the anticipated duration of treatment.

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[8] Xifyrm™ (Meloxicam Injection) Prescribing Information. Azurity Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218395s000lbl.pdf. Last revised 06/2025. Last accessed 01/27/2026.

Appendix P

Vote to Prior Authorize Zepbound® (Tirzepatide) and Update the Approval Criteria for the Adiposity-Based Chronic Disease (ABCD) Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5,6,7]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **December 2024:** The FDA approved Zepbound® (tirzepatide) for the treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity, to be used in combination with a reduced-calorie diet and increased physical activity.
- **December 2024:** The FDA approved an age expansion for Imcivree® (setmelanotide) for the indication to reduce excess body weight and maintain weight reduction long-term in patients 2 years of age and older with syndromic or monogenic obesity due to Bardet-Biedl syndrome (BBS) or genetically confirmed pro-opiomelanocortin (POMC), including proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency or leptin receptor (LEPR) deficiency. Previously, Imcivree® was only approved in patients 6 years of age and older.
- **August 2025:** The FDA granted accelerated approval for a new indication for Wegovy® (semaglutide) for the treatment of metabolic-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), in adults with moderate-to-advanced fibrosis. This approval was based on efficacy from part 1 of the Phase 3 ESSENCE trial comparing Wegovy® to placebo in 800 patients with biopsy-proven MASH and fibrosis stage 2 or 3. The primary endpoint was the resolution of steatohepatitis without worsening of liver fibrosis and ≥1 stage improvement in liver fibrosis without worsening of steatohepatitis, on post-baseline liver biopsies collected at 72 weeks. Interim results showed 63% of participants receiving Wegovy® had MASH resolution and no worsening of liver scarring compared to 34% of participants receiving placebo, and 37% of participants on Wegovy® had improvement in liver scarring and no worsening of MASH, compared to 22% of participants receiving placebo. The trial will continue for a total of 240 weeks to determine whether inflammation and scarring improvements seen after 72 weeks translate into decreases in death, liver transplant, and other liver-related events. Part 2 of the ESSENCE trial will serve as the confirmatory trial, with expected readout in 2029, and its primary objective is to demonstrate that treatment with

Wegovy® 2.4mg lowers the risk of liver-related clinical events compared to placebo in adults with MASH and moderate-to-advanced liver fibrosis at 240 weeks.

- **December 2025:** The FDA approved a once-daily oral tablet formulation of Wegovy® (semaglutide) for use in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular (CV) events (CV death, nonfatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight. The approval for this indication is based on data from the SELECT and STEP trials for the injection formulation and data from PIONEER PLUS for Rybelsus® (semaglutide tablets). Wegovy® tablets are available in a 1.5mg, 4mg, 9mg, and 25mg strength. The recommended starting dose is 1.5mg once daily followed by a dose escalation period up to the recommended maintenance dose of 25mg once daily. More information on additional FDA approved indications, dose escalation, and switching between formulations can be found in the *Prescribing Information*.

Zepbound® (Tirzepatide) Product Summary[8,9]

Therapeutic Class: GIP/GLP-1 receptor agonist

Indication(s): Treatment of moderate to severe OSA in adults with obesity in combination with a reduced calorie diet and increased physical activity[Δ]

- **Limitation(s) of Use:** Coadministration with other tirzepatide-containing products or with any other GLP-1 receptor agonist is not recommended.

How Supplied:

- 2.5mg/0.5mL, 5mg/0.5mL, 7.5mg/0.5mL, 10mg/0.5mL, 12.5mg/0.5mL, and 15mg/0.5mL single-dose pens or single-dose vials
- 10mg/2.4mL, 20mg/2.4mL 30mg/2.4mL, 40mg/2.4mL, 50mg/2.4mL, and 60mg/2.4mL single-patient-use KwikPens® or multi-dose vials

Dosing and Administration:

- The recommended starting dose is 2.5mg subcutaneously (sub-Q) once weekly for 4 weeks. After 4 weeks, the dosage should be increased to 5mg sub-Q once weekly. The dose may be increased in 2.5mg increments, after at least 4 weeks on the current dose.
- The recommended maintenance dose for OSA is 10mg or 15mg sub-Q once weekly with a maximum dose of 15mg once weekly for all indications.

[Δ] For full FDA approved indications, see the package labeling

Efficacy: The efficacy of Zepbound® for OSA was evaluated in 2 Phase 3, double-blind, placebo-controlled trials comparing Zepbound® to placebo for 52 weeks. Trial 1 included patients who were unable to use or refused positive airway pressure (PAP) therapy. Trial 2 included patients who had used PAP therapy for at least 3 months and planned to continue PAP through the trial.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Diagnosis of moderate-to-severe OSA defined as an apnea-hypopnea index (AHI) ≥15 events per hour
  - Presence of obesity defined as a BMI of ≥30kg/m^2
  - History of at least 1 self-reported unsuccessful dietary effort to lose body weight
- Key Exclusion Criteria:
  - Type 1 or 2 diabetes
  - Planned surgery for sleep apnea or obesity
  - Diagnosis of central or mixed sleep apnea
  - Major craniofacial abnormalities
- Intervention(s): Patients were randomized 1:1 to receive Zepbound® or placebo for 52 weeks.
  - Zepbound® doses were escalated over a period of up to 20 weeks to a maximum tolerated dosage of 10mg or 15mg sub-Q once weekly.
- Endpoint(s):
  - Primary Endpoint: Change from baseline in AHI at week 52
  - Key Secondary Endpoints:
    - Percent change in AHI
    - Percentage of patients with ≥50% reduction in AHI from baseline
    - Percentage of patients in remission or with mild non-symptomatic OSA [AHI <5 or AHI 5-14 and Epworth Sleepiness Scale (ESS) ≤10]
- Results:
  - Primary Endpoint:
    - Trial 1:
      - Mean change in AHI was -25.3 events per hour for the Zepbound® group vs. -5.3 events per hour for the placebo group [treatment difference: -20; 95% confidence interval (CI): -25.8, -14.2; P<0.001]
    - Trial 2:
      - Mean change in AHI was -29.3 events per hour for the Zepbound® group vs. -5.5 events per hour for the placebo group (treatment difference: -23.8; 95% CI: -29.6, -17.9; P<0.001)

- Key Secondary Endpoint(s):
  - Trial 1:
    - Percent change in AHI was -50.7% in the Zepbound® group vs. -3% in the placebo group (treatment difference: -47.7%; 95% CI: -65.8, -29.6; P<0.001)
    - 61.2% of patients on Zepbound® had a ≥50% reduction in AHI events vs. 19% of patients on placebo (treatment difference: 42.8%; 95% CI: 30.8, 54.8; P<0.001)
    - 42.2% of patients on Zepbound® were in remission or had mild non-symptomatic OSA vs. 15.9% of patients on placebo (treatment difference: 28.7%; 95% CI: 18.3, 39.2; P<0.001)
  - Trial 2:
    - Percent change in AHI was -58.7% in the Zepbound® group vs. -2.5% in the placebo group (treatment difference -56.2%; 95% CI: -73.7, -38.7; P<0.001)
    - 72.4% of patients on Zepbound® had a ≥50% reduction in AHI events vs. 23.3% of patients on placebo (treatment difference: 48.6%; 95% CI: 36.6, 60.7; P<0.001)
    - 50.2% of patients on Zepbound® were in remission or had mild non-symptomatic OSA vs. 14.3% of patients on placebo (treatment difference: 33.2%; 95% CI: 22.1, 44.3; P<0.001)

Cost: The National Average Drug Acquisition Cost (NADAC) of Zepbound® 15mg/0.5mL is $525.92 per mL. This results in an estimated cost of $1,051.84 per 28 days or $13,673.92 per year based on recommended maintenance dosing.

Cost Comparison: MASH/NASH Medications

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Wegovy® (semaglutide) 2.4mg/0.75mL	**$435.47**	**$1,306.41***	**$16,983.33**
Rezdiffra® (resmetirom) 100mg tablet	$141.31	$4,239.30+	$50,871.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per month based on the FDA recommended maintenance dose of 2.4mg once weekly.
+Cost per month based on the FDA recommended dose of 100mg once daily for patients ≥100kg.

Recommendations

The College of Pharmacy recommends the prior authorization of Zepbound® (tirzepatide) with the following criteria (shown in red):

Zepbound® (Tirzepatide) Approval Criteria [Obstructive Sleep Apnea (OSA) Indication Only]:

1. An FDA approved indication of moderate to severe OSA in members with obesity; and
    a. Zepbound® will not be approved for obese members in the absence of OSA; and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-severe OSA defined as an apnea-hypopnea index (AHI) ≥15 determined by a polysomnography (PSG) or home sleep apnea testing (HSAT) with a technically adequate device (AHI value must be provided); and
4. Member has a body mass index (BMI) ≥30kg/m^2; and
5. Member must not have central or mixed sleep apnea; and
6. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
7. Member has a hemoglobin A1C (HbA1c) <6.5%; and
8. Member will not be using Zepbound® in combination with other tirzepatide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
9. Zepbound® must be used in conjunction with behavioral changes and/or a reduced calorie diet [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and
10. For Zepbound® vials or KwikPen®, a patient-specific, clinically significant reason why the member cannot use the pen formulation must be provided (Zepbound® pens are preferred over the vials and KwikPen®); and
11. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation to at least 5mg after an additional 4-week approval will not be approved for continuation; and
12. Subsequent approvals for the maintenance dose (5mg to 15mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing and adherent to therapy; and

   b. Clinical improvement of OSA (e.g., patient-reported improvement in daytime sleepiness, partner-reported reduction of snoring episodes or pauses in breathing, reduction of AHI events); and
   c. Member has not developed T1DM or T2DM; and
   d. Member is continuing a reduced calorie diet and increased physical activity in conjunction with Zepbound®; and
13. A quantity limit of 4 pens or vials (2mL) per 28 days or 1 KwikPen® (2.4mL) per 28 days will apply; and
14. Zepbound® should be discontinued in members who cannot tolerate at least the 5mg once weekly maintenance dosing.

Additionally, the College of Pharmacy recommends the following changes to the Wegovy® (semaglutide) approval criteria based on the new FDA approved indication and formulation and recommends updating the Rezdiffra® (resmetirom) approval criteria based on net costs (changes shown in red):

Wegovy® (Semaglutide Injection) Approval Criteria [Metabolic Dysfunction-Associated Steatohepatitis (MASH) Diagnosis Only]:

1. An FDA approved indication of noncirrhotic MASH; and
   a. Wegovy® will not be approved for obese members in the absence of MASH; and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):
   a. FibroScan with vibration controlled transient elastography (VCTE) ≥8kPa and controlled attenuation parameter (CAP) ≥280dB/min; or
   b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
   c. Liver biopsy showing stage F2 or F3 fibrosis with MASH; and
4. Member must not have chronic liver disease other than metabolic dysfunction-associated steatotic liver disease (MASLD); and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Wegovy® must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and
7. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
   a. T2DM; and
   b. Dyslipidemia; and
   c. Hypertension; and

8. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
9. Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and
11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing a reduced calorie diet and increased physical activity in conjunction with Wegovy®; and
12. A quantity limit of 4 pens per 28 days will apply; and
13. Wegovy® should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.

Wegovy® (Semaglutide Injection and Tablets) Approval Criteria [Cardiovascular (CV) Risk Reduction Indication Only]:

1. An FDA approved indication to reduce the risk of major adverse cardiovascular (CV) events in members with established CV disease (CVD) and either obesity or overweight; and
    a. Wegovy® will not be approved for obese or overweight members in the absence of established CVD; and
2. Member must be 45 years of age or older; and
3. Member must have established CVD with a history of 1 of the following (documentation must be submitted with the request):
    a. Previous myocardial infarction; or
    b. Previous stroke; or
    c. Symptomatic peripheral arterial disease confirmed by 1 of the following:
        i. Intermittent claudication with ankle-brachial index <0.85 at rest; or
        ii. Peripheral arterial revascularization procedure; or
        iii. Amputation due to atherosclerotic disease; and

4. Member has a body mass index (BMI) ≥27kg/m^2; and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Member has a hemoglobin A1C (HbA1c) <6.5%; and
7. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
8. Member is currently receiving guideline-directed management and therapy (GDMT) for CVD (e.g., antihypertensives, lipid-lowering agents, antiplatelets), as documented in the member's pharmacy claims history, unless contraindicated; and
9. Wegovy® must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and
11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg for the injection and 25mg for the tablets) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing all of the following in conjunction with Wegovy®:
        i. Reduced calorie diet; and
        ii. Increased physical activity; and
        iii. GDMT for CVD where applicable; and
12. A quantity limit of 4 pens per 28 days or 30 tablets per 30 days will apply; and
13. Wegovy® should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.

Rezdiffra® (Resmetirom) Approval Criteria:

1. An FDA approved indication of noncirrhotic nonalcoholic steatohepatitis (NASH); and
2. Member must be 18 years of age or older; and

3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):
    a. FibroScan with vibration controlled transient elastography (VCTE) ≥8.5kPa and controlled attenuation parameter (CAP) ≥280dB/min; or
    b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
    c. Liver biopsy showing stage F2 or F3 fibrosis with NASH; and
4. Member must not have known liver cirrhosis (e.g., stage F4); and
5. Must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and
6. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
    a. Type 2 diabetes; and
    b. Dyslipidemia; and
    c. Hypertension; and
7. Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra; and
8. If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra®, prescriber must agree to reduce the dose as required in the package labeling; and
9. If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and
10. A trial of Wegovy® (semaglutide injection) at maintenance dosing for at least 3 months (unless contraindicated) that did not provide an adequate response; and
    a. If combination therapy of Rezdiffra® with Wegovy® is being requested, a patient-specific, clinically significant reason why the member requires combination therapy must be provided; and
11. Must be prescribed by, or in consultation with, a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
12. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber documents the member is tolerating and responding well to the medication; and
13. A quantity limit of 30 tablets per 30 days will apply.

Finally, the College of Pharmacy recommends the following changes to the Imcivree® (setmelanotide) approval criteria based on the new FDA approved age expansion and clinical practice (changes shown in red):

Imcivree® (Setmelanotide) Approval Criteria:

1. An FDA approved indication of chronic weight management in adult and pediatric members ~~6~~ 2 years of age and older with obesity due to 1 of following:
    a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or
    b. Bardet-Biedl syndrome (BBS); and
2. For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm homozygous or compound heterozygous variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (results of genetic testing must be submitted); and
3. For BBS, diagnosis must be confirmed by the following:
    a. Molecular genetic testing to confirm homozygous or compound heterozygous variants in a BBS gene that are interpreted as pathogenic or likely pathogenic (results of genetic testing must be submitted); and
    b. Clinical features of BBS supported by detailed clinical documentation of each feature (medical records/clinical documentation of each feature must be submitted), as follows:
        i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadotropic hypogonadism and/or genitourinary anomalies, renal anomalies); or
        ii. Three of the primary features previously listed in 3.b.i. plus 2 secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and
4. Requests for Imcivree® for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, or other types of obesity not related to POMC, PCSK1 or LEPR deficiency, or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and

5. Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and
6. Member's baseline weight and body mass index (BMI) must be provided; and
7. Baseline BMI must be ≥30kg/m^2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
8. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree® therapy and throughout treatment; and
9. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
10. Prescriber must verify member does not have end stage renal disease [estimated glomerular filtration rate (eGFR) <15mL/min/1.73m^2] and must confirm the dose will be adjusted per package labeling for members with severe renal impairment (eGFR 15 to 29mL/min/1.73m^2); and
11. Prescriber must verify female member is not pregnant or breastfeeding; and
12. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and
13. For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or
14. For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and
15. A quantity limit of 9mL per 30 days will apply.

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[6] Novo Nordisk. Novo Nordisk's Wegovy® (Semaglutide 2.4mg) Was Associated with Liver Health-Related Benefits Not Solely Based on Weight Loss in Adult Patients with MASH with Liver Scarring, According to A New Post Hoc Analysis. Available online at: https://www.novonordisk-us.com/media/news-archive/news-details.html?id=916456. Issued 11/10/2025. Last accessed 01/20/2026.
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[8] Zepbound® (Tirzepatide) Prescribing Information. Eli Lilly. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217806s031lbl.pdf. Last revised 09/2025. Last accessed 01/20/2026.
[9] Malhotra A, Grunstein R, Fietze I, et al. Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity. *N Engl J Med* 2024; 391:1193-205. doi: 10.1056/NEJMoa2404881.

Appendix Q

Vote to Prior Authorize Levofloxacin Ophthalmic Solution and Update the Approval Criteria for the Ophthalmic Antibiotic Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3]

News:

- **February 2022:** Levofloxacin ophthalmic solution is an approved generic of the brand name product, Quixin® (levofloxacin ophthalmic solution), which is now a discontinued product per the U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. The most recent marketing start date for the generic product was February 2022.
- **January 2026:** A first-time generic product and an authorized brand alternative for Zylet® (loteprednol etabonate/tobramycin) has been approved by the FDA and launched.

Recommendations

The College of Pharmacy recommends the following changes within the Ophthalmic Antibiotic Medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following tier chart):

1. The prior authorization of levofloxacin ophthalmic solution with placement into Tier-2 based on net cost; and
2. Designating Zylet® (tobramycin/loteprednol ophthalmic solution) as brand preferred based on the approval of first-time generic products and based on net costs.

Ophthalmic Antibiotic Medications: Liquids		
Tier-1	**Tier-2**	**Tier-3**
azithromycin (Azasite®)	gatifloxacin (Zymaxid®)	
besifloxacin (Besivance®)	**levofloxacin (Quixin®)**	
ciprofloxacin (Ciloxan®)	neomycin/polymyxin B/ gramicidin (Neosporin®)	
gentamicin (Gentak®)	sulfacetamide sodium (Bleph-10®)	
moxifloxacin (Vigamox®)		
ofloxacin (Ocuflox®)		
polymyxin B/ trimethoprim (Polytrim®)		
tobramycin (Tobrex®)		

Ophthalmic Antibiotic Medications: Ointments	
Tier-1	**Tier-2**
bacitracin/polymyxin B (AK-Poly-Bac®, Polycin®)	bacitracin (AK-Tracin®)
ciprofloxacin (Ciloxan®)	sodium sulfacetamide (Bleph-10®)
erythromycin (Ilotycin™, Romycin®)	
neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	
Ophthalmic Antibiotic/Steroid Combination Products	
Tier-1	**Tier-2**
bacitracin/polymyxin B/neomycin/ hydrocortisone (Neo-Polycin® HC) oint	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
neomycin/polymyxin B/ dexamethasone (Maxitrol®) oint & susp	
sulfacetamide/prednisolone 10%/0.23% solution	
tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) oint & susp	
tobramycin/dexamethasone 0.3%/0.05% (Tobradex® ST) susp	
tobramycin/loteprednol (Zylet®) susp **– Brand Preferred**	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC= hydrocortisone; oint= ointment; susp= suspension
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC= hydrocortisone; oint= ointment; susp= suspension

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 01/2026. Last accessed 01/26/2026.
[2] U.S. FDA. National Drug Code Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/. Last revised 01/26/2026. Last accessed 01/26/2026
[3] Zylet® (Loteprednol Etabonate/Tobramycin) – First Time Generic. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/new-generics/newgenerics-zylet-012026.pdf. Issued 01/13/2026. Last accessed 01/26/2026.

Appendix R

Vote to Prior Authorize Estradiol 0.06% Gel (Generic EstroGel®) and Lynkuet™ (Elinzanetant) and Update the Approval Criteria for the Vasomotor Symptom (VMS) Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **April 2024:** Solaris Pharma Corporation received FDA approval for an Abbreviated New Drug Application (ANDA) for estradiol 0.06% gel, a generic version of EstroGel® which was first approved in 2004. Currently, the manufacturer of the brand name product does not have a federal drug rebate agreement; therefore, it is not covered by SoonerCare.
- **October 2024:** Novitium Pharma received FDA approval for an Abbreviated New Drug Application (ANDA) for estradiol 0.06% gel, a generic version of EstroGel® which was first approved in 2004. Currently, the manufacturer of the brand name product does not have a federal drug rebate agreement; therefore, it is not covered by SoonerCare.
- **December 2024:** The FDA added a *Boxed Warning* to Veozah® (elinzanetant) to highlight the risk of a rare, but serious liver injury associated with Veozah®. The warning included updates to the timing of hepatic monitoring, counseling for signs/symptoms of hepatic injury, and when to discontinue therapy.
- **October 2025:** The FDA approved Lynkuet® (elinzanetant) for the treatment of moderate to severe VMS due to menopause.

Estradiol 0.06% Gel (Generic EstroGel®) Product Summary[6]

Therapeutic Class: Estrogen

Indication(s):

- Treatment of moderate to severe VMS due to menopause
- Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause
    - Limitation of Use: When prescribing solely for the treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause, consideration should be given to the use of topical vaginal products first.

How Supplied: Transdermal gel with 1 pump depression of delivering 1.25g of gel containing 0.75mg of estradiol

Dosing and Administration:

- The recommended dose is 1 pump (1.25g) per day for both indications.
- The recommended area of application is the arm, and the gel should be applied in a thin layer over the entire arm on the inside and outside from wrist to shoulder.

Efficacy:

- The efficacy of EstroGel® on VMS in postmenopausal women was studied in a placebo-controlled trial in 145 postmenopausal women who were randomly assigned to receive 1.25g of EstroGel® or placebo for 12 weeks. The results showed a statistically significant reduction in the frequency and severity of moderate to severe hot flushes per day (treatment difference versus placebo of 1.71, P=0.043).

Lynkuet™ (Elinzanetant) Product Summary[7,8]

Therapeutic Class: Neurokinin 1 (NK1) and Neurokinin 3 (NK3) receptor antagonist

Indication(s): Treatment of moderate to severe VMS due to menopause

How Supplied: 60mg capsule

Dosing and Administration:

- The recommended dose is 120mg (two 60mg capsules) orally once daily at bedtime with or without food.
- Capsules should be swallowed whole. The capsules should not be cut, crushed, or chewed.
- See full *Prescribing Information* for dosage modifications due to drug interactions.

Efficacy: The efficacy of Lynkuet® was evaluated in 2 randomized, double-blind, placebo-controlled, multicenter clinical trials (OASIS 1 & OASIS 2).

- Key Inclusion Criteria:
  - Postmenopausal women 40 to 65 years of age
  - Experiencing ≥50 moderate to severe VMS over 7 days during the screening
- Intervention: Randomized 1:1 to receive Lynkuet® or placebo.
  - After 12 weeks, women on placebo were switched over to Lynkuet® for a 14-week extension for up to 26 weeks total exposure.
- Primary Outcome: Mean change in frequency and severity of moderate to severe VMS from baseline to weeks 4 and 12, including day and night hot flashes measured using the Hot Flash Daily Diary (HFDD)

- Results:
  - OASIS 1:
    - Change from baseline to week 4:
      - Least squared (LS)-Means [Standard Error (SE)] in Lynkuet® treated group: -7.60 (0.43) versus -4.31 (0.43) in the placebo group
      - Treatment difference of -3.29 versus placebo [95% confidence interval (CI): -4.47, -2.10, P<0.0001]
    - Change from baseline to week 12:
      - LS-Means (SE) in Lynkuet® treated group: -8.66 (0.58) versus -5.44 (0.59) in the placebo group
      - Treatment difference of -3.22 versus placebo (95% CI: -4.81, -1.63, P<0.0001)
  - OASIS 2:
    - Change from baseline to week 4:
      - LS-Means (SE) in Lynkuet® treated group: -8.58 (0.49) versus -5.54 (0.49) in the placebo group
      - Treatment difference of -3.04 versus placebo (95% CI: -4.40, -1.68, P<0.0001)
    - Change from baseline to week 12:
      - LS-Means (SE) in Lynkuet® treated group: -9.72 (0.50) versus -6.48 (0.49) in the placebo group
      - Treatment difference of -3.24 versus placebo (95% CI: -4.60, -1.88, P<0.0001)

Cost Comparison: Menopausal Hormone Therapy

Product	Cost Per Unit	Cost Per Month	Cost Per Year
estradiol 0.06% gel pump (generic EstroGel®)	**$3.51**	**$131.63λ**	**$1,579.50**
estradiol 0.1% gel packet (generic Divigel®)	$1.31	$49.13Δ	$589.50
estradiol-norethindrone 0.5-0.1mg tablet (generic)	$0.44	$13.20*	$158.40
estradiol 1mg tablet (generic)	$0.06	$1.26α	$16.38

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = gram or tablet
λCost per month is based on the FDA approved dose of 1 pump (1.25g) per day or 37.5g per month.
ΔCost per month is based on 1 packet (1.25g) per day or 37.5g per month.
*Cost per month is based on the FDA approved dose of 1 tablet once daily.
αCost per month is based on the FDA approved dosing of 1mg once daily in a cyclical pattern (3 weeks on, 1 week off)

Cost Comparison: Non-Hormonal Therapy[9]

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Lynkuet™ (elinzanetant) 60mg capsule	**$10.42**	**$625.20**[α]	**$7,502.40**
Veozah® (fezolinetant) 45mg tablet	$18.63	$558.90*	$6,706.80
venlafaxine 75mg ER capsule (generic)	$0.09	$2.70[+]	$32.40
gabapentin 300mg capsule (generic)	$0.03	$2.70[β]	$32.40
paroxetine 10mg tablet (generic)	$0.06	$1.80[+]	$21.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ER = extended-release; Unit = capsule or tablet
[α]Cost per month is based on the FDA approved 120mg once daily dose.
*Cost per month is based on the FDA approved 45mg daily dose.
[+]Cost per month is based on the North American Menopause Society (NAMS) Nonhormone Therapy Position Statement 2023 recommended dosing for each product administered once daily.
[β]Cost per month is based on the NAMS guideline recommended dosing of 300mg three times daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Lynkuet® (elinzanetant) with the following criteria (shown in red):

Lynkuet® (Elinzanetant) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Prescriber must verify the following:
   a. Member will not use strong CYP3A4 inhibitors (e.g., clarithromycin, grapefruit juice, itraconazole, ketoconazole) or moderate/strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) concomitantly with Lynkuet®; and
   b. Liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be assessed prior to the initiation of Lynkuet®, and member will not start treatment with Lynkuet® if labs are ≥2 times the upper limit of normal; and
   c. Follow-up evaluations of LFTs will be done 3 months after initiation of therapy; and
3. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
5. A quantity limit of 60 capsules per 30 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Veozah® (fezolinetant) based on the FDA approved label updates (changes shown in red):

Veozah® (Fezolinetant) Approval Criteria:

1. An FDA approved ~~diagnosis~~ indication for the treatment of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Prescriber must verify the following:
    a. Member ~~must~~ will not use CYP1A2 inhibitors (e.g., cimetidine, ciprofloxacin, ethinyl estradiol, fluvoxamine, mexiletine) concomitantly with Veozah®; and
    b. Member ~~must~~ does not have a history of severe renal impairment, end-stage renal disease, or cirrhosis; and
    c. ~~Prescriber must verify~~ ~~b~~Baseline renal function has been assessed and member ~~must have~~ has an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
    ~~d. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Veozah®, every 3 months for the first 9 months of treatment, and as clinically indicated thereafter; and~~
    e. Liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be assessed prior to the initiation of Veozah®, and member will not start treatment with Veozah® if labs are ≥2 times the upper limit of normal; and
    f. Follow up evaluations of LFTs will be done monthly for the first 3 months of treatment, then at 6 months, and 9 months of treatment, and as clinically indicated thereafter; and
    g. Member will be counseled to discontinue Veozah® immediately and seek medical attention if they experience signs or symptoms that may suggest liver injury (i.e., new onset fatigue, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or right upper quadrant pain); and
3. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Finally, the College of Pharmacy recommends the prior authorization of estradiol 0.06% gel (generic EstroGel®) with the following criteria based on net cost (shown in red):

Estradiol 0.06% Gel (Generic EstroGel®) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of moderate to severe vasomotor symptoms due to menopause; or
   b. Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause; and
2. Member must not have any contraindications for use of estradiol 0.06% gel; and
3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member must be provided; and
4. Members older than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
6. Brand name EstroGel® is not a covered product; and
7. A quantity limit of 37.5 grams per 30 days will apply.

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[4] Veozah® (Fezolinetant) Prescribing Information. Astellas Pharma US, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216578s004lbl.pdf. Last revised 12/2024. Last accessed 01/20/2026.

[5] Bayer. Bayer's Lynkuet® (Elinzanetant), the First and Only Neurokinin 1 and Neurokinin 3 Receptor Antagonist, Receives FDA Approval for Moderate to Severe Hot Flashes Due to Menopause. Available online at: https://www.bayer.com/en/us/news-stories/lynkuet. Issued 10/24/2025. Last accessed 01/20/2026.

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Appendix S

Vote to Prior Authorize MoviPrep® [Polyethylene Glycol 3350 (PEG 3350)/Sodium Sulfate/Sodium Chloride/ Potassium Chloride/Sodium Ascorbate/Ascorbic Acid for Oral Solution] and Update the Approval Criteria for the Bowel Preparation Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates

News:

- **October 2025:** Salix Pharmaceuticals, the manufacturer of MoviPrep® (PEG 3350/sodium sulfate/sodium chloride/potassium chloride/sodium ascorbate/ascorbic acid), voluntarily ended their Federal Drug Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS). As a result, SoonerCare no longer covers brand name MoviPrep®. A generic formulation is available and is covered by SoonerCare; however, the net cost is significantly higher.

Recommendations

The College of Pharmacy recommends the prior authorization of generic MoviPrep® (PEG 3350/sodium sulfate/sodium chloride/potassium chloride/ sodium ascorbate/ascorbic acid) and recommends removing the prior authorization requirement for brand name Suprep® (sodium sulfate/ potassium sulfate/magnesium sulfate) based on net costs with the following criteria changes (shown in red):

Clenpiq®, Generic MoviPrep®, Suflave™, Generic Suprep®, and Sutab®
Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason, other than convenience, why the member cannot use other bowel preparation medications available without prior authorization must be provided; and
3. If the member requires a low volume ~~polyethylene glycol electrolyte lavage solution~~ product, ~~MoviPrep®~~ brand name Suprep® is available without prior authorization. Other medications currently available without a prior authorization include: Gavilyte® and Golytely®; and
    a. Suprep® is brand preferred. Requests for the generic will require a patient-specific, clinically significant reason why the member cannot use the brand name product.

Appendix T

Vote to Prior Authorize Aceon® (Perindopril), Arbli™ (Losartan Oral Suspension), Bisoprolol Fumarate 2.5mg Tablet, Hemiclor™ (Chlorthalidone 12.5mg Tablet), Inzirqo™ [Hydrochlorothiazide (HCTZ) Oral Suspension], Javadin™ (Clonidine Oral Solution), Lopressor® (Metoprolol Tartrate Oral Solution), and Univasc® (Moexipril) and Update the Approval Criteria for the Antihypertensive Medications

Oklahoma Health Care Authority
February 2026

Market News and Updates[1,2,3,4,5,6,7,8]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **January 2025:** The FDA approved Inzirqo™ (HCTZ oral suspension) for the treatment of hypertension (HTN) in adult and pediatric patients as monotherapy or in combination with other antihypertensive agents, to lower blood pressure and for the treatment of edema associated with congestive heart failure, hepatic cirrhosis, and renal disease including nephrotic syndrome. Inzirqo™ is supplied as a powder for oral suspension that is reconstituted to a concentration of 10mg/mL prior to dispensing.
- **March 2025:** The FDA approved Arbli™ (losartan oral suspension), a 10mg/mL oral suspension formulation of the angiotensin II receptor blocker (ARB) losartan. Arbli™ was approved for the treatment of HTN, to lower blood pressure in adult and pediatric patients 6 years of age and older; for the reduction of the risk of stroke in patients with HTN and left ventricular hypertrophy; and for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes mellitus and a history of HTN.
- **March 2025:** The FDA approved bisoprolol in a new 2.5mg tablet formulation through an Abbreviated New Drug Application (ANDA). Bisoprolol 2.5mg tablet joins the 5mg and 10mg tablets on the market.
- **March 2025:** The FDA approved Hemiclor™ (chlorthalidone 12.5mg tablet) for the treatment of HTN in adults, to lower blood pressure. Chlorthalidone was previously only available as generic chlorthalidone 25mg and 50mg tablets or branded Thalitone® 15mg or 25mg tablets.
- **March 2025:** The FDA determined that the Tryvio™ Risk Evaluation and Mitigation Strategy (REMS) is not necessary to ensure the benefits of use outweighs the risk of embryo-fetal toxicity. The Tryvio™ package

labeling was updated to remove text regarding the REMS and requirements for monthly pregnancy test monitoring during therapy.

- **April 2025:** The FDA approved Lopressor® (metoprolol tartrate oral solution), a 10mg/mL solution, for the treatment of HTN, to lower blood pressure; for the long-term treatment of angina pectoris; and for the treatment of hemodynamically stable patients with definite or suspected myocardial infarction, to reduce the risk of cardiovascular mortality when used in conjunction with intravenous metoprolol therapy.
- **October 2025:** The FDA approved Javadin™ (clonidine oral solution) for the treatment of HTN in adults to lower blood pressure. Javadin™ is supplied as a ready-to-use solution with a concentration of 0.02mg/mL.

Cost Comparison: Losartan Products

Product	Cost Per Unit	Cost Per 30 Days*
Arbli™ (losartan) 10mg/mL solution	**$3.61**	**$541.50**
losartan 50mg tablet (generic)	$0.03	$0.90

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days based on a dose of 50mg once daily, the usual adult dose and maximum pediatric dose for the treatment of HTN per FDA package labeling

Cost Comparison: Bisoprolol Products

Product	Cost Per Tablet	Cost Per 30 Days*
bisoprolol fumarate 2.5mg tablet (generic)	**$2.58**	**$77.40**
bisoprolol fumarate 5mg tablet (generic)	$0.18	$2.70

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on 2.5mg once daily for the treatment of HTN per FDA package labeling

Cost Comparison: Chlorthalidone Products

Product	Cost Per Tablet	Cost Per 30 Days*
Hemiclor™ (chlorthalidone) 12.5mg tablet	**$0.95**	**$28.50**
chlorthalidone 25mg tablet (generic)	$0.08	$1.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on a starting dose of 12.5mg once daily for the treatment of HTN per FDA package labeling

Cost Comparison: Hydrochlorothiazide Products

Product	Cost Per Unit	Cost Per 30 Days*
Inzirqo™ (hydrochlorothiazide) 10mg/mL suspension	**$4.69**	**$351.75**
hydrochlorothiazide 25mg tablet (generic)	$0.01	$0.30

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per day based on a starting dose of 25mg once daily for the treatment of HTN per FDA package labeling

Cost Comparison: Clonidine Products

Product	Cost Per Unit	Cost Per 30 Days*
Javadin™ (clonidine) 0.02mg/mL solution	**$1.60**	**$480.00**
clonidine 0.1mg tablet (generic)	$0.03	$1.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per day based on a recommended starting dose of 0.1mg twice daily for the treatment of HTN per FDA package labeling

Cost Comparison: Metoprolol Products

Product	Cost Per Unit	Cost Per 30 Days*
Lopressor® (metoprolol tartrate) 10mg/mL solution	**$1.25**	**$375.00**
metoprolol tartrate 50mg tablet (generic)	$0.02	$1.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per day based on the recommended starting dose of 50mg twice daily for the treatment of HTN per FDA package labeling

Recommendations

The College of Pharmacy recommends the following changes within the Antihypertensive Medication Product Based Prior Authorization (PBPA) category (changes noted in red in the following tier chart and in the following additional criteria):

1. Renaming Tier-3 of the Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products as a Special PA Tier and removing the associated Antihypertensive Medications Tier-3 Approval Criteria; and
2. Moving Aceon® (perindopril) and Univasc® (moexipril) from Tier-1 to Tier-2 based on net costs; and
3. Moving Monopril® HCT (fosinopril/HCTZ) from the Specia PA Tier to Tier-2 and removing the additional approval criteria based on net costs; and

4. Moving Edarbi® (azilsartan) and Edarbyclor® (azilsartan/chlorthalidone) from Tier-3 (now the Special PA Tier) to Tier-1 based on net costs; and
5. Moving Exforge® HCT (valsartan/amlodipine/HCTZ) from Tier-1 to Tier-2 based on net costs; and
6. Moving Atacand® HCT (candesartan/HCTZ) and Twynsta® (telmisartan/amlodipine) from Tier-3 (now the Special PA Tier) to Tier-2 based on clinical practice and net costs; and
7. Moving Micardis® HCT (telmisartan/HCTZ) from Tier-2 to Tier-1 based on net costs; and
8. The prior authorization of Arbli™ (losartan oral suspension) with placement into the Special PA Tier and with additional criteria; and
9. Moving Cardizem® CD (diltiazem CD 360mg) from the Special PA Tier to Tier-1 with the other strengths and removing the additional approval criteria based on net costs; and
10. Updating the Norliqva® (amlodipine oral solution), Katerzia® (amlodipine oral suspension), Epaned® (enalapril oral solution), Qbrelis® (lisinopril oral solution), and valsartan 4mg/mL oral solution approval criteria based on clinical practice, for clarity, and for consistency with other criteria within the Antihypertensive Medications PBPA category.

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	**Tier-2**	**Special PA**
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)	**moexipril (Univasc®)**	lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)	**perindopril (Aceon®)**	
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
~~**moexipril (Univasc®)**~~		
~~**perindopril (Aceon®)**~~		
quinapril (Accupril®)		
ramipril (Altace®)		
trandolapril (Mavik®)		
ACEI/Hydrochlorothiazide (HCTZ) Combination Products		
Tier-1	**Tier-2**	**Special PA**
benazepril/HCTZ (Lotensin® HCT)	captopril/HCTZ (Capozide®)	~~**fosinopril/HCTZ (Monopril® HCT)**~~
enalapril/HCTZ (Vaseretic®)	**fosinopril/HCTZ (Monopril® HCT)**	
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		

Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**~~Tier-3~~ Special PA**
azilsartan (Edarbi®)	**candesartan/HCTZ (Atacand® HCT)**	**~~azilsartan (Edarbi®)~~**
azilsartan/chlorthalidone (Edarbyclor®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	**~~azilsartan/chlorthalidone (Edarbyclor®)~~**
candesartan (Atacand®)	**~~telmisartan/HCTZ (Micardis® HCT)~~**	**~~candesartan/HCTZ (Atacand® HCT)~~**
irbesartan (Avapro®)	**telmisartan/amlodipine (Twynsta®)**	**losartan oral suspension (Arbli™)**
irbesartan/HCTZ (Avalide®)	**valsartan/amlodipine/HCTZ (Exforge® HCT)**	**~~telmisartan/amlodipine (Twynsta®)~~**
losartan (Cozaar®)		valsartan 4mg/mL oral solution+
losartan/HCTZ (Hyzaar®)		
olmesartan (Benicar®)		
olmesartan/amlodipine (Azor®)		
olmesartan/HCTZ (Benicar HCT®)		
telmisartan (Micardis®)		
telmisartan/HCTZ (Micardis® HCT)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
~~valsartan/amlodipine/HCTZ (Exforge® HCT)~~		
valsartan/HCTZ (Diovan HCT®)		
Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral solution (Norliqva®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine oral suspension (Katerzia®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	**~~diltiazem CD 360mg (Cardizem® CD)~~**
diltiazem CD (Cardizem® CD)**~~*~~**	isradipine (Dynacirc®, Dynacirc CR®)	levamlodipine (Conjupri®)
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	
diltiazem XR (Dilacor® XR)	nicardipine (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	

nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		
ACEI/CCB Combination Products		
Tier-1	**Tier-2**	**Special PA**
Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka®)	
benazepril/amlodipine (Lotrel®)		

~~*Unique criteria apply.~~
~~*All strengths other than 360mg.~~
CD = controlled-delivery; ER, XR, XL = extended-release; LA = long-acting; SR = sustained-release

~~**Antihypertensive Medications Tier-3 Approval Criteria:**~~

~~1. A documented inadequate response to 2 Tier-1 medications and documented inadequate response to all available Tier-2 medication(s); or~~
~~2. An adverse drug reaction to all Tier-1 and Tier-2 classes of medications; or~~
~~3. Previous stabilization on the Tier-3 medication; or~~
~~4. A unique indication which the lower tiered antihypertensive medications lack.~~

Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

1. **Angiotensin I Converting Enzyme Inhibitors (ACEIs):**
   - ~~**a. Epaned® (Enalapril Solution) Approval Criteria:**~~
     - ~~i. An age restriction of 7 years or older will apply with the following criteria:~~
       - ~~1. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed or used to prepare an oral suspension, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and~~
       - ~~2. Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and~~

ii. ~~For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.~~

b. Epaned® (Enalapril Solution) and Qbrelis® (Lisinopril Oral Solution) Approval Criteria:

i. A patient-specific, clinically significant reason why the member cannot use the ~~lisinopril~~ oral tablets in place of the oral solution formulation, even when the tablets are crushed, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and

ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

iii. A quantity limit of 300mL per 60 days will apply. For members who require doses exceeding this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

2. Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products:

a. Arbli™ (Losartan Oral Suspension) Approval Criteria:

i. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation in place of the oral suspension, even when the tablets are split or crushed, must be provided (e.g., dose stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and

ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.

iii. A quantity limit of 330mL per 33 days will apply.

b. Valsartan ~~4mg/mL~~ Oral Solution Approval Criteria:

~~i. An FDA approved diagnosis of 1 of the following:~~

~~1. Hypertension in adults and pediatric members 6 years of age and older; or~~

~~2. Heart failure; or~~

~~3. Post-myocardial infarction; and~~

ii. A patient specific, clinically significant, reason why the member cannot use the oral ~~valsartan~~ tablets or the oral suspension prepared from the tablets must be provided (i.e., dose was stabilized inpatient); and

iii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

iv. A quantity limit of 360mL per 36 days will apply.

~~**3. ACEI/Hydrochlorothiazide (HCTZ) Combination Products:**~~

~~**a. Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:**~~

~~i. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided.~~

4. Calcium Channel Blockers (CCBs):

~~**a. Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:**~~

~~i. A patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules must be provided.~~

b. Conjupri® (Levamlodipine Tablets) Approval Criteria:

i. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, which are available without prior authorization, must be provided.

c. Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:

~~i. An FDA approved diagnosis of 1 of the following:~~

~~1. Hypertension in adults and pediatric members 6 years of age and older; or~~

~~2. Coronary artery disease; or~~

~~3. Chronic stable angina; or~~

~~4. Vasospastic angina; and~~

ii. A patient specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when the tablets are split or crushed, must be provided (i.e., dose was stabilized inpatient or dose cannot be achieved with available tablet formulations); and

~~iii. Clinical exceptions for age restrictions may be considered for doses stabilized inpatient or for clinically indicated doses that cannot be achieved by splitting available tablet formulations; and~~

iv. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

v. A quantity limit of 300mL per 30 days will apply.

Next, the College of Pharmacy recommends the prior authorization of bisoprolol fumarate 2.5mg tablet, Hemiclor™ (chlorthalidone 12.5mg tablet), Inzirqo™ (hydrochlorothiazide oral suspension), and Lopressor® (metoprolol tartrate oral solution) with the following criteria (shown in red):

Bisoprolol Fumarate 2.5mg Tablet Approval Criteria:

1. A patient-specific, clinically specific reason (beyond convenience) why the member cannot split the 5mg tablet, which is available without prior authorization, to achieve the 2.5mg dose must be provided; and
2. A quantity limit of 30 tablets per 30 days will apply.

Hemiclor™ (Chlorthalidone 12.5mg Tablet) Approval Criteria:

1. A patient-specific, clinically specific reason (beyond convenience) why the member cannot split a generic chlorthalidone 25mg tablet, which is available without prior authorization, to achieve a 12.5mg dose must be provided; and
2. A quantity limit of 240 tablets per 30 days will apply.

Inzirqo™ (Hydrochlorothiazide Oral Suspension) Approval Criteria:

1. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet formulation available without prior authorization, even when the tablets are crushed or split, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and
2. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
3. A quantity limit of 240mL per 30 days will apply. For members who require doses that exceed this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

Lopressor® (Metoprolol Tartrate Oral Solution) Approval Criteria:

1. A patient-specific, clinically specific reason (beyond convenience) why the member cannot use oral tablet formulation available without prior authorization, even when the tablets are crushed or split, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved with available tablet formulations); and
2. A quantity limit of 1,200mL per 30 days will apply. For members who require doses that exceed this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

The College of Pharmacy also recommends the prior authorization of Javadin™ (clonidine oral solution) with criteria similar to Nexiclon™ XR (clonidine ER tablet) (changes shown in red):

Nexiclon™ XR [Clonidine Extended-Release (ER) Tablet] and Javadin™ (Clonidine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of hypertension; and

2. A patient-specific, clinically significant reason why the member cannot utilize clonidine immediate-release tablet and clonidine transdermal patch, which are available without a prior authorization, must be provided; and
3. For Nexiclon™ XR, the ~~R~~request must be for an FDA-approved once-daily dosing regimen, according to package labeling~~.~~; and
4. For Javadin™, the following will apply:
    a. Member must be 18 years of age or older; and
    b. A quantity limit of 1,000mL per 30 days will apply. For members who require doses greater than this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

Lastly, the College of Pharmacy recommends updating the Tryvio™ (aprocitentan) approval criteria based on changes to the FDA package labeling and the discontinuation of the REMS program (changes shown in red):

Tryvio™ (Aprocitentan) Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. Member has a reported systolic blood pressure of ≥140mmHg confirmed on at least 2 separate blood pressure readings on 2 separate occasions within the last month (documentation of blood pressure readings with dates must be submitted); and
3. Prescriber must rule out other causes of elevated blood pressure including:
    a. Inaccurate readings due to faulty or inappropriate equipment (i.e., cuff size) or improper technique; and
    b. White coat hypertension; and
    c. Prescription non-adherence. Compliance with antihypertensive medications will be evaluated prior to initiation of Tryvio™; and
4. Member must be currently on at least 3 antihypertensive medications at optimal (or maximally tolerated) doses for at least 4 weeks prior to systolic blood pressure reading of ≥140mmHg; and
5. Member must have tried at least 6 different classes of medications, including a diuretic, in the past 12 months that did not yield adequate blood pressure control. Medications can include, but are not limited to, angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and
6. Female members of reproductive potential must not be pregnant or breastfeeding during treatment with Tryvio™ and must be willing to

use an effective method of contraception during treatment and for 1 month after discontinuing Tryvio™; and

7. Female members of reproductive potential must have a negative pregnancy test prior to initiation of Tryvio™ and ~~must agree to take pregnancy tests monthly during treatment and for 1 month after discontinuing Tryvio™~~ if pregnancy occurs during therapy, Tryvio™ must be discontinued immediately; and
~~8. Member, pharmacy, and provider must be registered under the Tryvio™ Risk Evaluation and Mitigation Strategy (REMS) program; and~~
9. Member must not have elevated aminotransferases >3 times the upper limit of normal (ULN) or moderate to severe hepatic impairment (Child Pugh class B or C); and
10. Prescriber must attest that they will monitor liver transaminase levels during treatment and discontinue Tryvio™ if a sustained, unexplained, clinically relevant elevation occurs or if elevations occur with an increase in bilirubin that is >2 times the ULN; and
11. Member must not have severe anemia prior to initiation of aprocitentan; and
12. A quantity limit of 30 tablets per 30 days will apply; and
13. Initial approvals will be for the duration of 3 months. After 3 months, compliance with all antihypertensive medications, including aprocitentan, will be evaluated and the provider must provide documentation that the member has had a positive response to treatment, including a decrease in blood pressure. Inadequate compliance or a lack of positive response will result in denial of continuation. Subsequent approvals will be for 1 year.

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Appendix U

Fiscal Year 2025 Annual Review of Cholestatic Liver Disease and Bile Acid Disorder Medications

Oklahoma Health Care Authority
February 2026

Current Prior Authorization Criteria

Bylvay® (Odevixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in either the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
7. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
8. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
9. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and

10. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Bylvay® (Odevixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, or ABCB4* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ≥100micromol/L at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and

11. Initial approvals will be for 40mcg/kg/day for a duration of 3 months. After 3 months of treatment, further approval may be granted at the 40mcg/kg/day dose if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate; or
12. Dose increases to 80mcg/kg/day (for 3 months) and 120mcg/kg/day (for 3 months) may be approved if there is no improvement in pruritus after 3 months of treatment with the lower dose(s). Further approval may be granted if the prescriber documents the member is responding well to treatment at the current dose and is still not a candidate for surgical intervention; and
13. If there is no improvement in pruritus after 3 months of treatment with the maximum 120mcg/kg/day dose, further approval of Bylvay® will not be granted.

Cholbam® (Cholic Acid) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs); and
        i. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *AKR1D1, AMACR, BAAT, CYP7A1, CYP7B1, CYP27A1, DHCR7, HSD3B7,* or *SLC27A5* gene, or other gene with significant supporting evidence of pathogenicity (results of genetic testing must be submitted); or
    b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
        i. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *PEX1, PEX2, PEX3, PEX5, PEX6, PEX10, PEX11B, PEX12, PEX13, PEX14, PEX16, PEX19,* or *PEX26* gene (results of genetic testing must be submitted); and
2. Treatment with Cholbam® should be initiated and monitored by a hepatologist, pediatric gastroenterologist, or other specialist with expertise in the treatment of SEDs or PDs; and
3. The prescriber must verify that AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR will be monitored every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next 3 years, and annually thereafter; and
4. Cholbam® should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction

develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; and
5. Initial approvals will be for the duration of 3 months to monitor for compliance and liver function tests; and
6. Continuation approvals will be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests; and
7. A quantity limit of 120 capsules per 30 days will apply. Quantity limit requests will be based on the member's recent weight taken within the last 30 days.

Ctexli® (Chenodiol) Approval Criteria:

1. An FDA approved diagnosis of cerebrotendinous xanthomatosis (CTX); and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *CYP27A1* gene (results of genetic testing must be submitted); and
2. Member must be 16 years of age or older; and
3. Must be prescribed by a neurologist, geneticist, or other specialist with expertise in the treatment of CTX (or an advanced care practitioner with a supervising physician who is a neurologist, geneticist, or other specialist with expertise in the treatment of CTX); and
4. Prescriber must agree to obtain baseline liver transaminase, including alanine aminotransferase (ALT) and aspartate aminotransferase (AST), and total bilirubin levels prior to initiating treatment; and
5. Prescriber must agree to monitor liver transaminase and total bilirubin levels yearly and as clinically indicated and will interrupt or discontinue treatment with Ctexli®, if appropriate, per package labeling; and
6. Member must not be using bile acid sequestering agents (e.g., cholestyramine, colestipol) or aluminum-based antacids concomitantly with Ctexli®; and
7. Initial approvals will be for a duration of 3 months. After 3 months of treatment, subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in cholestanol or bile alcohol levels or documentation of other clinical improvements; and
8. A quantity limit of 90 tablets per 30 days will apply.

Iqirvo® (Elafibranor) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and
3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and

4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and
5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
    a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
6. Iqirvo® must be taken in combination with UDCA; or
    a. For Iqirvo® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
7. Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and
8. Prescriber must agree to monitor all of the following:
    a. Muscle pain or myopathy at baseline and periodically during treatment; and
    b. Fracture risk and bone health; and
    c. Liver function tests at baseline and thereafter; and
9. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy, must agree to use effective non-hormonal contraception (or add a barrier method when using hormonal contraception), and must not be breastfeeding during treatment and for 3 weeks following the last dose of Iqirvo®; and
10. A quantity limit of 30 tablets per 30 days will apply; and
11. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.

Livdelzi® (Seladelpar) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and
3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and
4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and

5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
    a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
6. Livdelzi® must be taken in combination with UDCA; or
    a. For Livdelzi® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
7. Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and
8. Prescriber must agree to monitor all of the following:
    a. Fracture risk and bone health; and
    b. Liver function tests at baseline and thereafter; and
9. Member must not be taking OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors concurrently with Livdelzi®; and
10. A patient-specific, clinically significant reason why the member cannot use Iqirvo® (elafibranor) must be provided; and
11. A quantity limit of 30 capsules per 30 days will apply; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.

Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or

    d. Naltrexone; and
5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:
    a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
    b. Conjugated bilirubin >1mg/dL; or
    c. Fat soluble vitamin deficiency otherwise unexplainable; or
    d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
    e. Intractable pruritus explainable only by liver disease; and
6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
10. Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. The request must be for the 9.5mg/mL solution; and
13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Livmarli® (Maralixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a

gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Livmarli®; and
8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. The request must be for the 19mg/mL solution; and
13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Ocaliva® (Obeticholic Acid) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and
3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and
4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist,

hepatologist, or other specialist with expertise in the treatment of PBC); and

5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
    a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
6. Ocaliva® must be taken in combination with UDCA; or
    a. For Ocaliva® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
7. Member must not have any of the following:
    a. Decompensated cirrhosis (e.g., Child-Pugh class B or C) or a prior decompensation event; or
    b. Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia); or
    c. Complete biliary obstruction; and
8. Prescriber must agree to monitor liver tests frequently and to discontinue Ocaliva® if there is any evidence of liver disease progression while on treatment; and
9. Initial approvals will be for a dose of 5mg once daily for a duration of 3 months. After 3 months of treatment, information regarding efficacy must be submitted; and
    a. If an adequate improvement in liver function tests is not achieved with the 5mg dose, a dose of 10mg once daily may be approved for a duration of 3 months; and
10. Subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests; and
11. A quantity limit of 1 tablet per day will apply.

Reltone® (Ursodiol Capsule) Approval Criteria:

1. An FDA approved indication for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter or the prevention of gallstone formation in obese members experiencing rapid weight loss; and
2. For the indication of dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter:
    a. Prescriber must confirm member is not a candidate for elective cholecystectomy due to 1 or more of the following:
        i. Increased surgical risk due to systemic disease; or
        ii. Advanced age; or
        iii. Idiosyncratic reaction to general anesthesia; or

        iv. Member refuses surgery; and
    b. Prescriber must confirm the member does not have compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula; and
3. For the indication of prevention of gallstone formation in obese members experiencing rapid weight loss:
    a. Member's baseline body mass index (BMI) and weight must be provided; and
    b. Member's current weight must be provided supporting rapid weight loss compared to baseline; and
4. For both FDA approved indications, a patient-specific, clinically significant reason why the member cannot use other generic formulations of ursodiol must be provided; and
5. Initial approvals for the indication of dissolution of gallstones will be for the duration of 6 months, after which time the prescriber must confirm (via ultrasound imaging) partial or complete dissolution of gallstone(s). Subsequent approvals will be for the duration of 12 months; and
6. Approvals for prevention of gallstone formation in obese members experiencing rapid weight loss will be for 6 months, after which time the member's current weight must be provided to justify continued rapid weight loss and need for preventative treatment; and
7. Treatment duration will be limited to a maximum of 24 months for all diagnoses.

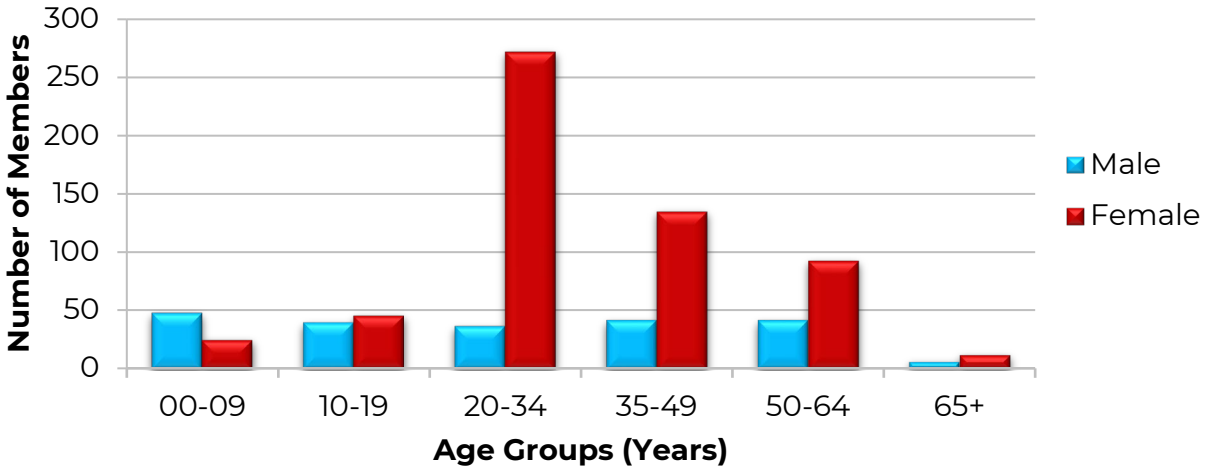
Utilization of Cholestatic Liver Disease and Bile Acid Disorder Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

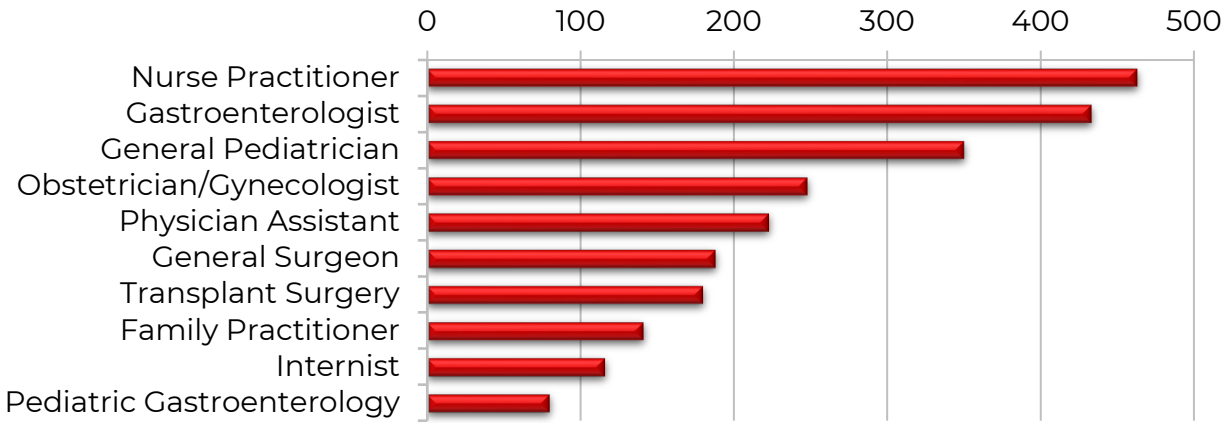
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	658	2,133	$364,313.73	$170.80	$5.38	172,887	67,686
Aetna	71	128	$19,626.34	$153.33	$5.19	9,397	3,779
Humana	88	147	$58,449.11	$397.61	$13.33	10,207	4,384
OCH	59	105	$13,424.61	$127.85	$4.34	7,587	3,096
2024 Total	**742**	**2,513**	**$455,813.79**	**$181.38**	**$5.77**	**200,079**	**78,945**
Fiscal Year 2025							
FFS	326	1,229	$300,489.63	$244.50	$7.74	110,034	38,826
Aetna	157	391	$77,292.27	$197.68	$5.07	34,913	15,231
Humana	191	577	$316,416.63	$548.38	$15.18	53,342	20,849
OCH	165	434	$18,346.65	$42.27	$1.44	37,105	12,753
2025 Total	**793**	**2,631**	**$712,545.18**	**$270.83**	**$8.13**	**235,394**	**87,659**
% Change	**6.90%**	**4.70%**	**56.30%**	**49.30%**	**40.90%**	**17.70%**	**11.00%**
Change	**51**	**118**	**$256,731.39**	**$89.45**	**$2.36**	**35,315**	**8,714**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Cholestatic Liver Disease and Bile Acid Disorder Medications: Pharmacy Claims (All Plans)



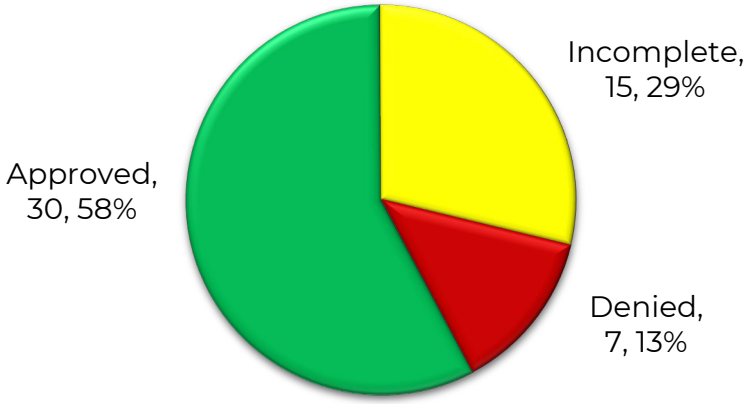
Top Prescriber Specialties of Cholestatic Liver Disease and Bile Acid Disorder Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Cholestatic Liver Disease and Bile Acid Disorder Medications

There were 52 prior authorization requests submitted for cholestatic liver disease and bile acid disorder medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	27	59%	15	33%	4	9%	**46**
Aetna	0	0%	0	0%	2	100%	**2**
Humana	2	67%	0	0%	1	33%	**3**
OCH	1	100%	0	0%	0	0%	**1**
Total	**30**	**58%**	**15**	**29%**	**7**	**13%**	**52**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7]

Anticipated Patent Expiration(s):

- Livdelzi® (seladelpar): March 2035
- Iqirvo® (elafibranor): March 2037
- Livmarli® (maralixibat solution): February 2040
- Bylvay® (odevixibat): November 2041
- Livmarli® (maralixibat tablet): October 2043

New U.S. Food and Drug Administration (FDA) Approval(s):

- **March 2025:** The FDA approved a label update for Bylvay® (odevixibat) to add a new contraindication, stating that ileal bile acid transporter (IBAT) inhibitors, including Bylvay®, are contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).
- **April 2025:** The FDA approved a new oral tablet formulation of Livmarli® (maralixibat) for the treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS) and for the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Livmarli® is not recommended in a subgroup of PFIC type 2 patients with specific *ABCB11* variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein. Livmarli® was previously FDA approved as a 9.5mg/mL oral solution for the treatment of ALGS and a 19mg/mL oral solution for the treatment of PFIC. The tablets are available in 10mg, 15mg, 20mg, and 30mg strengths and the recommended dosing varies by indication and the patient's weight. The tablets can be used in patients weighing ≥25kg who are able to swallow tablets; however, patients weighing 25kg to 43kg (for ALGS) or 25kg to 32kg (for PFIC) are required to complete the initial dosing titration using the oral solution formulation before transitioning to the tablets.

News:

- **September 2025:** Intercept Pharmaceuticals announced the voluntary withdrawal of Ocaliva® (obeticholic acid) from the United States market and that the FDA has placed a clinical hold on all clinical trials involving obeticholic acid in the United States. Ocaliva® received accelerated approval in May 2016 for the treatment of adults with primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. In May 2021, due to an identified risk of serious liver injury in patients with advanced cirrhosis taking Ocaliva® to treat PBC, the indication was narrowed and new contraindications were added to the labeling for patients with decompensated cirrhosis (e.g.,

Child-Pugh class B or C) or a prior decompensation event, or patients with compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). Then, in September 2024, the FDA's Gastrointestinal Drugs Advisory Committee voted against recommending full approval of Ocaliva® based on concerns that the medication does not have a favorable benefit-risk profile. According to Intercept, Ocaliva® was officially withdrawn from the market in the United States as of November 14, 2025.

Recommendations

The College of Pharmacy recommends updating the Bylvay® (odevixibat) and Livmarli® (maralixibat) approval criteria based on recent FDA approvals and to be consistent with clinical trial inclusion criteria for baseline serum bile acid levels (changes shown in red):

Bylvay® (Odevixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in either the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ~~>3x~~ >1x the upper limit of normal (ULN) for age at baseline; and
6. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and

8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Bylvay® (Odevixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, or ABCB4* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ≥100micromol/L at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Bylvay®; and

8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for 40mcg/kg/day for a duration of 3 months. After 3 months of treatment, further approval may be granted at the 40mcg/kg/day dose if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate; or
13. Dose increases to 80mcg/kg/day (for 3 months) and 120mcg/kg/day (for 3 months) may be approved if there is no improvement in pruritus after 3 months of treatment with the lower dose(s). Further approval may be granted if the prescriber documents the member is responding well to treatment at the current dose and is still not a candidate for surgical intervention; and
14. If there is no improvement in pruritus after 3 months of treatment with the maximum 120mcg/kg/day dose, further approval of Bylvay® will not be granted.

Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:

a. Cholestyramine; or
b. Rifampin; or
c. Sertraline; or
d. Naltrexone; and

5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:
   a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
   b. Conjugated bilirubin >1mg/dL; or
   c. Fat soluble vitamin deficiency otherwise unexplainable; or
   d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
   e. Intractable pruritus explainable only by liver disease; and
6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
10. Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Requests must be for an appropriate formulation for the member's weight, including:
    a. Solution: The request must be for the 9.5mg/mL solution; ~~and~~ or
    b. Tablet: The member must weigh ≥25kg. Additionally, members weighing 25-43kg must have already completed dosing titration using the oral solution; and
13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Livmarli® (Maralixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Livmarli®; and
8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Requests must be for an appropriate formulation for the member's weight, including:
    a. Solution: The request must be for the 19mg/mL solution; ~~and~~ or

b. Tablet: The member must weigh ≥25kg. Additionally, members weighing 25-32kg must have already completed dosing titration using the oral solution; and

13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Next, the College of Pharmacy recommends updating the Livdelzi® (seladelpar) approval criteria based on net cost (changes shown in red):

Livdelzi® (Seladelpar) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and
3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and
4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and
5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
   a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
6. Livdelzi® must be taken in combination with UDCA; or
   a. For Livdelzi® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
7. Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and
8. Prescriber must agree to monitor all of the following:
   a. Fracture risk and bone health; and
   b. Liver function tests at baseline and thereafter; and
9. Member must not be taking OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors concurrently with Livdelzi®; and
10. ~~A patient-specific, clinically significant reason why the member cannot use Iqirvo® (elafibranor) must be provided; and~~
11. A quantity limit of 30 capsules per 30 days will apply; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if

the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.

Lastly, the College of Pharmacy also recommends removing SoonerCare coverage and the approval criteria for Ocaliva® (obeticholic acid) based on its withdrawal from the market (changes shown in red):

~~**Ocaliva® (Obeticholic Acid) Approval Criteria:**~~

1. ~~An FDA approved diagnosis of primary biliary cholangitis (PBC); and~~
2. ~~Member must be 18 years of age or older; and~~
3. ~~Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and~~
4. ~~Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and~~
5. ~~Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and~~
    a. ~~Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and~~
6. ~~Ocaliva® must be taken in combination with UDCA; or~~
    a. ~~For Ocaliva® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and~~
7. ~~Member must not have any of the following:~~
    a. ~~Decompensated cirrhosis (e.g., Child-Pugh class B or C) or a prior decompensation event; or~~
    b. ~~Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia); or~~
    c. ~~Complete biliary obstruction; and~~
8. ~~Prescriber must agree to monitor liver tests frequently and to discontinue Ocaliva® if there is any evidence of liver disease progression while on treatment; and~~
9. ~~Initial approvals will be for a dose of 5mg once daily for a duration of 3 months. After 3 months of treatment, information regarding efficacy must be submitted; and~~
    a. ~~If an adequate improvement in liver function tests is not achieved with the 5mg dose, a dose of 10mg once daily may be approved for a duration of 3 months; and~~

~~10. Subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests; and~~
~~11. A quantity limit of 1 tablet per day will apply.~~

Utilization Details of Cholestatic Liver Disease and Bile Acid Disorder Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
URSODIOL PRODUCTS						
URSODIOL CAP 300MG	1,570	584	$68,205.66	$43.44	2.69	9.57%
URSODIOL TAB 250MG	733	142	$27,452.90	$37.45	5.16	3.85%
URSODIOL TAB 500MG	286	83	$16,932.79	$59.21	3.45	2.38%
SUBTOTAL	**2,589**	**809**	**$112,591.35**	**$43.49**	**3.2**	**15.80%**
OBETICHOLIC ACID PRODUCTS						
OCALIVA TAB 5MG	17	2	$163,740.20	$9,631.78	8.5	22.98%
SUBTOTAL	**17**	**2**	**$163,740.20**	**$9,631.78**	**8.5**	**22.98%**
CHOLIC ACID PRODUCTS						
CHOLBAM CAP 250MG	10	1	$289,880.48	$28,988.05	10	40.68%
SUBTOTAL	**10**	**1**	**$289,880.48**	**$28,988.05**	**10**	**40.68%**
ODEVIXIBAT PRODUCTS						
BYLVAY CAP 200MCG	8	1	$58,011.28	$7,251.41	8	8.14%
SUBTOTAL	**8**	**1**	**$58,011.28**	**$7,251.41**	**8**	**8.14%**
SELADELPAR PRODUCTS						
LIVDELZI CAP 10MG	7	1	$88,321.87	$12,617.41	7	12.40%
SUBTOTAL	**7**	**1**	**$88,321.87**	**$12,617.41**	**7**	**12.40%**
TOTAL	**2,631**	**793***	**$712,545.18**	**$270.83**	**3.32**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[2] Bylvay® (Odevixibat) Prescribing Information. Ipsen Biopharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215498s006lbl.pdf. Last revised 03/2025. Last accessed 01/21/2026.
[3] Mirum Pharmaceuticals, Inc. Mirum's Livmarli® Now FDA Approved in Tablet Formulation. Available online at: https://ir.mirumpharma.com/news/news-details/2025/Mirums-LIVMARLI-Now-FDA-Approved-in-Tablet-Formulation/default.aspx. Issued 04/14/2025. Last accessed 01/21/2026.
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[6] Ingram I. FDA Rejects Full Approval of Liver Disease Drug. *Medpage Today*. Available online at: https://www.medpagetoday.com/gastroenterology/generalhepatology/112874. Issued 11/12/2024. Last accessed 01/21/2026.
[7] Intercept Pharmaceuticals, Inc. FAQs: Ocaliva® US Market Withdrawal. Available online at: https://www.interceptpharma.com/about-us/ocaliva-withdrawal-faq/. Last accessed 01/21/2026.

Appendix V

Fiscal Year 2025 Annual Review of Anticonvulsants

Oklahoma Health Care Authority
February 2026

Current Prior Authorization Criteria

1. Anticonvulsants are included in the mandatory generic plan.
    a. All brand-name anticonvulsants (with a generic equivalent) will require prior authorization.
        i. Brand-name medications (with a generic equivalent) will be approved for all members who are currently stable on these medications and have a seizure diagnosis.
2. Prior authorization will be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.
    a. Members 12 years of age and older must have a documented medical reason demonstrating the need for non-standard dosage forms.
    b. Criteria for approval of extended-release formulations:
        i. Previously stabilized on the short-acting formulation; and
        ii. Dosing is not more than once daily; and
        iii. A reason why the short-acting formulation is not adequate must be provided; and
    c. Dose packs will not be approved if standard dosage forms are available.
3. Quantity limit restrictions will be placed on lower strength tablets and capsules. The highest strengths will continue to have no quantity restrictions unless a maximum dose is specified for a particular medication.

Afinitor® (Everolimus) Approval Criteria* [Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures Diagnosis]:

1. An FDA approved diagnosis of TSC-associated partial-onset seizures; and
2. Initial prescription must be written by a neurologist or neuro-oncologist; and
3. Member must have failed therapy with at least 3 anticonvulsants; and
4. Afinitor® must be used as adjunctive treatment; and
5. Member must not be taking any P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin) concurrently with Afinitor®; and

6. Member must not be taking St. John's wort concurrently with Afinitor®; and
7. Prescriber must verify that Afinitor® trough levels and adverse reactions (e.g., non-infectious pneumonitis, stomatitis, hyperglycemia, dyslipidemia, thrombocytopenia, neutropenia, febrile neutropenia) will be monitored, and dosing changes or discontinuations will correspond with recommendations in the drug labeling; and
8. Prescriber must verify that female members will use contraception while receiving Afinitor® therapy and for 8 weeks after the last dose of Afinitor® and that male members with female partners of reproductive potential will use contraception while receiving Afinitor® therapy and for 4 weeks after the last dose of Afinitor®; and
9. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.
    *Approval criteria for Afinitor® (everolimus) for indications other than seizure diagnoses can be found in the September 2025 DUR Board packet. Afinitor® is reviewed annually with the breast cancer medications.

Aptiom® (Eslicarbazepine) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
3. A patient-specific, clinically significant reason why the member cannot use oxcarbazepine must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 tablets per 30 days on the higher strength tablets (600mg and 800mg).

Banzel® (Rufinamide) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Authorization of generic rufinamide (in place of brand Banzel®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and

5. Members currently stable on Banzel® (rufinamide) and who have a seizure diagnosis will be approved for continuation of therapy.

Briviact® (Brivaracetam) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be prescribed by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Briviact® and who have a seizure diagnosis will be approved for continuation of therapy; and
5. For Briviact® oral solution, an age restriction of 12 years of age and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral tablet formulation; and
6. Approval length for Briviact® intravenous (IV) will be for a maximum of 7 days of therapy. Further approval may be granted if the prescriber documents an ongoing need for Briviact® IV therapy over Briviact® oral formulations.

Carbamazepine 200mg Chewable Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other forms of carbamazepine that are available without a prior authorization, including using 2 of the 100mg chewable tablets to achieve the 200mg dose must be provided; and
2. A quantity limit of 720 chewable tablets per 90 days will apply.

Diacomit® (Stiripentol) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Dravet syndrome; and
2. Member must be 6 months of age or older and weigh ≥7kg; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed or be inadequately controlled with clobazam and valproate; and
5. Member must take clobazam and valproate concomitantly with Diacomit® or a reason why concomitant clobazam and valproate are not appropriate for the member must be provided; and
6. Members currently stable on Diacomit® and who have a seizure diagnosis will be approved for continuation of therapy; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. For Diacomit® powder for oral suspension, an age restriction of 12 years and younger will apply. Members older than 12 years of age will require

a patient-specific, clinically significant reason why the member cannot take the oral capsule formulation; and
9. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Elepsia™ XR [Levetiracetam Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic formulations of levetiracetam ER must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

Epidiolex® (Cannabidiol Oral Solution) Approval Criteria:

1. Diagnosis* of 1 of the following:
   a. Lennox-Gastaut syndrome (LGS); or
   b. Dravet syndrome; or
   c. Tuberous sclerosis complex (TSC)-associated seizures; or
   d. Intractable epilepsy; and

   *The manufacturer has provided a supplemental rebate to allow Epidiolex® claims to pay at the point of sale if the member has a reported diagnosis of LGS, Dravet syndrome, TSC-associated seizures, or intractable epilepsy within the past 12 months of claims history; however, Epidiolex® will follow the original criteria if the manufacturer chooses not to participate in supplemental rebates.
2. Member must be 1 year of age or older; and
3. Members currently stable on Epidiolex® and who have a seizure diagnosis will be approved for continuation of therapy.

Eprontia® (Topiramate Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use topiramate tablets and sprinkle capsules must be provided; and
3. An age restriction of 11 years of age and younger will apply. Members older than 11 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
4. A quantity limit of 473mL per 29 days will apply.

Felbatol® (Felbamate) Approval Criteria:

1. Initial prescription must be written by, or in consultation with, a neurologist; and
2. Member must have failed therapy with at least 3 other anticonvulsants.

Fintepla® (Fenfluramine) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Dravet syndrome; or
   b. Lennox-Gastaut syndrome (LGS); and
2. Member must be 2 years of age or older; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must not be taking monoamine oxidase inhibitors within 14 days of administration of Fintepla®; and
5. Prescriber must verify the member's blood pressure will be monitored; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla® therapy and throughout treatment; and
7. For a diagnosis of Dravet syndrome, the member must have failed or be inadequately controlled with at least 2 other anticonvulsants; and
8. For a diagnosis of LGS, the member must have failed or be inadequately controlled with at least 3 other anticonvulsants; and
9. Pharmacy and provider must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Fintepla® REMS program; and
11. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
12. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; and
13. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
14. A quantity limit of 360mL per 30 days will apply.

Fycompa® (Perampanel) Approval Criteria:

1. An FDA approved indication of the treatment of partial-onset seizures with or without secondarily generalized seizures or adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures; and
2. Initial prescription must be written by, or in consultation with, a neurologist; and

3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. For Fycompa® oral suspension, a patient-specific, clinically significant reason why Fycompa® oral tablets cannot be used must be provided; and
5. Members currently stable on Fycompa® and who have a seizure diagnosis will be approved for continuation of therapy.

Motpoly XR™ [Lacosamide Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must weigh ≥50kg; and
3. A patient specific, clinically significant reason why the member cannot use the immediate-release tablets must be provided; and
4. The following quantity limits will apply:
    a. Motpoly XR™ 100mg: 30 capsules per 30 days; or
    b. Motpoly XR™ 150mg and 200mg: 60 capsules per 30 days.

Oxtellar XR® [Oxcarbazepine Extended-Release (ER)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation must be provided; and
2. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (150mg and 300mg).

Primidone 125mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific clinically significant reason why the member cannot split the 250mg tablet to achieve the 125mg dose must be provided.

Qudexy® XR [Topiramate Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
    b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
    c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (150mg and 200mg).

Sabril® (Vigabatrin) Approval Criteria:

1. An FDA approved diagnosis of refractory complex seizures in adults and pediatric members 2 years of age or older, or infantile spasms in children 1 month to 2 years of age; and
2. Authorization of generic vigabatrin (in place of brand Sabril®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
3. Members with refractory complex seizures must have previous trials of at least 3 other anticonvulsants; or
4. Prescription must be written by, or in consultation with, a neurologist; and
5. Member, prescriber, and pharmacy must all register in the Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

Spritam® (Levetiracetam Tablet for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures, myoclonic seizures, or primary generalized tonic-clonic (PGTC) seizures; and
2. A patient-specific, clinically significant reason why the member cannot use generic formulations of levetiracetam must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

Sympazan® (Clobazam Oral Film) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in members 2 years of age and older; and
2. Previous failure of at least 2 non-benzodiazepine anticonvulsants; and
3. Previous failure of clonazepam; and
4. A patient-specific, clinically significant reason why the member cannot use clobazam oral tablets or clobazam oral suspension must be provided; and
5. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Topiramate 50mg Sprinkle Capsule Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use other available generic topiramate products, including using 2 topiramate 25mg sprinkle capsules to achieve the 50mg dose, must be provided; and
3. Members 12 years of age and older will require a patient-specific, clinically significant reason why a special formulation product is needed; and
4. A quantity limit of 240 capsules per 30 days will apply.

Trokendi XR® [Topiramate Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
    b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
    c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. Members currently stable on Trokendi XR® (topiramate ER) and who have a seizure diagnosis will be approved for continuation of therapy; and
4. Authorization of generic topiramate ER (in place of brand Trokendi XR®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
5. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (200mg).

Vigafyde® (Vigabatrin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of infantile spasms in children 1 month to 2 years of age; and
2. A patient-specific, clinically significant reason why the member cannot use brand Sabril® (vigabatrin) for oral solution must be provided; and
3. Prescription must be written by, or in consultation with, a neurologist; and
4. Member, prescriber, and pharmacy must all register in the Vigabatrin REMS program and maintain enrollment throughout therapy.

Xcopri® (Cenobamate) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants.

Zonisade® (Zonisamide Oral Suspension) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of partial-onset seizures; and
2. A patient-specific, clinically significant reason why the member cannot use zonisamide capsules must be provided; and
3. A quantity limit of 900mL per 30 days will apply.

Ztalmy® (Ganaxolone) Approval Criteria:

1. An FDA approved diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD); and
    a. Diagnosis must be confirmed by genetic testing identifying a mutation in the CDKL5 gene that is pathogenic or likely pathogenic; and
2. Member must be 2 years of age or older; and
3. The initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed at least 2 other anticonvulsants; and
5. Members currently stable on Ztalmy® and who have a CDD diagnosis confirmed by genetic testing will be approved for continuation of therapy; and
6. The member's recent weight (kg), taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
7. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
8. Subsequent approvals will be for the duration of 1 year; and
9. A quantity limit of 1,100mL per 30 days will apply.

Utilization of Anticonvulsants: Fiscal Year 2025

The following utilization data includes medications indicated for seizure diagnoses; however, the data does not differentiate between seizure diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

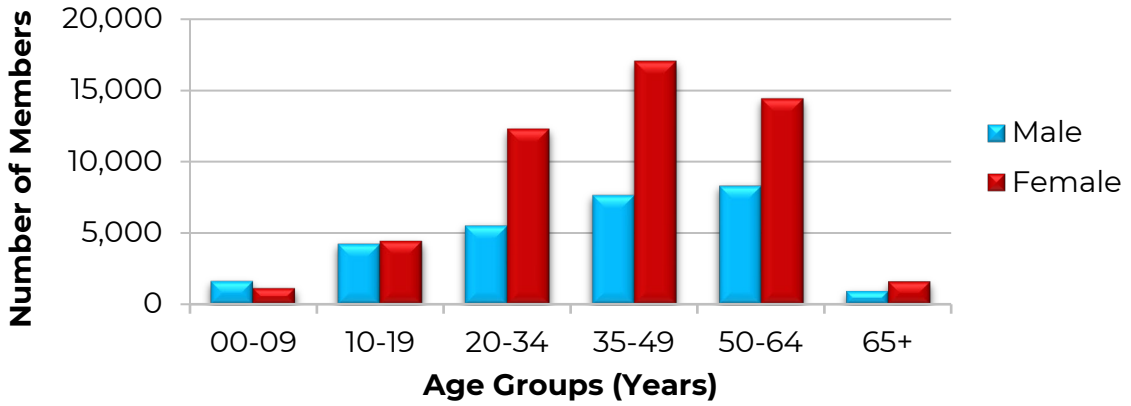
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	77,073	401,250	$30,151,824.99	$75.14	$2.05	43,375,255	14,725,362
Aetna	7,677	15,286	$596,711.38	$39.04	$1.02	1,471,695	582,801
Humana	9,500	20,040	$919,916.66	$45.90	$1.20	1,911,574	764,283
OCH	8,333	16,402	$1,086,496.51	$66.24	$1.77	1,584,215	614,554
2024 Total	**82,120**	**452,978**	**$32,754,949.54**	**$72.31**	**$1.96**	**48,342,739**	**16,687,000**
Fiscal Year 2025							
FFS	41,130	232,773	$26,459,114.03	$113.67	$3.17	27,758,865	8,339,175
Aetna	14,861	64,028	$2,612,770.97	$40.81	$1.07	6,168,749	2,439,165
Humana	17,763	84,395	$4,056,187.00	$48.06	$1.27	7,877,387	3,185,758
OCH	16,303	70,924	$4,835,836.66	$68.18	$1.70	7,284,706	2,841,713
2025 Total	**79,137**	**452,120**	**$37,963,908.66**	**$83.97**	**$2.26**	**49,089,707**	**16,805,811**
% Change	**-3.60%**	**-0.20%**	**15.90%**	**16.10%**	**15.30%**	**1.50%**	**0.70%**
Change	**-2,983**	**-858**	**$5,208,959.12**	**$11.66**	**$0.30**	**746,968**	**118,811**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

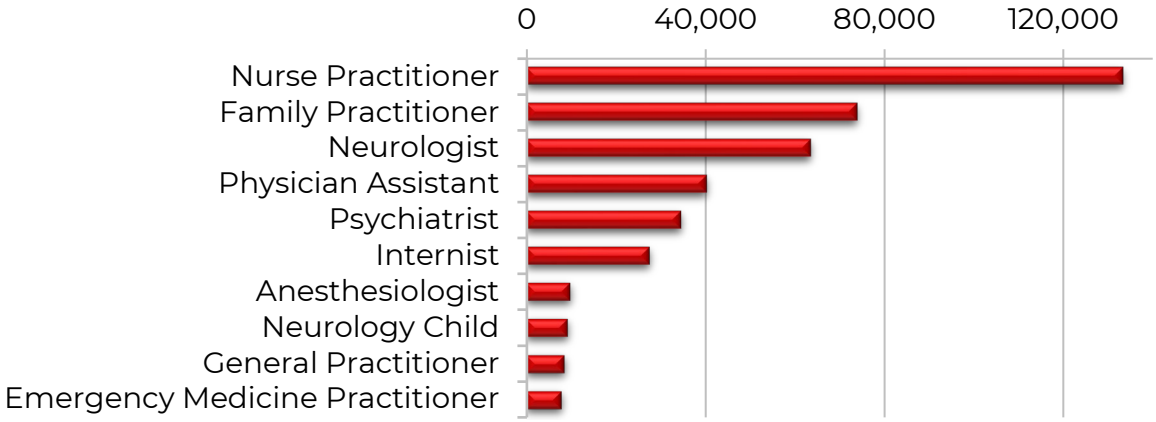
- Aggregate drug rebates collected during fiscal year 2025 for anticonvulsants totaled $15,948,787.28.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Anticonvulsants: Pharmacy Claims (All Plans)



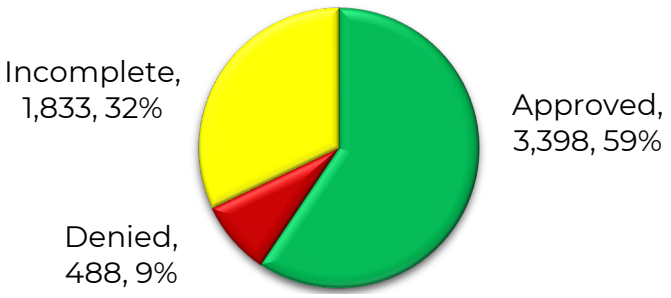
Top Prescriber Specialties of Anticonvulsants by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anticonvulsants

There were 5,719 prior authorization requests submitted for anticonvulsants during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	2,571	60%	1,542	36%	179	4%	**4,292**
Aetna	109	29%	129	35%	135	36%	**373**
Humana	43	57%	0	0%	32	43%	**75**
OCH	675	69%	162	17%	142	15%	**979**
Total	**3,398**	**59%**	**1,833**	**32%**	**488**	**9%**	**5,719**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9,10]

Anticipated Patent Expiration(s):

- Briviact® [brivaracetam oral solution, intravenous (IV) solution]: February 2026
- Fycompa® (perampanel tablets, oral suspension): July 2026
- Oxtellar XR® [oxcarbazepine extended-release (ER) tablets]: April 2027
- Elepsia™ XR (levetiracetam ER tablets): October 2027
- Nayzilam® (midazolam nasal spray): January 2028
- Trokendi XR® (topiramate ER capsules): April 2028
- Valtoco® (diazepam nasal spray): October 2032
- Diacomit® (stiripentol capsules, oral suspension): July 2029*
  *Diacomit® does not have any unexpired patents; however, it does currently have exclusivity through July 2029.
- Briviact® (brivaracetam tablets): April 2030
- Aptiom® (eslicarbazepine tablets): August 2032
- Qudexy® XR (topiramate ER capsules): March 2033
- Spritam® (levetiracetam tablets for oral suspension): March 2034
- Ztalmy® (ganaxolone oral suspension): August 2037
- Zonisade® (zonisamide oral suspension: August 2038
- Fintepla® (fenfluramine oral solution): December 2038
- Xcopri® (cenobamate tablets): June 2039
- Sympazan® (clobazam oral films): January 2040
- Eprontia® (topiramate oral solution): August 2040
- Epidiolex® (cannabidiol oral solution): March 2041

News:

- **September 2024:** According to the U.S. Food and Drug Administration (FDA)'s National Drug Code (NDC) Directory, a generic formulation of Oxtellar XR® (oxcarbazepine ER) tablets began being marketed in September 2024.
- **January 2025:** According to the FDA's NDC Directory, a generic formulation of Spritam® (levetiracetam tablets for oral suspension)

250mg began being marketed in January 2025. Currently the other strengths of Spritam® are only available as the brand name formulation.

- **May 2025:** According to the FDA's NDC Directory, a generic formulation of Fycompa® (perampanel) tablets and Aptiom® (eslicarbazepine) tablets began being marketed in May 2025.
- **July 2025:** An AB-rated generic version of Eprontia® (topiramate oral solution) was launched by Ascend for all of the same FDA approved indications.
- **January 2026:** According to the FDA's NDC Directory, a generic formulation of Briviact® (brivaracetam) tablets began being marketed in January 2026.

Pipeline:

- **Bexicaserin:** Bexicaserin is an investigational oral, centrally acting 5-hydroxytryptamine 2C (5-HT2C) receptor agonist with no engagement of the 5-HT2B and 5-HT2A receptor subtypes, potentially minimizing the risk of cardiovascular toxicity. Bexicaserin is being studied for the treatment of seizures associated with developmental and epileptic encephalopathies (DEEs), a group of rare, heterogenous neurodevelopmental disorders that typically manifest in early childhood and are characterized by refractory seizures, frequent epileptiform activity on electroencephalogram (EEG), and developmental stagnation or regression. Bexicaserin has been evaluated in the Phase 1a/2b PACIFIC trial followed by a 12-month open label extension (OLE), and these patients have now received up to 2 years of bexicaserin treatment. During the 2-year follow-up, patients receiving bexicaserin experienced a median reduction in countable motor seizures of -60.2% at 18 months (n=30) and -53.7% at 24 months (n=17), compared to the start of the PACIFIC trial. Notably, the reductions were consistent across DEE types and similar to the results of the PACIFIC trial and OLE. The FDA has granted Breakthrough Therapy designation for bexicaserin for the treatment of seizures associated with DEEs for patients 2 years of age and older. Phase 3 trials are currently ongoing.
- **Fenfluramine:** Fenfluramine is a serotonin agonist that has been shown to stimulate multiple 5-HT receptor sub-types through the release of serotonin and is being studied for the treatment of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Fintepla® (fenfluramine) is currently FDA approved for the treatment of seizures associated with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older. The Phase 3 GEMZ trial evaluated the efficacy and safety of adjunctive fenfluramine treatment in patients with a confirmed or likely pathogenic *CDKL5* mutation, a clinical CDD diagnosis, and uncontrolled seizures. The trial met its

primary endpoint of a reduction in countable motor seizure frequency (CMSF), where patients treated with fenfluramine (n=42) (0.7mg/kg/day, maximum 26mg/day) experienced a median reduction of 47.6% in CMSF from baseline, compared with a 2.8% reduction for placebo (n=44) (P<0.001). This translated into an estimated median difference of -52.7% [95% confidence interval (CI): -70.0, -36.7] between treatment groups during a 14-week titration and maintenance period. Two key secondary endpoints were also met showing a significant number of patients demonstrating ≥50% reduction in CMSF and a clinically meaningful improvement on the Clinical Global Impression-Improvement (CGI-I) scale (as rated by investigator) in patients treated with fenfluramine compared to placebo over 14 weeks. Based on this positive Phase 3 data, UCB is currently preparing to submit for regulatory approval.

- **NRTX-1001:** NRTX-1001 is an investigational neuron cell therapy being studied for adults with drug-resistant, unilateral or bilateral mesial temporal lobe epilepsy (MTLE). NRTX-1001 inhibitory neurons are targeted at the seizure-onset zone to enhance GABAergic inhibition, reduce seizure activity, and repair the affected neural network. NRTX-1001 is delivered as a single, 1-time dose and is intended to persist and provide long-term seizure suppression. The ongoing multicenter Phase 1/2 trial for unilateral MTLE has shown patients in the low-dose cohort 1 achieved median disabling seizure reduction of 92% from baseline during the primary efficacy evaluation period in months 7-12 post-treatment and a 97% median reduction of disabling seizures after month 13. In the high dose cohort 2, patients achieved median disabling seizure reduction of 72% from baseline in months 4-9. A Phase 3 trial started enrolling in 2025 and this trial will be used to support submission of a Biologics License Application (BLA).
- **Relutrigine:** Relutrigine is an investigational sodium channel modulator being studied for the treatment of *SCN2A*- or *SCN8A*-DEEs. Relutrigine has been generally well-tolerated in 3 Phase 1 trials and has demonstrated biomarker changes indicative of sodium channel modulation. Data from the Phase 2 EMBOLD trial demonstrated a well-tolerated safety profile with robust, short- and long-term improvement in motor seizures in a heavily pre-treated population, alongside maintained seizure freedom in some patients with *SCN2A*- and *SCN8A*-DEE. Relutrigine has received Orphan Drug and Rare Pediatric Disease designations from the FDA for the treatment of *SCN2A*-DEE, SCN8A-DEE, and DS. A New Drug Application (NDA) is expected to be submitted to the FDA in early 2026.
- **Zorevunersen:** Zorevunersen is an investigational antisense oligonucleotide that is designed to treat the underlying cause of DS by increasing functional NaV1.1 protein production in brain cells from the

non-mutated (wild-type) copy of the *SCN1A* gene. The EMPEROR Phase 3 trial will evaluate the efficacy, safety, and tolerability of zorevunersen in children 2 years to younger than 18 years of age with DS with a confirmed variant in the *SCN1A* gene not associated with gain-of-function. The primary endpoint of the trial is the percent change from baseline in major motor seizure frequency at week 28 in patients receiving zorevunersen as compared to sham. The trial is currently enrolling and a read out of the data is expected in 2027. This data is anticipated to support the submission of an NDA in the first half of 2027. Zorevunersen has been granted Orphan Drug, Rare Pediatric Disease, and Breakthrough Therapy designations by the FDA.

Recommendations

The College of Pharmacy recommends updating the Banzel® (rufinamide), Briviact® (brivaracetam), Eprontia® (topiramate oral solution), Fycompa® (perampanel), and Qudexy® XR (topiramate ER) approval criteria based on net costs and clinical practice (changes shown in red):

Banzel® (Rufinamide) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. ~~Authorization of generic rufinamide (in place of brand Banzel®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and~~
5. Members currently stable on Banzel® (rufinamide) and who have a seizure diagnosis will be approved for continuation of therapy.

Briviact® (Brivaracetam) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be prescribed by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Briviact® and who have a seizure diagnosis will be approved for continuation of therapy; and
5. For Briviact® oral solution, an age restriction of 12 years of age and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral tablet formulation; and

6. Authorization of generic brivaracetam (in place of brand Briviact®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
7. Approval length for Briviact® intravenous (IV) will be for a maximum of 7 days of therapy. Further approval may be granted if the prescriber documents an ongoing need for Briviact® IV therapy over Briviact® oral formulations.

Eprontia® (Topiramate Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use topiramate tablets and sprinkle capsules must be provided; and
3. Authorization of generic topiramate oral solution (in place of brand Eprontia®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
4. An age restriction of 11 years of age and younger will apply. Members older than 11 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
5. A quantity limit of 473mL per 29 days will apply.

Fycompa® (Perampanel) Approval Criteria:

1. An FDA approved indication of the treatment of partial-onset seizures with or without secondarily generalized seizures or adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures; and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. For Fycompa® oral suspension, a patient-specific, clinically significant reason why Fycompa® oral tablets cannot be used must be provided; and
5. Authorization of generic perampanel (in place of brand Fycompa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
6. Members currently stable on Fycompa® and who have a seizure diagnosis will be approved for continuation of therapy.

Qudexy® XR [Topiramate Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use brand name Trokendi XR® (topiramate ER) must be provided; and
4. Members currently stable on Qudexy® XR and who have a seizure diagnosis will be approved for continuation of therapy; and
5. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (150mg and 200mg).

Additionally, the College of Pharmacy recommends the following changes to Aptiom® (eslicarbazepine), Felbatol® (felbamate), Fintepla® (fenfluramine), Sabril® (vigabatrin), and Xcopri® (cenobamate) approval criteria to be consistent with the other anticonvulsant medications regarding stability (changes shown in red):

Aptiom® (Eslicarbazepine) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
3. A patient-specific, clinically significant reason why the member cannot use oxcarbazepine must be provided; and
4. Members currently stable on Aptiom® and who have a seizure diagnosis will be approved for continuation of therapy; and
5. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 tablets per 30 days on the higher strength tablets (600mg and 800mg).

Felbatol® (Felbamate) Approval Criteria:

1. Initial prescription must be written by, or in consultation with, a neurologist; and
2. Member must have failed therapy with at least 3 other anticonvulsants; and
3. Members currently stable on Felbatol® and who have a seizure diagnosis will be approved for continuation of therapy.

Fintepla® (Fenfluramine) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Dravet syndrome; or
   b. Lennox-Gastaut syndrome (LGS); and
2. Member must be 2 years of age or older; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must not be taking monoamine oxidase inhibitors within 14 days of administration of Fintepla®; and
5. Prescriber must verify the member's blood pressure will be monitored; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla® therapy and throughout treatment; and
7. Member must meet 1 of the following:
   a. For a diagnosis of Dravet syndrome, the member must have failed or be inadequately controlled with at least 2 other anticonvulsants; or ~~and~~
   b. For a diagnosis of LGS, the member must have failed or be inadequately controlled with at least 3 other anticonvulsants; or ~~and~~
   c. Members currently stable on Fintepla® and who have a diagnosis of Dravet syndrome or LGS will be approved for continuation of therapy; and
8. Pharmacy and provider must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; and
9. Member must be enrolled in the Fintepla® REMS program; and
10. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
11. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; and
12. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
13. A quantity limit of 360mL per 30 days will apply.

Sabril® (Vigabatrin) Approval Criteria:

1. An FDA approved diagnosis of refractory complex seizures in adults and pediatric members 2 years of age or older, or infantile spasms in children 1 month to 2 years of age; and

2. Authorization of generic vigabatrin (in place of brand Sabril®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
3. Members with refractory complex seizures must have previous trials of at least 3 other anticonvulsants; or
4. Prescription must be written by, or in consultation with, a neurologist; and
5. Members currently stable on Sabril® and who have a seizure diagnosis will be approved for continuation of therapy; and
6. Member, prescriber, and pharmacy must all register in the Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

Xcopri® (Cenobamate) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Xcopri® and who have a seizure diagnosis will be approved for continuation of therapy.

Utilization Details of Anticonvulsants: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GABAPENTIN PRODUCTS						
GABAPENTIN CAP 300MG	55,332	19,111	$828,534.06	$14.97	2.9	2.18%
GABAPENTIN TAB 600MG	28,449	7,110	$554,683.35	$19.50	4	1.46%
GABAPENTIN CAP 100MG	21,950	9,413	$284,712.20	$12.97	2.33	0.75%
GABAPENTIN TAB 800MG	21,727	4,526	$498,869.60	$22.96	4.8	1.31%
GABAPENTIN CAP 400MG	9,302	2,674	$149,637.29	$16.09	3.48	0.39%
GABAPENTIN SOL 250MG/5ML	2,051	375	$83,526.83	$40.72	5.47	0.22%
GABARONE TAB 400MG	20	9	$39,696.20	$1,984.81	2.22	0.10%
GABARONE TAB 100MG	18	12	$51,535.53	$2,863.09	1.5	0.14%
NEURONTIN CAP 300MG	7	2	$10,650.04	$1,521.43	3.5	0.03%
SUBTOTAL	**138,856**	**43,232**	**$2,501,845.10**	**$18.02**	**3.21**	**6.59%**
LAMOTRIGINE PRODUCTS						
LAMOTRIGINE TAB 100MG	16,477	4,574	$220,851.41	$13.40	3.6	0.58%
LAMOTRIGINE TAB 25MG	14,729	5,764	$198,321.72	$13.46	2.56	0.52%
LAMOTRIGINE TAB 200MG	9,712	2,131	$147,360.20	$15.17	4.56	0.39%
LAMOTRIGINE TAB 150MG	6,697	1,764	$93,506.44	$13.96	3.8	0.25%
LAMOTRIGINE CHW 25MG	301	64	$9,952.04	$33.06	4.7	0.03%
LAMOTRIGINE TAB 200MG ER	284	66	$17,128.54	$60.31	4.3	0.05%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LAMOTRIGINE TAB 300MG ER	255	44	$21,697.64	$85.09	5.8	0.06%
LAMOTRIGINE TAB 50MG ER	183	60	$7,182.48	$39.25	3.05	0.02%
LAMOTRIGINE TAB 250MG ER	178	39	$16,574.85	$93.12	4.56	0.04%
LAMOTRIGINE TAB 100MG ER	164	45	$7,493.95	$45.69	3.64	0.02%
LAMOTRIGINE CHW 5MG	163	35	$6,807.77	$41.77	4.66	0.02%
LAMOTRIG ODT 100MG	76	12	$10,892.88	$143.33	6.33	0.03%
LAMOTRIGINE TAB 50MG ODT	74	12	$8,113.29	$109.64	6.17	0.02%
LAMOTRIGINE TAB 25MG ODT	61	9	$16,512.90	$270.70	6.78	0.04%
LAMOTRIGINE TAB 25MG ER	53	20	$1,514.72	$28.58	2.65	0.00%
LAMICTAL TAB 100MG	41	6	$38,555.78	$940.38	6.83	0.10%
LAMICTAL TAB 150MG	32	7	$41,570.74	$1,299.09	4.57	0.11%
LAMICTAL TAB 200MG	31	4	$37,729.04	$1,217.07	7.75	0.10%
LAMOTRIGINE TAB 200MG	28	6	$3,467.77	$123.85	4.67	0.01%
LAMICTAL TAB 25MG	23	4	$15,333.13	$666.66	5.75	0.04%
LAMICTAL XR TAB 200MG	10	1	$11,702.96	$1,170.30	10	0.03%
LAMOTRIGINE KIT ODT	8	8	$2,558.56	$319.82	1	0.01%
LAMOTRIGINE TAB 100MG	6	2	$756.01	$126.00	3	0.00%
SUBVENITE KIT START 49	4	4	$2,577.96	$644.49	1	0.01%
SUBVENITE TAB 25MG	2	2	$26.71	$13.36	1	0.00%
LAMOTRIGINE KIT START 49	2	2	$1,288.98	$644.49	1	0.00%
LAMICTAL ODT KIT	2	2	$1,361.74	$680.87	1	0.00%
LAMICTAL CHW 25MG	1	1	$1,323.95	$1,323.95	1	0.00%
SUBVENITE TAB 200MG	1	1	$18.25	$18.25	1	0.00%
LAMICTAL KIT START 49	1	1	$449.12	$449.12	1	0.00%
SUBVENITE TAB 100MG	1	1	$12.91	$12.91	1	0.00%
SUBTOTAL	**49,600**	**14,691**	**$942,644.44**	**$19.00**	**3.38**	**2.48%**
LEVETIRACETAM PRODUCTS						
LEVETIRACETAM SOL 100MG/ML	11,941	1,778	$271,661.98	$22.75	6.72	0.72%
LEVETIRACETAM TAB 500MG	11,141	3,384	$185,643.96	$16.66	3.29	0.49%
LEVETIRACETAM TAB 1000MG	7,720	1,820	$203,237.88	$26.33	4.24	0.54%
LEVETIRACETAM TAB 750MG	6,354	1,555	$137,063.04	$21.57	4.09	0.36%
LEVETIRACETAM TAB 250MG	1,699	490	$24,587.82	$14.47	3.47	0.06%
LEVETIRACETAM TAB 750MG ER	804	135	$24,743.85	$30.78	5.96	0.07%
LEVETIRACETAM TAB 500MG ER	793	183	$20,928.40	$26.39	4.33	0.06%
KEPPRA XR TAB 750MG	49	5	$65,802.40	$1,342.91	9.8	0.17%
KEPPRA XR TAB 500MG	42	4	$44,243.29	$1,053.41	10.5	0.12%
KEPPRA TAB 1000MG	41	6	$93,151.49	$2,271.99	6.83	0.25%
KEPPRA TAB 500MG	27	5	$28,288.36	$1,047.72	5.4	0.07%
KEPPRA SOL 100MG/ML	20	4	$13,903.69	$695.18	5	0.04%
KEPPRA TAB 250MG	13	2	$6,337.40	$487.49	6.5	0.02%
KEPPRA TAB 750MG	4	1	$3,203.52	$800.88	4	0.01%
SPRITAM TAB 750MG	1	1	$3,747.54	$3,747.54	1	0.01%
SUBTOTAL	**40,649**	**9,373**	**$1,126,544.62**	**$27.71**	**4.34**	**2.97%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLONAZEPAM PRODUCTS						
CLONAZEPAM TAB 1MG	15,943	3,043	$196,882.35	$12.35	5.24	0.52%
CLONAZEPAM TAB 0.5MG	14,080	3,536	$167,105.34	$11.87	3.98	0.44%
CLONAZEPAM TAB 2MG	3,803	676	$47,969.45	$12.61	5.63	0.13%
CLONAZEPAM ODT 0.25MG	1,516	493	$51,191.08	$33.77	3.08	0.13%
CLONAZEPAM ODT 0.125MG	896	351	$26,428.46	$29.50	2.55	0.07%
CLONAZEPAM ODT 0.5MG	856	295	$28,949.16	$33.82	2.9	0.08%
CLONAZEPAM ODT 1MG	489	146	$17,500.56	$35.79	3.35	0.05%
CLONAZEPAM ODT 2MG	98	31	$2,484.99	$25.36	3.16	0.01%
KLONOPIN TAB 2MG	4	1	$496.17	$124.04	4	0.00%
SUBTOTAL	**37,685**	**8,572**	**$539,007.56**	**$14.30**	**4.4**	**1.42%**
TOPIRAMATE PRODUCTS						
TOPIRAMATE TAB 50MG	13,323	4,807	$166,042.64	$12.46	2.77	0.44%
TOPIRAMATE TAB 25MG	12,485	5,564	$148,462.36	$11.89	2.24	0.39%
TOPIRAMATE TAB 100MG	8,023	2,220	$116,919.35	$14.57	3.61	0.31%
TOPIRAMATE TAB 200MG	2,475	534	$42,369.23	$17.12	4.63	0.11%
EPRONTIA SOL 25MG/ML	334	43	$116,947.13	$350.14	7.77	0.31%
TOPIRAMATE SPR CAP 25MG	204	53	$15,877.17	$77.83	3.85	0.04%
TOPIRAMATE SPR CAP 15MG	130	50	$4,535.15	$34.89	2.6	0.01%
TOPIRAMATE CAP 50MG ER	61	15	$13,923.94	$228.26	4.07	0.04%
TOPIRAMATE CAP 200MG ER	53	11	$41,308.65	$779.41	4.82	0.11%
TROKENDI XR CAP 200MG	52	10	$68,975.63	$1,326.45	5.2	0.18%
TOPIRAMATE CAP 100MG ER	51	15	$22,540.75	$441.98	3.4	0.06%
TOPIRAMATE SPR CAP 150MG ER	46	5	$17,490.84	$380.24	9.2	0.05%
TROKENDI XR CAP 100MG	33	4	$60,473.49	$1,832.53	8.25	0.16%
TOPIRAMATE SPR CAP 100MG ER	31	4	$8,925.55	$287.92	7.75	0.02%
TOPIRAMATE SPR CAP 200MG ER	23	8	$8,234.42	$358.02	2.88	0.02%
TOPAMAX TAB 200MG	22	3	$43,925.46	$1,996.61	7.33	0.12%
TOPIRAMATE SPR CAP 50MG ER	18	7	$2,924.67	$162.48	2.57	0.01%
TOPIRAMATE CAP ER 25MG	18	6	$2,804.04	$155.78	3	0.01%
TOPIRAMATE SPR CAP 25MG ER	16	8	$1,921.92	$120.12	2	0.01%
TOPAMAX TAB 50MG	15	2	$10,955.73	$730.38	7.5	0.03%
TOPAMAX TAB 100MG	14	3	$47,682.89	$3,405.92	4.67	0.13%
TOPIRAMATE SPR CAP 200MG	2	1	$813.12	$406.56	2	0.00%
TROKENDI XR CAP 50MG	1	1	$471.18	$471.18	1	0.00%
SUBTOTAL	**37,430**	**13,374**	**$964,525.31**	**$25.77**	**2.8**	**2.54%**
PREGABALIN PRODUCTS						
PREGABALIN CAP 150MG	7,517	1,679	$109,903.83	$14.62	4.48	0.29%
PREGABALIN CAP 100MG	7,093	1,861	$107,643.69	$15.18	3.81	0.28%
PREGABALIN CAP 75MG	7,076	2,442	$111,624.50	$15.78	2.9	0.29%
PREGABALIN CAP 50MG	4,931	1,908	$71,562.52	$14.51	2.58	0.19%
PREGABALIN CAP 200MG	3,751	709	$59,406.07	$15.84	5.29	0.16%
PREGABALIN CAP 300MG	1,988	317	$33,309.93	$16.76	6.27	0.09%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREGABALIN CAP 25MG	1,664	775	$25,077.49	$15.07	2.15	0.07%
PREGABALIN CAP 225MG	322	73	$4,774.57	$14.83	4.41	0.01%
PREGABALIN SOL 20MG/ML	87	12	$4,054.67	$46.61	7.25	0.01%
LYRICA CAP 200MG	50	7	$34,931.15	$698.62	7.14	0.09%
LYRICA CAP 150MG	35	9	$32,126.98	$917.91	3.89	0.08%
LYRICA CAP 75MG	27	7	$20,616.28	$763.57	3.86	0.05%
LYRICA CAP 100MG	18	3	$17,628.07	$979.34	6	0.05%
LYRICA CAP 300MG	12	4	$7,125.86	$593.82	3	0.02%
LYRICA CAP 50MG	9	3	$7,723.89	$858.21	3	0.02%
SUBTOTAL	**34,580**	**9,809**	**$647,509.50**	**$18.72**	**3.53**	**1.71%**
DIVALPROEX PRODUCTS						
DIVALPROEX TAB 500MG DR	9,952	2,335	$231,885.93	$23.30	4.26	0.61%
DIVALPROEX TAB 500MG ER	7,124	1,690	$172,752.81	$24.25	4.22	0.46%
DIVALPROEX TAB 250MG DR	6,257	1,694	$105,450.12	$16.85	3.69	0.28%
DIVALPROEX TAB 250MG ER	2,711	754	$54,161.06	$19.98	3.6	0.14%
VALPROIC ACID SOL 250MG/5ML	2,134	302	$49,770.98	$23.32	7.07	0.13%
DIVALPROEX TAB 125MG DR	2,113	600	$30,383.63	$14.38	3.52	0.08%
DIVALPROEX CAP 125MG DR	1,525	240	$76,839.76	$50.39	6.35	0.20%
VALPROIC ACID CAP 250MG	780	174	$29,025.00	$37.21	4.48	0.08%
DEPAKOTE SPR CAP 125MG	82	10	$36,535.11	$445.55	8.2	0.10%
DEPAKOTE TAB 500MG DR	29	5	$24,802.36	$855.25	5.8	0.07%
DEPAKOTE ER TAB 250MG	25	3	$15,027.98	$601.12	8.33	0.04%
DEPAKOTE TAB 250MG DR	11	3	$4,842.64	$440.24	3.67	0.01%
DEPAKOTE ER TAB 500MG	7	3	$7,170.15	$1,024.31	2.33	0.02%
DEPAKOTE TAB 125MG DR	2	1	$260.00	$130.00	2	0.00%
SUBTOTAL	**32,752**	**7,814**	**$838,907.53**	**$25.61**	**4.19**	**2.21%**
OXCARBAZEPINE PRODUCTS						
OXCARBAZEPINE TAB 300MG	10,546	2,520	$226,996.11	$21.52	4.18	0.60%
OXCARBAZEPINE TAB 600MG	8,124	1,503	$291,927.88	$35.93	5.41	0.77%
OXCARBAZEPINE TAB 150MG	6,680	1,947	$131,145.76	$19.63	3.43	0.35%
OXCARBAZEPINE SUS 300MG/5ML	3,875	583	$413,238.83	$106.64	6.65	1.09%
OXTELLAR XR TAB 600MG	160	25	$255,576.67	$1,597.35	6.4	0.67%
OXCARBAZEPINE TAB 600MG ER	73	15	$66,946.37	$917.07	4.87	0.18%
TRILEPTAL SUS 300MG/5ML	64	8	$59,845.57	$935.09	8	0.16%
OXTELLAR XR TAB 300MG	47	7	$17,699.55	$376.59	6.71	0.05%
OXCARBAZEPINE TAB 300MG ER	24	5	$10,007.85	$416.99	4.8	0.03%
OXTELLAR XR TAB 150MG	20	2	$5,484.37	$274.22	10	0.01%
TRILEPTAL TAB 300MG	11	1	$10,058.48	$914.41	11	0.03%
OXCARBAZEPINE TAB 150MG ER	9	4	$6,843.93	$760.44	2.25	0.02%
TRILEPTAL TAB 150MG	6	1	$3,053.29	$508.88	6	0.01%
TRILEPTAL TAB 600MG	1	1	$561.38	$561.38	1	0.00%
SUBTOTAL	**29,640**	**6,622**	**$1,499,386.04**	**$50.59**	**4.48**	**3.95%**
LACOSAMIDE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LACOSAMIDE TAB 200MG	3,425	472	$96,322.25	$28.12	7.26	0.25%
LACOSAMIDE TAB 100MG	2,952	586	$68,233.03	$23.11	5.04	0.18%
LACOSAMIDE SOL 10MG/ML	2,540	343	$185,245.14	$72.93	7.41	0.49%
LACOSAMIDE TAB 150MG	1,868	305	$46,385.31	$24.83	6.12	0.12%
LACOSAMIDE TAB 50MG	1,326	351	$23,729.41	$17.90	3.78	0.06%
VIMPAT TAB 200MG	276	36	$329,571.67	$1,194.10	7.67	0.87%
VIMPAT SOL 10MG/ML	248	40	$416,276.91	$1,678.54	6.2	1.10%
VIMPAT TAB 100MG	112	20	$98,737.54	$881.59	5.6	0.26%
VIMPAT TAB 150MG	64	11	$70,357.66	$1,099.34	5.82	0.19%
VIMPAT TAB 50MG	57	13	$40,083.39	$703.22	4.38	0.11%
MOTPOLY XR CAP 200MG	2	1	$1,897.82	$948.91	2	0.00%
SUBTOTAL	**12,870**	**2,178**	**$1,376,840.13**	**$106.98**	**5.91**	**3.63%**
CLOBAZAM PRODUCTS						
CLOBAZAM SUS 2.5MG/ML	2,558	292	$166,543.68	$65.11	8.76	0.44%
CLOBAZAM TAB 10MG	2,023	277	$49,052.02	$24.25	7.3	0.13%
CLOBAZAM TAB 20MG	1,428	168	$56,920.41	$39.86	8.5	0.15%
ONFI TAB 20MG	40	6	$168,742.97	$4,218.57	6.67	0.44%
ONFI SUS 2.5MG/ML	27	4	$118,526.98	$4,389.89	6.75	0.31%
ONFI TAB 10MG	25	3	$32,742.17	$1,309.69	8.33	0.09%
SYMPAZAN FILM 10MG	16	3	$28,555.37	$1,784.71	5.33	0.08%
SYMPAZAN FILM 5MG	12	1	$10,568.02	$880.67	12	0.03%
SYMPAZAN FILM 20MG	1	1	$3,879.09	$3,879.09	1	0.01%
SUBTOTAL	**6,130**	**755**	**$635,530.71**	**$103.68**	**8.12**	**1.67%**
CARBAMAZEPINE PRODUCTS						
CARBAMAZEPINE TAB 200MG	2,517	609	$60,913.89	$24.20	4.13	0.16%
CARBAMAZEPINE TAB 400MG ER	425	86	$29,776.48	$70.06	4.94	0.08%
CARBAMAZEPINE TAB 200MG ER	335	89	$16,578.83	$49.49	3.76	0.04%
CARBAMAZEPINE CHW 100MG	308	69	$14,385.27	$46.71	4.46	0.04%
CARBAMAZEPINE TAB 100MG ER	241	89	$7,797.26	$32.35	2.71	0.02%
CARBAMAZEPINE CAP 300MG ER	219	51	$26,474.35	$120.89	4.29	0.07%
CARBAMAZEPINE CAP 200MG ER	204	68	$20,878.28	$102.34	3	0.05%
CARBAMAZEPINE SUS 100MG/5ML	183	27	$14,067.15	$76.87	6.78	0.04%
CARBAMAZEPINE CAP 100MG ER	117	46	$8,844.53	$75.59	2.54	0.02%
TEGRETOL TAB 200MG	47	8	$27,102.87	$576.66	5.88	0.07%
TEGRETOL-XR TAB 400MG	24	4	$17,048.31	$710.35	6	0.04%
TEGRETOL SUS 100/5ML	21	3	$14,782.00	$703.90	7	0.04%
CARBATROL CAP 200MG	19	2	$2,107.85	$110.94	9.5	0.01%
TEGRETOL-XR TAB 200MG	18	2	$8,102.60	$450.14	9	0.02%
CARBATROL CAP 300MG	5	2	$566.22	$113.24	2.5	0.00%
EPITOL TAB 200MG	1	1	$17.94	$17.94	1	0.00%
TEGRETOL-XR TAB 100MG	1	1	$166.21	$166.21	1	0.00%
SUBTOTAL	**4,685**	**1,157**	**$269,610.04**	**$57.55**	**4.05**	**0.71%**
ZONISAMIDE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ZONISAMIDE CAP 100MG	3,324	596	$76,156.90	$22.91	5.58	0.20%
ZONISAMIDE CAP 50MG	647	135	$9,317.47	$14.40	4.79	0.02%
ZONISAMIDE CAP 25MG	269	73	$4,273.91	$15.89	3.68	0.01%
ZONISADE SUS 100MG/5ML	174	29	$158,672.37	$911.91	6	0.42%
ZONEGRAN CAP 100MG	4	1	$64,140.37	$16,035.09	4	0.17%
SUBTOTAL	**4,418**	**834**	**$312,561.02**	**$70.75**	**5.3**	**0.82%**
DIAZEPAM PRODUCTS						
VALTOCO SPRAY 10MG	1,242	821	$1,396,906.43	$1,124.72	1.51	3.68%
DIAZEPAM GEL 10MG	789	552	$280,294.43	$355.25	1.43	0.74%
VALTOCO SPRAY 15MG	570	373	$686,594.79	$1,204.55	1.53	1.81%
VALTOCO SPRAY 20MG	229	148	$283,157.08	$1,236.49	1.55	0.75%
VALTOCO SPRAY 5MG	228	152	$265,526.23	$1,164.59	1.5	0.70%
DIAZEPAM GEL 20MG	160	73	$84,884.52	$530.53	2.19	0.22%
DIAZEPAM GEL 2.5MG	48	42	$13,943.96	$290.50	1.14	0.04%
DIAZEPAM INJ 10MG/2ML	1	1	$60.63	$60.63	1	0.00%
SUBTOTAL	**3,267**	**2,162**	**$3,011,368.07**	**$921.75**	**1.51**	**7.93%**
CANNABIDIOL PRODUCTS						
EPIDIOLEX SOL 100MG/ML	2,441	246	$6,712,579.82	$2,749.93	9.92	17.68%
SUBTOTAL	**2,441**	**246**	**$6,712,579.82**	**$2,749.93**	**9.92**	**17.68%**
PHENYTOIN AND FOSPHENYTOIN PRODUCTS						
PHENYTOIN EX CAP 100MG	1,766	377	$50,601.38	$28.65	4.68	0.13%
DILANTIN CAP 100MG	133	26	$34,206.39	$257.19	5.12	0.09%
PHENYTOIN SUS 125MG/5ML	109	19	$3,189.20	$29.26	5.74	0.01%
PHENYTOIN CHW 50MG	94	22	$2,999.05	$31.90	4.27	0.01%
PHENYTEK CAP 300MG	79	18	$7,693.59	$97.39	4.39	0.02%
DILANTIN CAP 30MG	59	11	$6,791.46	$115.11	5.36	0.02%
PHENYTEK CAP 200MG	41	12	$7,071.32	$172.47	3.42	0.02%
DILANTIN CHW 50MG	13	1	$2,373.75	$182.60	13	0.01%
DILANTIN-125 SUS 125MG/5ML	10	3	$3,202.78	$320.28	3.33	0.01%
FOSPHENYTOIN INJ 100MG/2ML	6	1	$758.10	$126.35	6	0.00%
PHENYTOIN EX CAP 200MG	2	2	$116.45	$58.23	1	0.00%
SUBTOTAL	**2,312**	**492**	**$119,003.47**	**$51.47**	**4.7**	**0.31%**
CENOBAMATE PRODUCTS						
XCOPRI TAB 150MG	681	99	$1,003,980.36	$1,474.27	6.88	2.64%
XCOPRI TAB 200MG	559	79	$702,105.71	$1,256.00	7.08	1.85%
XCOPRI TAB 100MG	425	82	$495,122.81	$1,164.99	5.18	1.30%
XCOPRI TAB 50MG	253	51	$279,998.92	$1,106.72	4.96	0.74%
XCOPRI TITR PAK 100-150MG	124	18	$142,824.15	$1,151.81	6.89	0.38%
XCOPRI PAK 250MG DAILY DOSE	51	6	$119,190.36	$2,337.07	8.5	0.31%
XCOPRI TITR PAK 50-100MG	33	30	$38,299.76	$1,160.60	1.1	0.10%
XCOPRI TITR PAK 12.5-25MG	30	30	$3,382.76	$112.76	1	0.01%
XCOPRI TAB 25MG	27	9	$32,297.43	$1,196.20	3	0.09%
XCOPRI TITR PAK 150-200MG	6	6	$6,931.38	$1,155.23	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**2,189**	**410**	**$2,824,133.64**	**$1,290.15**	**5.34**	**7.44%**
BRIVARACETAM PRODUCTS						
BRIVIACT TAB 100MG	1,033	149	$1,458,127.16	$1,411.55	6.93	3.84%
BRIVIACT TAB 50MG	628	106	$808,561.64	$1,287.52	5.92	2.13%
BRIVIACT SOL 10MG/ML	262	37	$336,850.73	$1,285.69	7.08	0.89%
BRIVIACT TAB 75MG	156	26	$252,845.10	$1,620.80	6	0.67%
BRIVIACT TAB 25MG	80	15	$111,157.59	$1,389.47	5.33	0.29%
BRIVIACT TAB 10MG	6	3	$5,810.65	$968.44	2	0.02%
SUBTOTAL	**2,165**	**336**	**$2,973,352.87**	**$1,373.37**	**6.44**	**7.83%**
PHENOBARBITAL PRODUCTS						
PHENOBARBITAL TAB 64.8MG	415	51	$8,021.57	$19.33	8.14	0.02%
PHENOBARBITAL SOL 20MG/5ML	305	76	$8,795.55	$28.84	4.01	0.02%
PHENOBARBITAL TAB 32.4MG	303	49	$5,981.60	$19.74	6.18	0.02%
PHENOBARBITAL TAB 97.2MG	176	20	$3,264.43	$18.55	8.8	0.01%
PHENOBARBITAL ELX 20MG/5ML	174	54	$5,312.41	$30.53	3.22	0.01%
PHENOBARBITAL TAB 30MG	110	21	$2,143.10	$19.48	5.24	0.01%
PHENOBARBITAL TAB 16.2MG	88	15	$1,482.93	$16.85	5.87	0.00%
PHENOBARBITAL TAB 100MG	76	9	$1,826.81	$24.04	8.44	0.00%
PHENOBARBITAL TAB 60MG	70	13	$1,368.96	$19.56	5.38	0.00%
PHENOBARBITAL TAB 15MG	34	6	$550.87	$16.20	5.67	0.00%
SUBTOTAL	**1,751**	**314**	**$38,748.23**	**$22.13**	**5.58**	**0.10%**
ETHOSUXIMIDE PRODUCTS						
ETHOSUXIMIDE CAP 250MG	1,148	177	$41,285.65	$35.96	6.49	0.11%
ETHOSUXIMIDE SOL 250MG/5ML	598	101	$21,112.82	$35.31	5.92	0.06%
ZARONTIN CAP 250MG	3	1	$273.21	$91.07	3	0.00%
SUBTOTAL	**1,749**	**279**	**$62,671.68**	**$35.83**	**6.27**	**0.17%**
PRIMIDONE PRODUCTS						
PRIMIDONE TAB 50MG	1,331	300	$24,713.50	$18.57	4.44	0.07%
PRIMIDONE TAB 250MG	271	57	$6,114.00	$22.56	4.75	0.02%
MYSOLINE TAB 250MG	21	2	$119,884.62	$5,708.79	10.5	0.32%
PRIMIDONE TAB 125MG	11	3	$1,038.56	$94.41	3.67	0.00%
SUBTOTAL	**1,634**	**362**	**$151,750.68**	**$92.87**	**4.51**	**0.40%**
ACETAZOLIMIDE PRODUCTS						
ACETAZOLAMIDE TAB 250MG	652	225	$15,710.53	$24.10	2.9	0.04%
ACETAZOLAMIDE CAP 500MG ER	482	159	$14,216.13	$29.49	3.03	0.04%
ACETAZOLAMIDE TAB 125MG	179	61	$3,416.94	$19.09	2.93	0.01%
SUBTOTAL	**1,313**	**445**	**$33,343.60**	**$25.39**	**2.95**	**0.09%**
MIDAZOLAM PRODUCTS						
NAYZILAM SPR 5MG	1,078	579	$1,029,412.89	$954.93	1.86	2.71%
MIDAZOLAM INJ 50MG/10ML	35	2	$596.99	$17.06	17.5	0.00%
MIDAZOLAM SYRUP 2MG/ML	25	14	$551.84	$22.07	1.79	0.00%
MIDAZOLAM INJ 5MG/ML PF	10	6	$117.67	$11.77	1.67	0.00%
MIDAZOLAM INJ 5MG/ML	5	3	$80.18	$16.04	1.67	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MIDAZOLAM INJ 25MG/5ML	4	1	$54.06	$13.52	4	0.00%
MIDAZOLAM INJ 10MG/2ML	3	1	$48.55	$16.18	3	0.00%
SUBTOTAL	**1,160**	**606**	**$1,030,862.18**	**$888.67**	**1.91**	**2.72%**
PERAMPANEL PRODUCTS						
FYCOMPA SUS 0.5MG/ML	371	47	$538,719.45	$1,452.07	7.89	1.42%
FYCOMPA TAB 6MG	170	31	$193,273.87	$1,136.91	5.48	0.51%
FYCOMPA TAB 8MG	141	24	$147,179.38	$1,043.83	5.88	0.39%
FYCOMPA TAB 4MG	130	24	$153,903.97	$1,183.88	5.42	0.41%
FYCOMPA TAB 12MG	113	15	$126,889.03	$1,122.91	7.53	0.33%
FYCOMPA TAB 10MG	84	12	$96,688.31	$1,151.05	7	0.25%
FYCOMPA TAB 2MG	51	15	$35,046.39	$687.18	3.4	0.09%
PERAMPANEL TAB 12MG	2	2	$2,076.97	$1,038.49	1	0.01%
PERAMPANEL TAB 8MG	2	2	$2,143.08	$1,071.54	1	0.01%
PERAMPANEL TAB 4MG	1	1	$1,005.43	$1,005.43	1	0.00%
SUBTOTAL	**1,065**	**173**	**$1,296,925.88**	**$1,217.77**	**6.16**	**3.42%**
RUFINAMIDE PRODUCTS						
RUFINAMIDE TAB 400MG	214	20	$58,417.49	$272.98	10.7	0.15%
BANZEL SUS 40MG/ML	143	17	$451,046.44	$3,154.17	8.41	1.19%
RUFINAMIDE SUS 40MG/ML	127	18	$41,206.61	$324.46	7.06	0.11%
BANZEL TAB 400MG	106	12	$446,275.52	$4,210.15	8.83	1.18%
RUFINAMIDE TAB 200MG	39	6	$7,623.80	$195.48	6.5	0.02%
BANZEL TAB 200MG	36	6	$57,320.59	$1,592.24	6	0.15%
SUBTOTAL	**665**	**79**	**$1,061,890.45**	**$1,596.83**	**8.42**	**2.80%**
FELBAMATE PRODUCTS						
FELBAMATE TAB 600MG	196	19	$25,643.71	$130.84	10.32	0.07%
FELBAMATE SUS 600MG/5ML	87	8	$16,447.36	$189.05	10.88	0.04%
FELBAMATE TAB 400MG	51	9	$5,103.88	$100.08	5.67	0.01%
FELBATOL TAB 400MG	4	2	$6,864.05	$1,716.01	2	0.02%
FELBATOL TAB 600MG	3	2	$2,291.29	$763.76	1.5	0.01%
SUBTOTAL	**341**	**40**	**$56,350.29**	**$165.25**	**8.53**	**0.15%**
ESLICARBAZEPINE PRODUCTS						
APTIOM TAB 800MG	100	15	$164,315.60	$1,643.16	6.67	0.43%
APTIOM TAB 600MG	69	9	$161,437.83	$2,339.68	7.67	0.43%
APTIOM TAB 400MG	20	6	$16,048.57	$802.43	3.33	0.04%
APTIOM TAB 200MG	11	1	$13,865.93	$1,260.54	11	0.04%
ESLICARBAZEPINE TAB 600MG	7	6	$3,465.09	$495.01	1.17	0.01%
ESLICARBAZEPINE TAB 400MG	2	2	$199.66	$99.83	1	0.00%
ESLICARBAZEPINE TAB 800MG	2	2	$696.72	$348.36	1	0.00%
ESLICARBAZEPINE TAB 200MG	1	1	$662.01	$662.01	1	0.00%
SUBTOTAL	**212**	**42**	**$360,691.41**	**$1,701.37**	**5.05**	**0.95%**
VIGABATRIN PRODCUTS						
SABRIL POW 500MG	115	17	$3,106,930.78	$27,016.79	6.76	8.18%
VIGABATRIN POW 500MG	55	18	$99,126.22	$1,802.29	3.06	0.26%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SABRIL TAB 500MG	17	2	$502,709.54	$29,571.15	8.5	1.32%
VIGAFYDE SOL 100MG/ML	12	2	$80,297.11	$6,691.43	6	0.21%
VIGABATRIN TAB 500MG	4	2	$0.00	$0.00	2	0.00%
VIGADRONE POW 500MG	2	1	$25,918.58	$12,959.29	2	0.07%
SUBTOTAL	**205**	**42**	**$3,814,982.23**	**$18,609.67**	**4.88**	**10.05%**
FENFLURAMINE PRODUCTS						
FINTEPLA SOL 2.2MG/ML	200	28	$2,373,518.64	$11,867.59	7.14	6.25%
SUBTOTAL	**200**	**28**	**$2,373,518.64**	**$11,867.59**	**7.14**	**6.25%**
TIAGABINE PRODUCTS						
TIAGABINE TAB 4MG	56	6	$9,017.14	$161.02	9.33	0.02%
TIAGABINE TAB 12MG	22	2	$8,969.83	$407.72	11	0.02%
TIAGABINE TAB 2MG	19	2	$1,893.62	$99.66	9.5	0.00%
TIAGABINE TAB 16MG	3	1	$2,299.38	$766.46	3	0.01%
SUBTOTAL	**100**	**11**	**$22,179.97**	**$221.80**	**9.09**	**0.06%**
METHSUXIMIDE PRODUCTS						
CELONTIN CAP 300MG	19	2	$7,794.06	$410.21	9.5	0.02%
METHSUXIMIDE CAP 300MG	15	2	$6,489.45	$432.63	7.5	0.02%
SUBTOTAL	**34**	**4**	**$14,283.51**	**$420.10**	**8.5**	**0.04%**
GANAXOLONE PRODUCTS						
ZTALMY SUS 50MG/ML	20	3	$350,328.70	$17,516.44	6.67	0.92%
SUBTOTAL	**20**	**3**	**$350,328.70**	**$17,516.44**	**6.67**	**0.92%**
LORAZEPAM PRODUCTS						
LORAZEPAM INJ 2MG/ML	2	2	$31.34	$15.67	1	0.00%
SUBTOTAL	**2**	**2**	**$31.34**	**$15.67**	**1**	**0.00%**
TOTAL	**452,120**	**79,137***	**$37,963,908.66**	**$83.97**	**5.71**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CHW = chewable; DR = delayed-release; ELX = elixir; ER = extended-release; EX = extended; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; PF = preservative-free; POW = powder; SOL = solution; SPR = sprinkle; SUS = suspension; TAB = tablet; TITR = titration; XR = extended-release
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix W

Fiscal Year 2025 Annual Review of Insomnia Medications

Oklahoma Health Care Authority
February 2026

Current Prior Authorization Criteria

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem ER (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq®)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)
flurazepam (Dalmane®)			quazepam (Doral®)
ramelteon (Rozerem®)			tasimelteon (Hetlioz®, Hetlioz LQ®)⁺
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			zolpidem 7.5mg capsule
zaleplon (Sonata®)			zolpidem SL tablets (Edluar®)
zolpidem (Ambien®)			zolpidem SL tablets (Intermezzo®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.
⁺Individual criteria specific to tasimelteon applies.
ER = extended-release; PA = prior authorization; SL = sublingual

- Tier-1 medications are available without a prior authorization for members 19 years of age and older.
- Members 18 years of age or younger will be required to submit a prior authorization for consideration of all insomnia medications.
- All medications have a quantity limit of 30 units per 30 days.

Insomnia Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and

4. Approvals will be granted for the duration of 6 months.

Insomnia Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. Member must have a minimum of a 30-day trial with at least 2 Tier-2 medications; and
    a. If only 1 Tier-2 medication is available, a minimum of a 30-day trial with 1 Tier-2 medication will be required; and
4. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
5. Approvals will be granted for the duration of 6 months.

Hetlioz® (Tasimelteon Capsule) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; or
    b. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older for a diagnosis of Non-24 or 16 years of age or older for a diagnosis of SMS; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
5. A quantity limit of 30 capsules for 30 days will apply.

Hetlioz LQ® (Tasimelteon Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 3 to 15 years of age; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Hetlioz LQ® package labeling; and
5. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.

Utilization of Insomnia Medications: Fiscal Year 2025

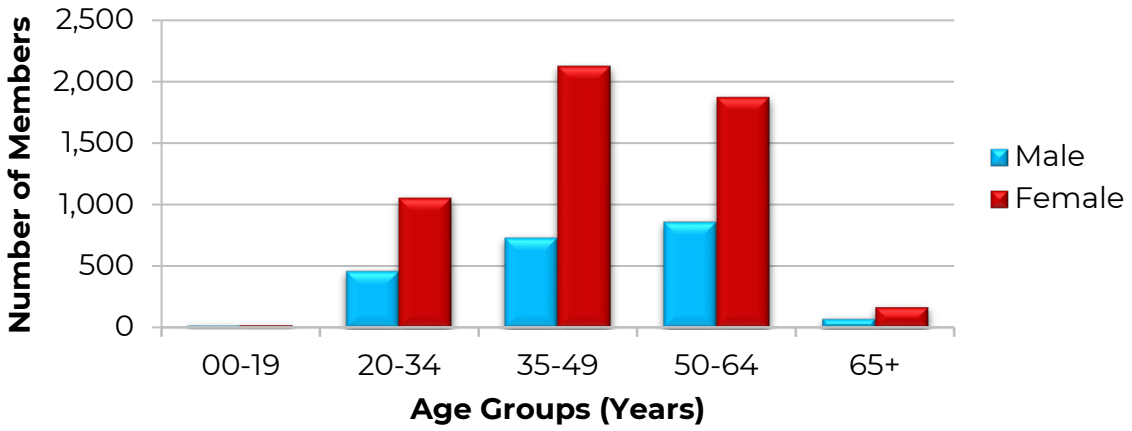
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	7,503	30,113	$2,106,599.07	$69.96	$2.48	850,443	848,225
Aetna	792	1,449	$89,983.05	$62.10	$2.22	40,774	40,602
Humana	982	1,975	$67,645.97	$34.25	$1.23	56,099	54,793
OCH	798	1,395	$42,098.15	$30.18	$1.09	38,925	38,791
2024 Total	**8,269**	**34,932**	**$2,306,326.24**	**$66.02**	**$2.35**	**986,241**	**982,411**
Fiscal Year 2025							
FFS	3,499	14,246	$1,620,230.88	$113.73	$4.03	404,103	402,291
Aetna	1,462	5,624	$412,564.08	$73.36	$2.58	160,916	160,037
Humana	1,805	7,968	$358,004.49	$44.93	$1.58	230,604	226,509
OCH	1,562	6,192	$174,857.42	$28.24	$1.00	175,451	174,796
2025 Total	**7,400**	**34,030**	**$2,565,656.87**	**$75.39**	**$2.66**	**971,074**	**963,633**
% Change	**-10.50%**	**-2.60%**	**11.20%**	**14.20%**	**13.20%**	**-1.50%**	**-1.90%**
Change	**-869**	**-902**	**$259,330.63**	**$9.37**	**$0.31**	**-15,167**	**-18,778**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

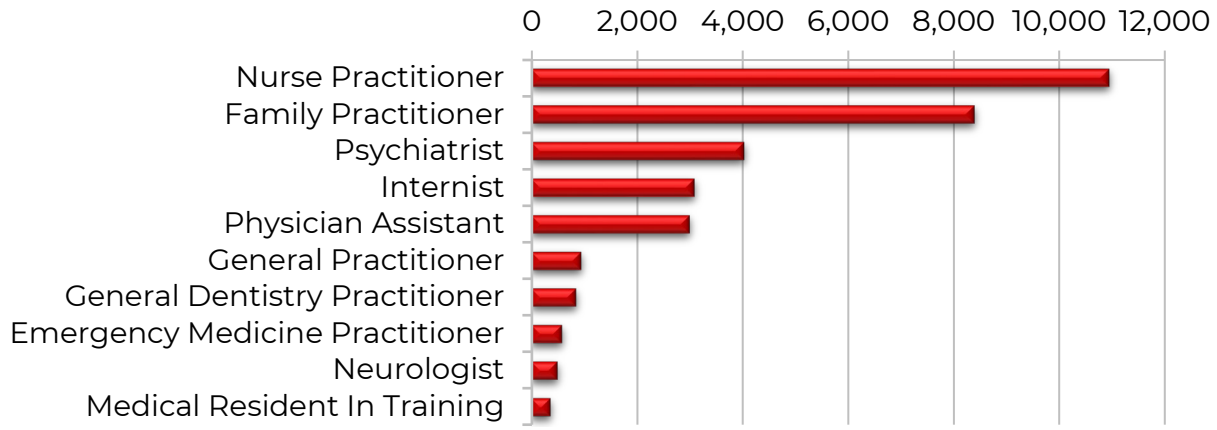
- Aggregate drug rebates collected during fiscal year 2025 for insomnia medications totaled $1,533,904.56.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Insomnia Medications: Pharmacy Claims (All Plans)



[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

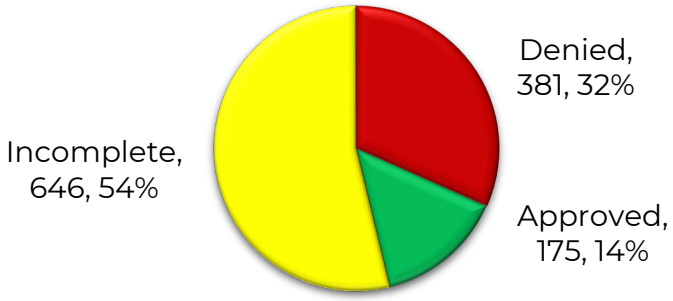
Top Prescriber Specialties of Insomnia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Insomnia Medications

There were 1,202 prior authorization requests submitted for insomnia medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	63	9%	538	75%	119	17%	**720**
Aetna	16	9%	79	44%	83	47%	**178**
Humana	9	11%	0	0%	75	89%	**84**
OCH	87	40%	29	13%	104	47%	**220**
Total	**175**	**14%**	**646**	**54%**	**381**	**32%**	**1,202**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Doral® (quazepam tablets): June 2028
- Silenor® (doxepin tablets): September 2030
- Edluar® (zolpidem sublingual tablets): February 2031
- Belsomra® (suvorexant tablets): May 2033
- Quviviq® (daridorexant tablets): December 2034
- Dayvigo® (lemborexant tablets): October 2035
- Hetlioz® (tasimelteon capsules): February 2041
- Hetlioz LQ® (tasimelteon oral suspension): February 2041

Recommendations

The College of Pharmacy recommends the following additions and changes to the Insomnia Medications Product Based Prior Authorization (PBPA) Tier chart (changes shown in red in the following Tier chart and additional criteria:

1. Moving Dalmane® (flurazepam) from Tier-1 to the Special PA Tier based on net costs; and
2. Moving Belsomra® (suvorexant) from Tier-3 to Tier-1 based on net costs; and
3. Moving ProSom® (estazolam) from Tier-1 to Tier-2 based on net costs; and
4. Creating specific criteria for the Special PA Tier for clarity.

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
~~**estazolam (ProSom®)**~~	**estazolam (ProSom®)**	lemborexant (Dayvigo®)	daridorexant (Quviviq®)
eszopiclone (Lunesta®)	zolpidem ER (Ambien® CR)	~~**suvorexant (Belsomra®)**~~	doxepin (Silenor®)
~~**flurazepam (Dalmane®)**~~			**flurazepam (Dalmane®)**
ramelteon (Rozerem®)			quazepam (Doral®)
suvorexant (Belsomra®)			tasimelteon (Hetlioz®, Hetlioz LQ®)[+]
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			zolpidem 7.5mg capsule
zaleplon (Sonata®)			zolpidem SL tablets (Edluar®)
zolpidem (Ambien®)			zolpidem SL tablets (Intermezzo®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
~~*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.~~
[+]Individual criteria specific to tasimelteon applies.
ER = extended-release; PA = prior authorization; SL = sublingual

Insomnia Medications Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why all lower-tiered medications are not appropriate for the member must be provided; and
3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
4. Approvals will be granted for the duration of 6 months.

Utilization Details of Insomnia Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
ZOLPIDEM PRODUCTS						
ZOLPIDEM TAB 10MG	13,975	2,527	$161,074.38	$11.53	5.53	6.28%
ZOLPIDEM TAB 5MG	3,419	1,172	$38,747.25	$11.33	2.92	1.51%
AMBIEN TAB 10MG	3	1	$1,886.43	$628.81	3	0.07%
AMBIEN TAB 5MG	1	1	$630.02	$630.02	1	0.02%
SUBTOTAL	**17,398**	**3,701**	**$202,338.08**	**$11.63**	**4.7**	**7.89%**
ESZOPICLONE PRODUCTS						
ESZOPICLONE TAB 3MG	3,462	751	$47,256.57	$13.65	4.61	1.84%
ESZOPICLONE TAB 2MG	1,874	639	$25,735.43	$13.73	2.93	1.00%
ESZOPICLONE TAB 1MG	926	480	$13,425.21	$14.50	1.93	0.52%
SUBTOTAL	**6,262**	**1,870**	**$86,417.21**	**$13.80**	**3.35**	**3.37%**
TEMAZEPAM PRODUCTS						
TEMAZEPAM CAP 30MG	2,186	439	$28,367.40	$12.98	4.98	1.11%
TEMAZEPAM CAP 15MG	1,435	480	$15,845.68	$11.04	2.99	0.62%
SUBTOTAL	**3,621**	**919**	**$44,213.08**	**$12.21**	**3.94**	**1.72%**
RAMELTEON PRODUCTS						
ROZEREM TAB 8MG	2,568	520	$923,809.21	$359.74	4.94	36.01%
RAMELTEON TAB 8MG	79	52	$2,669.48	$33.79	1.52	0.10%
SUBTOTAL	**2,647**	**572**	**$926,478.69**	**$350.01**	**4.63**	**36.11%**
TRIAZOLAM PRODUCTS						
TRIAZOLAM TAB 0.25MG	1,084	831	$13,992.67	$12.91	1.3	0.55%
TRIAZOLAM TAB 0.125MG	69	63	$899.15	$13.03	1.1	0.04%
SUBTOTAL	**1,153**	**894**	**$14,891.82**	**$12.92**	**1.29**	**0.58%**
ZALEPLON PRODUCTS						
ZALEPLON CAP 10MG	536	218	$8,278.95	$15.45	2.46	0.32%
ZALEPLON CAP 5MG	226	146	$2,867.83	$12.69	1.55	0.11%
SUBTOTAL	**762**	**364**	**$11,146.78**	**$14.63**	**2.09**	**0.43%**
ESTAZOLAM PRODUCTS						
ESTAZOLAM TAB 2MG	23	4	$730.37	$31.76	5.75	0.03%
ESTAZOLAM TAB 1MG	6	1	$172.12	$28.69	6	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**29**	**5**	**$902.49**	**$31.12**	**5.8**	**0.04%**
TIER-1 SUBTOTAL	**31,872**	**8,325**	**$1,286,388.15**	**$40.36**	**3.83**	**50.14%**
TIER-2 UTILIZATION						
ZOLPIDEM PRODUCTS						
ZOLPIDEM ER TAB 12.5MG	1,354	263	$19,223.21	$14.20	5.15	0.75%
ZOLPIDEM ER TAB 6.25MG	159	56	$2,375.83	$14.94	2.84	0.09%
AMBIEN CR TAB 12.5MG	11	1	$6,886.84	$626.08	11	0.27%
TIER-2 SUBTOTAL	**1,524**	**320**	**$28,485.88**	**$18.69**	**4.76**	**1.11%**
TIER-3 UTILIZATION						
SUVOREXANT PRODUCTS						
BELSOMRA TAB 20MG	180	45	$80,399.76	$446.67	4	3.13%
BELSOMRA TAB 10MG	85	40	$37,012.30	$435.44	2.13	1.44%
BELSOMRA TAB 15MG	72	21	$32,011.38	$444.60	3.43	1.25%
BELSOMRA TAB 5MG	7	6	$3,119.58	$445.65	1.17	0.12%
SUBTOTAL	**344**	**112**	**$152,543.02**	**$443.44**	**3.07**	**5.95%**
LEMBOREXANT PRODUCTS						
DAYVIGO TAB 10MG	92	25	$30,027.21	$326.38	3.68	1.17%
DAYVIGO TAB 5MG	36	12	$12,226.28	$339.62	3	0.48%
SUBTOTAL	**128**	**37**	**$42,253.49**	**$330.11**	**3.46**	**1.65%**
TIER-3 SUBTOTAL	**472**	**149**	**$194,796.51**	**$412.70**	**3.17**	**7.59%**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
TASIMELTEON PRODUCTS						
TASIMELTEON CAP 20MG	18	2	$342,691.38	$19,038.41	9	13.36%
HETLIOZ LQ SUS 4MG/ML	16	2	$401,443.20	$25,090.20	8	15.65%
HETLIOZ CAP 20MG	12	1	$285,802.68	$23,816.89	12	11.14%
SUBTOTAL	**46**	**5**	**$1,029,937.26**	**$22,389.94**	**9.2**	**40.14%**
DOXEPIN PRODUCTS						
DOXEPIN TAB 3MG	27	19	$2,580.11	$95.56	1.42	0.10%
DOXEPIN TAB 6MG	17	17	$1,924.79	$113.22	1	0.08%
SUBTOTAL	**44**	**36**	**$4,504.90**	**$102.38**	**1.22**	**0.18%**
DARIDOREXANT PRODUCTS						
QUVIVIQ TAB 50MG	27	8	$13,227.85	$489.92	3.38	0.52%
QUVIVIQ TAB 25MG	15	5	$6,634.82	$442.32	3	0.26%
SUBTOTAL	**42**	**13**	**$19,862.67**	**$472.92**	**3.23**	**0.77%**
TEMAZEPAM PRODUCTS						
TEMAZEPAM CAP 7.5MG	24	19	$928.04	$38.67	1.26	0.04%
TEMAZEPAM CAP 22.5MG	4	2	$230.64	$57.66	2	0.01%
SUBTOTAL	**28**	**21**	**$1,158.68**	**$41.38**	**1.33**	**0.05%**
ZOLPIDEM PRODUCTS						
ZOLPIDEM TAR CAP 7.5MG	2	1	$522.82	$261.41	2	0.02%
SUBTOTAL	**2**	**1**	**$522.82**	**$261.41**	**2**	**0.02%**
SPECIAL PA SUBTOTAL	**162**	**76**	**$1,055,986.33**	**$6,518.43**	**2.13**	**41.16%**
TOTAL	**34,030**	**7,400***	**$2,565,656.87**	**$75.39**	**4.6**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; SUS = suspension; TAB = tablet; TAR = tartrate
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 01/2026. Last accessed 01/20/2026.

Appendix X

30-Day Notice to Prior Authorize Cardamyst™ (Etripamil Nasal Spray)

Oklahoma Health Care Authority
February 2026

Introduction[1,2,3]

Paroxysmal supraventricular tachycardia (PSVT) is characterized by the abrupt onset and termination of regular and rapid tachycardia. It can affect patients with or without underlying cardiac structural abnormalities or heart diseases. When symptomatic, PSVT can cause palpitations, chest discomfort, shortness of breath, lightheadedness, or dizziness. Symptoms can range from mild to severe, which can lead to emergency department visits and hospital admissions. Episodes of PSVT may terminate spontaneously or require medical intervention to resolve. In the United States, the prevalence of PSVT is estimated to be 0.2% with an incidence of 1 to 3 cases per 1,000 patients, making it the second most common tachyarrhythmia following atrial fibrillation.

The 2015 American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) Guideline for the Management of Adult Patients with Supraventricular Tachycardia recommend promptly terminating the PSVT episode and resolving symptoms using vagal maneuvers followed by intravenous (IV) medications such as adenosine, non-dihydropyridine calcium channel blockers (CCBs), and beta-blockers (BBs) if the vagal maneuvers are ineffective. Synchronized cardioversion is recommended for patients who are hemodynamically unstable. Ongoing management options include catheter ablation, which is considered curative for most forms of PSVT, or using oral preventative therapies including but not limited to non-dihydropyridine CCBs, BBs, flecainide, propafenone, dofetilide, sotalol, or amiodarone. As needed “pill-in-the-pocket” medications such as diltiazem, verapamil, or BBs can be considered in patients with infrequent, well-tolerated arrhythmia episodes of atrioventricular nodal reentrant tachycardia (ANRT), a subtype of PSVT; however, data for the efficacy of this strategy is limited.

In December 2025, the U.S. Food and Drug Administration (FDA) approved Cardamyst™ (etripamil nasal spray), a rapid-acting non-dihydropyridine CCB nasal spray, for the conversion of acute symptomatic episodes of PSVT to sinus rhythm in adults. The dosing and formulation allow for self-administration to treat episodes of PSVT outside of an emergency department or other health care setting.

Cardamyst™ (Etripamil Nasal Spray) Product Summary[4,5]

Therapeutic Class: Non-dihydropyridine CCB

Indication(s): Conversion of acute symptomatic episodes of PSVT to sinus rhythm in adults

How Supplied: Nasal spray device containing 2 sprays, which is a total dose of 70mg of etripamil

Dosing and Administration:

- One spray (35mg) should be administered into each nostril for a total dose of 70mg as soon as possible after PSVT onset.
- A second dose of 70mg may be administered if symptoms persist for more than 10 minutes after the first dose.
- The maximum dose is 140mg in a 24-hour period.
- If symptoms do not improve within 20 minutes of a second dose, patients and caregivers should contact a heath care provider or seek emergency medical attention.

Efficacy: The safety and efficacy of Cardamyst™ were evaluated in RAPID, a randomized, double-blind, placebo-controlled, multicenter, event-driven Phase 3 clinical trial.

- Key Inclusion Criteria:
  - History of PSVT with sustained, symptomatic episodes ≥20 minutes as documented by electrocardiogram (ECG)
  - 18 years of age or older
- Intervention(s): Patients were randomized 1:1 to Cardamyst™ or placebo to administer intranasally in a medically unsupervised setting; patients could self-administer a second dose if symptoms did not resolve after the first dose.
- Primary Endpoint(s): Time-to-conversion of confirmed PSVT to sinus rhythm for at least 30 seconds within 30 minutes of the first dose
- Results:
  - 255/692 randomized patients perceived an episode of PSVT and self-administered the intervention
  - 72% (184/255) were confirmed by blinded adjudication to be PSVT
  - 64% of participants who received Cardamyst™ met the primary endpoint compared to 31% for placebo, with a hazard ratio of 2.6 [95% confidence interval (CI): 1.7, 4.2; P<0.001].
  - Median time-to-conversion was 17.2 minutes (95% CI: 12.4, 26.5) for Cardamyst™ compared to 53.5 minutes (95% CI: 38.7, 87.3) with placebo.

Cost: The Wholesale Acquisition Cost (WAC) of Cardamyst™ is $824.50 per 70mg nasal spray device, with each package containing 2 devices, resulting in an estimated cost of $1,649 per treatment course based on the maximum FDA-approved dosing regimen of up to 140mg in a 24-hour period.

Recommendations

The College of Pharmacy recommends the prior authorization of Cardamyst™ (etripamil nasal spray) with the following criteria (shown in red):

Cardamyst™ (Etripamil Nasal Spray) Approval Criteria:

1. An FDA approved indication of the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm; and
2. Member must 18 years of age or older; and
3. Member must not have any of the contraindications for use of Cardamyst™, including:
    a. Hypersensitivity to Cardamyst™ or any of its components; and
    b. New York Heart Association (NYHA) Class II to IV heart failure; and
    c. Wolff-Parkinson-White (WPW), Lown-Ganong-Levine (LGL) syndromes, or manifest pre-excitation (delta wave) on a 12-lead electrocardiogram (ECG); and
    d. Sick sinus syndrome without a permanent pacemaker; and
    e. Second degree atrioventricular (AV) Mobitz 2 block or higher degree of AV block; and
4. Prescriber must verify the member or caregiver will be counseled on all of the following:
    a. PVST symptoms; and
    b. Timing of Cardamyst™ administration in relation to the onset of the PVST episode; and
    c. The proper storage and administration of Cardamyst™; and
    d. When to contact a health care provider or seek emergency medical attention; and
5. Prescriber must verify members with a history of hypotensive episodes or those at increased risk for hemodynamic instability will be monitored appropriately when initiating Cardamyst™; and
6. Must be prescribed by, or in consultation with, a cardiologist or a specialist with expertise in the treatment of PSVT; and
7. Approvals will be for up to 6 cartons (i.e., 12 nasal spray devices) per year; and
    a. A quantity limit of 1 carton (i.e., 2 nasal spray devices) per 30 days will apply; or

b. For requests exceeding the quantity limit, clinical documentation (i.e., recent office notes) supporting the need for additional supply must be provided for consideration of a quantity limit override; and

8. Subsequent approvals may be granted if the prescriber documents the member has responded well to treatment and continues to require treatment with Cardamyst™.

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[1] Hafeez Y, Quintanilla Rodriguez BS, Ahmed I, Grossman SA. Paroxysmal Supraventricular Tachycardia. *StatPearls*. Available online at: https://www.ncbi.nlm.nih.gov/books/NBK507699/. Last revised 02/28/2024. Last accessed 01/27/2026.

[2] American College of Cardiology/American Heart Association/Heart Rhythm Society. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia. *Circulation* 2016; 133(14): e506-e574. doi: 10.1161/CIR. 0000000000000311.

[3] Milestone Pharmaceuticals. Milestone Receives FDA Approval of Cardamyst™ (Etripamil) as First and Only Self-Administered Nasal Spray for Adults with Paroxysmal Supraventricular Tachycardia (PSVT). Available online at: https://investors.milestonepharma.com/news-releases/news-release-details/milestone-receives-fda-approval-cardamysttm-etripamil-first-and. Issued 12/15/2025. Last accessed 01/27/2026.

[4] Cardamyst™ (Etripamil) Prescribing Information. Milestone Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218571s000lbl.pdf. Last revised 12/2025. Last accessed 01/27/2026.

[5] Stambler BS, Camm AJ, Alings M, et al. Self-administered Intranasal Etripamil Using a Symptom-prompted, Repeat-dose Regimen for Atrioventricular-nodal-dependent Supraventricular Tachycardia (RAPID): A Multicentre Randomized Trial. *Lancet* 2023; 402: 118-128. doi: 10.1016/S0140-6736(23)00776-6.

Appendix Y

Fiscal Year 2025 Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector]

Oklahoma Health Care Authority
February 2026

Current Prior Authorization Criteria

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	DHE injection (D.H.E. 45®)
naratriptan tablet (Amerge®)	sumatriptan/ naproxen tablet (Treximet®)	DHE nasal spray (Migranal®)	ergotamine sublingual tablet (Ergomar®)
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)		sumatriptan autoinjector pen and vial (Imitrex®)	lasmiditan tablet (Reyvow®)
sumatriptan tablet (Imitrex®)		sumatriptan nasal spray (Imitrex®)	meloxicam/rizatriptan (Symbravo®)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			rimegepant ODT (Nurtec® ODT)
			sumatriptan injection (Imitrex® STATdose System)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DHE = dihydroergotamine; ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Tier-2 Approval Criteria:

1. A trial of 2 Tier-1 products with inadequate response or a patient-specific, clinically significant reason why a Tier-1 product is not appropriate for the member must be provided; or
2. Documented adverse effect(s) to all available Tier-1 products; or
3. Previous success with a Tier-2 product within the last 60 days.

Anti-Migraine Medications Tier-3 Approval Criteria:

1. A trial of 3 Tier-1 and Tier-2 products with inadequate response or a patient-specific, clinically significant reason why a lower tiered product is not appropriate for the member must be provided; or
2. Documented adverse effect(s) to all available Tier-1 and Tier-2 products; or
3. Previous success with a Tier-3 product within the last 60 days.

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
    b. A quantity limit of 20 tablets per 28 days will apply.
2. Use of D.H.E. 45® [dihydroergotamine (DHE) injection] will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray), and lower-tiered triptan medications.
3. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]+:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
    c. A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.

†Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.

4. Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
5. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).
6. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications, Nurtec® ODT (rimegepant), and Reyvow® (lasmiditan); and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
7. Use of Imitrex® STATdose System (sumatriptan injection), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

Aimovig® (Erenumab-aooe), Ajovy® (Fremanezumab-vfrm), and Emgality® (Galcanezumab-gnlm) Approval Criteria [Migraine Diagnosis]:

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and
4. Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
    a. Red flags; and
    b. Possible indicators of secondary headache; and

    c. Medication overuse; and
5. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
6. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
7. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
8. Quantity limits will apply based on FDA-approved dosing:
    a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
    b. For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for a quantity limit override upon meeting Ajovy® approval criteria; and
    c. For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as 2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.

Emgality® (Galcanezumab-gnlm) Approval Criteria [Episodic Cluster Headache Diagnosis]:

1. An FDA approved indication for the treatment of episodic cluster headache in adults; and
2. Member must be 18 years of age or older; and
3. Member has a diagnosis of episodic cluster headache as defined by the International Headache Society (IHS) International Classification of Headache Disorders (ICHD) guideline and meets the following criteria:
    a. Member has a history of episodic cluster headache with at least 2 cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥3 months; and
4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. Member will not use Emgality® concurrently with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
6. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
7. Initial approvals will be for the duration of 3 months. Continuation approvals will be granted until the end of the cluster period if the

prescriber documents that the member is responding well to treatment as indicated by a reduction in cluster headache attack frequency; and
8. A quantity limit of (3) 100mg/mL syringes per 30 days will apply.

Nurtec® ODT (Rimegepant)*, Qulipta® (Atogepant)*, and Vyepti® (Eptinezumab-jjmr) Approval Criteria:

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT is only FDA approved for the preventive treatment of episodic migraines.); and
4. Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
    a. Red flags; and
    b. Possible indicators of secondary headache; and
    c. Medication overuse; and
5. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
6. For Vyepti®, prescriber must verify the medication will be prepared and administered according to the Vyepti® package labeling; and
7. For Vyepti®, a patient-specific, clinically significant reason (beyond convenience) why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), and Emgality® (galcanezumab-gnlm) must be provided; and
8. For Nurtec® ODT and Qulipta®, a patient-specific, clinically significant reason (beyond convenience) why member cannot use 2* of the preferred CGRP inhibitors [i.e., Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), Emgality® (galcanezumab-gnlm)] must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement; *the manufacturer of Nurtec® ODT and Qulipta® has currently provided a supplemental rebate to only require 2 preferred injectable CGRP inhibitors; however, Nurtec® ODT and Qulipta® will follow the original criteria and require a reason why the member cannot use all preferred CGRP inhibitors if the manufacturer chooses not to participate in supplemental rebates); and

9. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
10. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
11. Quantity limits will apply based on FDA-approved dosing:
    a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
    b. For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and
    c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Utilization of Anti-Migraine Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	10,423	23,419	$3,687,059.39	$157.44	$7.43	238,052	496,507
Aetna	1,119	1,701	$419,673.19	$246.72	$15.96	16,584	26,301
Humana	1,506	2,631	$1,062,060.79	$403.67	$19.77	28,383	53,733
OCH	1,129	1,683	$465,997.18	$276.88	$14.03	18,499	33,220
2024 Total	**12,040**	**29,434**	**$5,634,790.55**	**$191.44**	**$9.24**	**301,517**	**609,761**
Fiscal Year 2025							
FFS	4,027	9,054	$1,820,433.01	$201.06	$9.26	89,656	196,625
Aetna	2,731	7,077	$1,704,679.52	$240.88	$13.67	74,154	124,744
Humana	3,465	11,050	$4,290,514.50	$388.28	$19.63	112,772	218,579
OCH	3,036	7,706	$1,983,562.50	$257.40	$13.38	85,562	148,208
2025 Total	**12,370**	**34,887**	**$9,799,189.53**	**$280.88**	**$14.24**	**362,143**	**688,156**
% Change	**2.70%**	**18.50%**	**73.90%**	**46.70%**	**54.10%**	**20.10%**	**12.90%**
Change	**330**	**5,453**	**$4,164,398.98**	**$89.44**	**$5.00**	**60,626**	**78,395**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

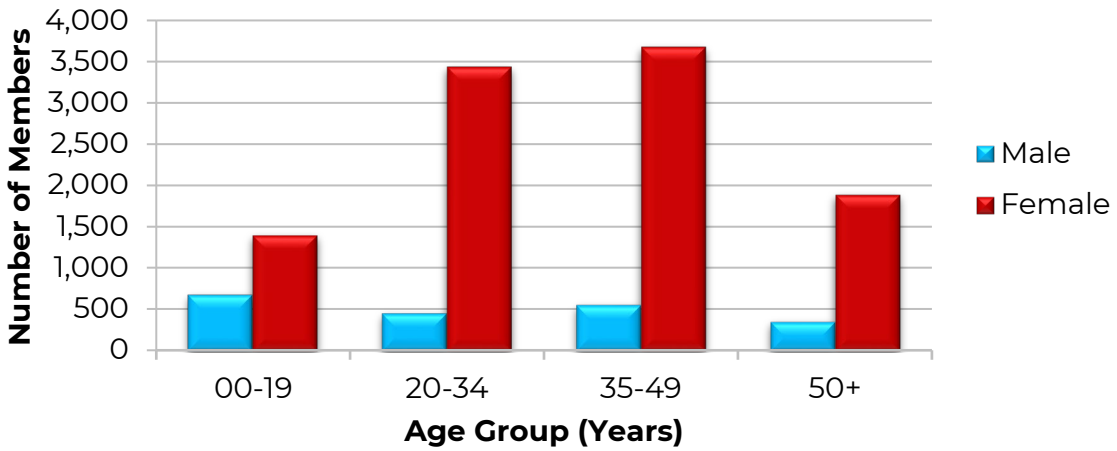
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	19	32	$104,696.30	$3,271.76	1.68
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	1	1	$1,805.00	$1,805.00	1
2024 Total	**20**	**33**	**$106,501.30**	**$3,227.31**	**1.65**
Fiscal Year 2025					
FFS	10	21	$97,056.00	$4,621.71	2.1
Aetna	5	9	$26,604.00	$2,956.00	1.8
Humana	13	23	$66,849.01	$2,906.48	1.77
OCH	6	11	$45,398.00	$4,127.09	1.83
2025 Total	**33**	**64**	**$235,907.01**	**$3,686.05**	**1.94**
% Change	**65.00%**	**93.94%**	**121.51%**	**14.21%**	**17.58%**
Change	**13**	**31**	**$129,405.71**	**$458.74**	**0.29**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

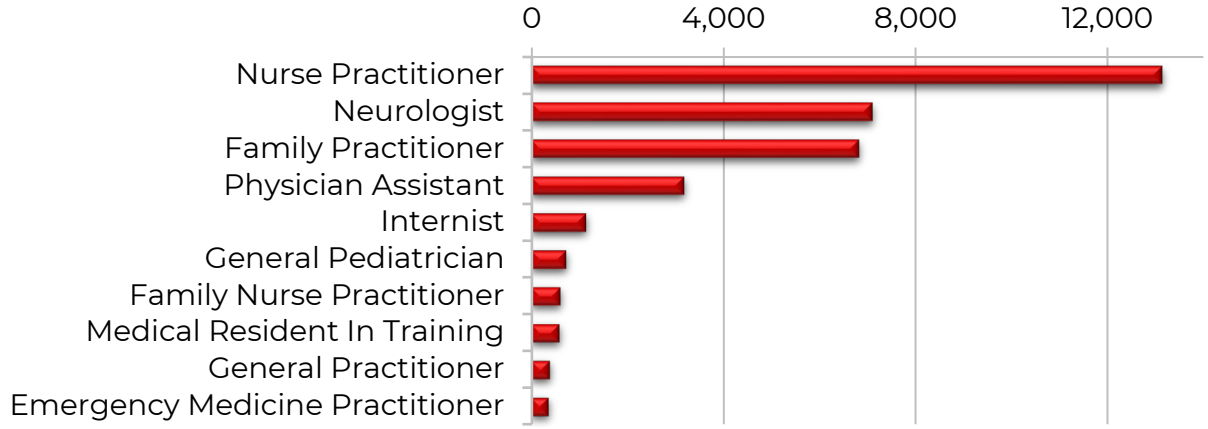
- Aggregate drug rebates collected during fiscal year 2025 for the anti-migraine medications totaled $7,124,345.23.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Anti-Migraine Medications: Pharmacy Claims (All Plans)



[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

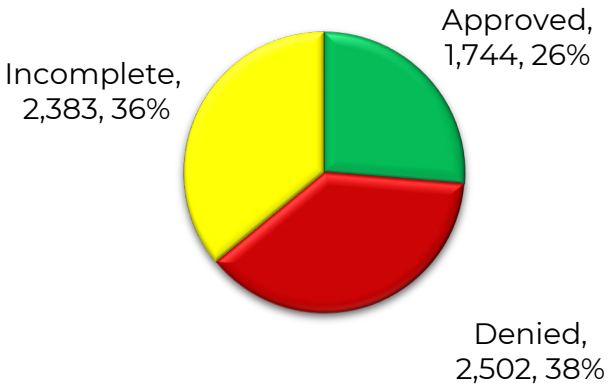
Top Prescriber Specialties of Anti-Migraine Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anti-Migraine Medications

There were 6,629 prior authorization requests submitted for anti-migraine medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	759	21%	1,726	49%	1,064	30%	**3,549**
Aetna	258	21%	501	42%	445	37%	**1,204**
Humana	380	53%	0	0%	342	47%	**722**
OCH	347	30%	156	14%	651	56%	**1,154**
Total	**1,744**	**26%**	**2,383**	**36%**	**2,502**	**38%**	**6,629**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9]

Anticipated Patent Expiration(s):

- Zavzpret™ (zavegepant nasal spray): October 2031
- Zembrace® SymTouch® [sumatriptan subcutaneous (sub-Q) injection]: January 2036
- Brekiya® [dihydroergotamine (DHE) mesylate autoinjector]: February 2039
- Nurtec® ODT [rimegepant orally disintegrating tablet (ODT)]: March 2039
- Reyvow® (lasmiditan tablet): July 2040
- Ubrelvy® (ubrogepant tablet): December 2041
- Qulipta® (atogepant tablet): February 2043

New U.S. Food and Drug Administration (FDA) Approval(s):

- **March 2025:** The FDA approved label updates to the *Warnings and Precautions* section for all calcitonin gene-related peptide (CGRP) antagonists regarding the risk of Raynaud's phenomenon and hypertension (HTN) following the administration of these products.
- **May 2025:** The FDA approved Brekiya® (DHE autoinjector) for the acute treatment of migraine with or without aura and of acute cluster headaches (HA) in adults. This is the first autoinjector of DHE approved by the FDA. DHE was previously FDA approved as a nasal spray (i.e., Migranal®) and as an injectable solution in ampules (i.e., D.H.E. 45®).
- **August 2025:** The FDA approved an age expansion for Ajovy® (fremanezumab-vfrm) for the preventative treatment of episodic migraine to include pediatric patients 6 to 17 years of age who weigh ≥45kg. The approval was based on the results of the Phase 3 SPACE trial, which showed Ajovy® significantly reduced monthly migraine days (-2.5 vs. -1.4; P=0.0210) and monthly HA days (-2.6 vs. -1.5; P=0.0172) in pediatric patients over 12 weeks compared to placebo, with a safety profile consistent with that observed in the adult population.

News:

- **November 2025:** Eli Lilly announced they are discontinuing Reyvow® (lasmiditan tablets) based on a business decision.

Guidelines:

- **<u>International Headache Society (IHS):</u>**
  - In February 2025, the IHS issued a position statement, published in *Cephalalgia,* recommending updating the measure of success with migraine therapy from a percent reduction in monthly migraines to a more ambitious goal of migraine freedom or a very low number of migraine days per month. The statement emphasized this is not to be used to change the standards of

practice in clinical trials but aims to change real-world clinical practice considering new therapies have improved migraine prevention and migraine freedom is now possible. The IHS proposed a new framework that categorizes outcomes into 4 tiers:

- Migraine freedom: No days with migraine or moderate-to-severe HA
- Optimal control: <4 days per month with migraine or moderate-to-severe HA
- Modest control: 4-6 days per month with migraine or moderate-to-severe HA
- Insufficient control: >6 days per month with migraine or moderate-to-severe HA

Cost Comparison: DHE Products[10,11]

Product	Cost Per mL	Cost Per Month	Cost Per Year
Brekiya® (DHE 1mg/mL autoinjector)	**$875.00**	**$21,000.00**[α]	**$273,000.00**
DHE 1mg/mL injection (generic D.H.E. 45®)	$57.08	$1,369.92[α]	$17,808.96
DHE 4mg/mL nasal spray (generic Migranal®)	$30.12	$240.96[+]	$3,132.48

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), Specialty Pharmaceutical Allowable Costs (SPAC), or State Maximum Allowable Costs (SMAC).
DHE = dihydroergotamine
[α]Cost per month is based on the maximum FDA approved dose of 3mg in a 24-hour period with no more than 6mg (6 doses) in a total week.
[+]Cost per month is based on the maximum FDA approved dose of 4mg in a 7-day period. Please note each vial is 4mg/mL but only delivers 2mg of DHE after being primed; therefore, to achieve the maximum dose per month 8 vials will be needed.

Recommendations

The College of Pharmacy recommends the following changes to the current Anti-Migraine Medications Product Based Prior Authorization (PBPA) category based on the new FDA approval, product discontinuation, and net costs (changes shown in red):

1. Prior authorization of Brekiya® (DHE autoinjector) and placement into the Special PA Tier with the following additional criteria; and
2. Updating the approval criteria for Reyvow® (lasmiditan), Ubrelvy® (ubrogepant), and Zavzpret™ (zavegepant nasal spray).

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	**DHE autoinjector (Brekiya®)**
naratriptan tablet (Amerge®)	sumatriptan/ naproxen tablet (Treximet®)	DHE nasal spray (Migranal®)	DHE injection (D.H.E. 45®)

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)		sumatriptan autoinjector pen and vial (Imitrex®)	ergotamine sublingual tablet (Ergomar®)
sumatriptan tablet (Imitrex®)		sumatriptan nasal spray (Imitrex®)	lasmiditan tablet (Reyvow®)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			meloxicam/rizatriptan (Symbravo®)
			rimegepant ODT (Nurtec® ODT)
			sumatriptan injection (Imitrex® STATdose System)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DHE = dihydroergotamine; ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
    b. A quantity limit of 20 tablets per 28 days will apply.
2. Use of Brekiya® [dihydroergotamine (DHE) autoinjector] or D.H.E. 45® ~~[dihydroergotamine~~ (DHE~~)~~ injection)~~]~~ will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray) and lower-tiered triptan medications.

3. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)][+]:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
    c. A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.

    [+]Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.
4. Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
5. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).
6. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications~~,~~ and Nurtec® ODT (rimegepant)~~, and Reyvow® (lasmiditan)~~; and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
7. Use of Imitrex® STATdose System (sumatriptan injection), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

Additionally, the College of Pharmacy recommends updating the approval criteria for Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), and Emgality® (galcanezumab-gnlm) based on the FDA age expansion for Ajovy® (changes shown in red):

Aimovig® (Erenumab-aooe), Ajovy® (Fremanezumab-vfrm), and Emgality® (Galcanezumab-gnlm) Approval Criteria [Migraine Diagnosis]:

1. An FDA approved indication for the preventive treatment of migraine ~~in adults~~; and
2. Member must be 18 years of age or older;~~ and~~ or
    a. For Ajovy®, pediatric members must be 6 to 17 years of age, weigh at least 45kg, and have a diagnosis of episodic migraine, as defined below; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and
4. Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
    a. Red flags; and
    b. Possible indicators of secondary headache; and
    c. Medication overuse; and
5. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
6. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
7. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
8. Quantity limits will apply based on FDA-approved dosing:
    a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
    b. For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for adults only for a quantity limit override upon meeting Ajovy® approval criteria; and
    c. For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as

2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.

Utilization Details of Anti-Migraine Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 MEDICATIONS						
SUMATRIPTAN PRODUCTS						
SUMATRIPTAN TAB 50MG	6,394	3,485	$98,244.75	$15.37	1.83	1.00%
SUMATRIPTAN TAB 100MG	5,724	2,304	$92,784.78	$16.21	2.48	0.95%
SUMATRIPTAN TAB 25MG	3,301	1,889	$48,746.60	$14.77	1.75	0.50%
SUBTOTAL	**15,419**	**7,678**	**$239,776.13**	**$15.55**	**2.01**	**2.45%**
RIZATRIPTAN PRODUCTS						
RIZATRIPTAN TAB 10MG	3,765	1,667	$62,980.73	$16.73	2.26	0.64%
RIZATRIPTAN ODT 10MG	2,537	1,212	$44,393.24	$17.50	2.09	0.45%
RIZATRIPTAN TAB 5MG	813	434	$13,902.63	$17.10	1.87	0.14%
RIZATRIPTAN ODT 5MG	728	363	$12,581.39	$17.28	2.01	0.13%
SUBTOTAL	**7,843**	**3,676**	**$133,857.99**	**$17.07**	**2.13**	**1.37%**
ELETRIPTAN PRODUCTS						
ELETRIPTAN TAB 40MG	818	299	$25,955.73	$31.73	2.74	0.26%
ELETRIPTAN TAB 20MG	238	121	$8,212.30	$34.51	1.97	0.08%
RELPAX TAB 40MG	3	1	$2,825.82	$941.94	3	0.03%
RELPAX TAB 20MG	1	1	$942.29	$942.29	1	0.01%
SUBTOTAL	**1,060**	**422**	**$37,936.14**	**$35.79**	**2.51**	**0.39%**
ZOLMITRIPTAN PRODUCTS						
ZOLMITRIPTAN TAB 5MG	119	67	$2,245.84	$18.87	1.78	0.02%
ZOLMITRIPTAN TAB 2.5MG	42	25	$743.91	$17.71	1.68	0.01%
ZOLMITRIPTAN ODT 5MG	25	17	$718.98	$28.76	1.47	0.01%
ZOLMITRIPTAN ODT 2.5MG	23	13	$624.74	$27.16	1.77	0.01%
SUBTOTAL	**209**	**122**	**$4,333.47**	**$20.73**	**1.71**	**0.04%**
NARATRIPTAN PRODUCTS						
NARATRIPTAN TAB 2.5MG	136	60	$2,924.51	$21.50	2.27	0.03%
NARATRIPTAN TAB 1MG	21	8	$541.99	$25.81	2.63	0.01%
SUBTOTAL	**157**	**68**	**$3,466.50**	**$22.08**	**2.31**	**0.04%**
TIER-1 SUBTOTAL	**24,688**	**11,966**	**$419,370.23**	**$16.99**	**2.06**	**4.28%**
TIER-2 MEDICATIONS						
FROVATRIPTAN PRODUCTS						
FROVATRIPTAN TAB 2.5MG	22	9	$842.65	$38.30	2.44	0.01%
SUBTOTAL	**22**	**9**	**$842.65**	**$38.30**	**2.44**	**0.01%**
SUMATRIPTAN/NAPROXEN COMBINATION PRODUCTS						
SUMAT-NAPROX TAB 85-500MG	20	7	$3,149.21	$157.46	2.86	0.03%
SUBTOTAL	**20**	**7**	**$3,149.21**	**$157.46**	**2.86**	**0.03%**
TIER-2 SUBTOTAL	**42**	**16**	**$3,991.86**	**$95.04**	**2.63**	**0.04%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-3 MEDICATIONS						
SUMATRIPTAN PRODUCTS						
SUMATRIPTAN SPR 20MG/ACT	46	18	$6,945.43	$150.99	2.56	0.07%
SUMAT AUTO-INJ 6MG/0.5ML	38	14	$7,691.94	$202.42	2.71	0.08%
SUMATRIPTAN SPR 5MG/ACT	12	10	$1,950.48	$162.54	1.2	0.02%
SUMATRIPTAN INJ 6MG/0.5ML	6	4	$252.20	$42.03	1.5	0.00%
SUBTOTAL	**102**	**46**	**$16,840.05**	**$165.10**	**2.22**	**0.17%**
DIHYDROERGOTAMINE PRODUCTS						
DIHYDROERGOT SPR 4MG/ML	6	4	$1,281.12	$213.52	1.5	0.01%
SUBTOTAL	**6**	**4**	**$1,281.12**	**$213.52**	**1.5**	**0.01%**
ALMOTRIPTAN PRODUCTS						
ALMOTRIPTAN TAB 12.5MG	2	2	$422.12	$211.06	1	0.00%
ALMOTRIPTAN TAB 6.25MG	1	1	$126.99	$126.99	1	0.00%
SUBTOTAL	**3**	**3**	**$549.11**	**$183.04**	**1**	**0.01%**
TIER-3 SUBTOTAL	**111**	**53**	**$18,670.28**	**$168.20**	**2.09**	**0.19%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
ZOLMITRIPTAN PRODUCTS						
ZOLMITRIPTAN SPR 5MG	40	14	$13,423.44	$335.59	2.86	0.14%
ZOLMITRIPTAN SPR 2.5MG	2	2	$1,059.28	$529.64	1	0.01%
ZOMIG SPR 5MG	1	1	$571.75	$571.75	1	0.01%
SUBTOTAL	**43**	**17**	**$15,054.47**	**$350.10**	**2.53**	**0.15%**
LASMIDITAN PRODUCTS						
REYVOW TAB 100MG	31	12	$22,385.08	$722.10	2.58	0.23%
REYVOW TAB 50MG	6	6	$4,324.83	$720.81	1	0.04%
SUBTOTAL	**37**	**18**	**$26,709.91**	**$721.89**	**2.06**	**0.27%**
SUMATRIPTAN PRODUCTS						
IMITREX AUTO-INJ 4MG/0.5ML	4	2	$2,197.72	$549.43	2	0.02%
IMITREX CARTRIDGE 6MG/0.5ML	3	1	$6,159.99	$2,053.33	3	0.06%
IMITREX AUTO-INJ 6MG/0.5ML	3	1	$1,420.56	$473.52	3	0.01%
ZEMBRACE SYM INJ 3MG/0.5ML	1	1	$1,544.83	$1,544.83	1	0.02%
SUBTOTAL	**11**	**5**	**$11,323.10**	**$1,029.37**	**2.2**	**0.12%**
SPECIAL PA SUBTOTAL	**91**	**40**	**$53,087.48**	**$583.38**	**2.28**	**0.54%**
CALCITONIN GENE-RELATED PEPTIDE (CGRP) PRODUCTS⁺						
GALCANEZUMAB PRODUCTS						
EMGALITY INJ 120MG/ML	2,657	524	$1,972,760.38	$742.48	5.07	20.13%
EMGALITY SYR 120MG/ML	266	57	$187,431.02	$704.63	4.67	1.91%
EMGALITY SYR 100MG/ML	15	9	$26,400.53	$1,760.04	1.67	0.27%
SUBTOTAL	**2,938**	**590**	**$2,186,591.93**	**$744.25**	**4.98**	**22.31%**
RIMEGEPANT PRODUCTS						
NURTEC ODT 75MG	2,675	883	$2,992,610.88	$1,118.73	3.03	30.54%
SUBTOTAL	**2,675**	**883**	**$2,992,610.88**	**$1,118.73**	**3.03**	**30.54%**
FREMANEZUMAB PRODUCTS						
AJOVY INJ 225MG/1.5ML	1,362	338	$1,000,353.08	$734.47	4.03	10.21%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AJOVY SYR 225MG/1.5ML	246	66	$181,786.46	$738.97	3.73	1.86%
SUBTOTAL	**1,608**	**404**	**$1,182,139.54**	**$735.16**	**3.98**	**12.06%**
ATOGEPANT PRODUCTS						
QULIPTA TAB 60MG	844	248	$914,224.44	$1,083.20	2.59	10.96%
QULIPTA TAB 30MG	74	30	$80,209.56	$1,083.91	1.56	1.41%
QULIPTA TAB 10MG	10	5	$10,903.64	$1,090.36	2.41	12.37%
SUBTOTAL	**928**	**283**	**$1,005,337.64**	**$1,083.34**	**2.59**	**10.96%**
UBROGEPANT PRODUCTS						
UBRELVY TAB 100 MG	807	312	$1,074,161.32	$1,331.05	2.59	10.96%
UBRELVY TAB 50 MG	98	63	$138,031.61	$1,408.49	1.56	1.41%
SUBTOTAL	**905**	**375**	**$1,212,192.93**	**$1,339.44**	**2.41**	**12.37%**
ERENUMAB PRODUCTS						
AIMOVIG INJ 140MG/ML	612	143	$468,612.44	$765.71	4.28	4.78%
AIMOVIG INJ 70MG/ML	261	72	$202,088.37	$774.28	3.63	2.06%
SUBTOTAL	**873**	**215**	**$670,700.81**	**$768.27**	**4.06**	**6.84%**
ZAVEGEPANT PRODUCTS						
ZAVZPRET SPR 10MG	21	14	$22,739.77	$1,082.85	1.5	0.23%
SUBTOTAL	**21**	**14**	**$22,739.77**	**$1,082.85**	**1.5**	**0.23%**
EPTINEZUMAB PRODUCTS						
VYEPTI INJ 100MG/ML	7	4	$31,756.18	$4,536.60	1.75	0.32%
SUBTOTAL	**7**	**4**	**$31,756.18**	**$4,536.60**	**1.75**	**0.32%**
CGRP SUBTOTAL	**9,955**	**2,768**	**$9,304,069.68**	**$934.61**	**3.6**	**94.95%**
TOTAL	**34,887**	**12,370***	**$9,799,189.53**	**$280.88**	**2.82**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Please note: Zavzpret®, Nurtec® ODT and Ubrelvy® are CGRP products but are included in the Anti-Migraine Medications Special PA Tier for acute migraine treatment. Nurtec® ODT is also FDA approved for the preventive treatment of episodic migraine and has separate criteria for preventive treatment.
ACT = actuation; DIHYDROERGOT = dihydroergotamine; INJ = injection; NAPROX = naproxen; ODT = orally disintegrating tablet; SPR = nasal spray; SUMAT = sumatriptan; SYM = SymTouch™; SYR = prefilled syringe; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
EPTINEZUMAB-JJMR INJ 1MG	64	33	$235,907.01	$3,686.05	1.94
TOTAL	**64**	**33**	**$235,907.01**	**$3,686.05**	**1.94**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix Z

Fiscal Year 2025 Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation)

Oklahoma Health Care Authority
February 2026

Current Prior Authorization Criteria

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; or
4. A clinical exception for use as initial combination therapy with Letairis® (ambrisentan) applies; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 60 tablets per 30 days will apply

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of PAH must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
        i. Adcirca® (tadalafil) or Revatio® (sildenafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and
4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonia (PH-IIP); and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® Risk Evaluation and Mitigation Strategy (REMS) program; and
6. Members who are stabilized inpatient and who have a PAH or CTEPH diagnosis will be approved for continuation of therapy; and

7. A quantity limit of 90 tablets per 30 days will apply.

Liqrev® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A patient-specific, clinically significant reason why the member cannot use generic sildenafil 20mg oral tablets, even when tablets are crushed, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension (generic Revatio®) must be provided.

Opsumit® (Macitentan) and Opsynvi® (Macitentan/Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Requests for Opsynvi® will also require a patient-specific, clinically significant reason why the member cannot use Opsumit® in combination with generic sildenafil or tadalafil; and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program or the Macitentan-Containing Products REMS program; and
6. A quantity limit of 30 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have contraindication to use of all alternatives:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
5. A quantity limit of 180 tablets per 30 days will apply.

Revatio® (Sildenafil Tablets) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. An age restriction will apply. The oral suspension formulation may be approvable for members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member is not able to use the oral tablet formulation; and
4. A quantity limit of 224mL (2 bottles) per 30 days will apply.

Tadliq® (Tadalafil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension must be provided; and
4. An age restriction will apply. The oral suspension formulation may be approvable for members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member cannot use generic tadalafil 20mg oral tablets, even when the tablets are crushed; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 300mL per 30 days (2 bottles) will apply.

Tyvaso DPI® (Treprostinil Powder for Inhalation) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Pulmonary arterial hypertension (PAH); or
    b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and
        i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. For a diagnosis of PAH:
    a. Member must have previous failed trials of at least 1 of each of the following categories or have a contraindication to use of all alternatives:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and

ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and

4. A patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and
5. For a diagnosis of PH-ILD, a patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination) or have a contraindication to use of all alternatives:
   a. Adcirca® (tadalafil), Adempas® (riociguat), or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
4. Medical supervision by a pulmonary specialist or cardiologist; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

Winrevair™ (Sotatercept-csrk) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Member is currently taking PAH medications from at least 2 of the following categories for ≥90 days or has a contraindication to use of all alternatives:
   a. Phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil, tadalafil) or soluble guanylate cyclase stimulator (e.g., riociguat); or
   b. Endothelin-receptor antagonist (e.g., ambrisentan, bosentan); or
   c. Prostacyclin analogue or receptor agonist (e.g., epoprostenol, treprostinil); and
4. Prescriber must verify that Winrevair™ will be used concurrently with member's current PAH therapies; and
5. Medical supervision by a pulmonary specialist and/or cardiologist; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the preparation, subcutaneous (sub-Q) administration, and proper storage of Winrevair™; and

7. Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and
8. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 4 months after the last dose; and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. A quantity limit of 1 kit every 3 weeks will apply.
    a. Members requiring (2) 45mg or (2) 60mg vials based on their body weight will not be approved for multiple 1-vial kits but should use the 2-vial kits to achieve the dose required.

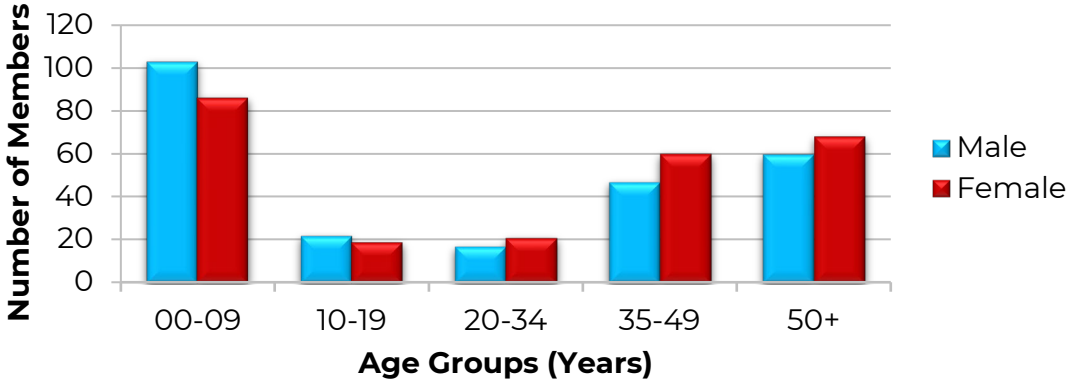
Utilization of Pulmonary Hypertension Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

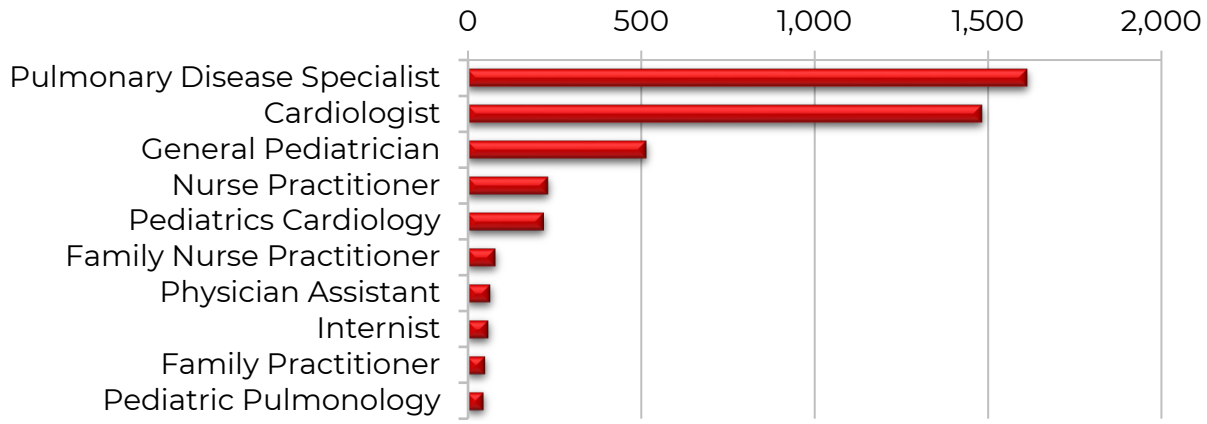
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	395	3,210	$13,511,760.62	$4,209.27	$136.89	240,388	98,705
Aetna	55	147	$391,400.98	$2,662.59	$92.77	10,377	4,219
Humana	76	192	$685,202.66	$3,568.76	$130.94	12,329	5,233
OCH	80	194	$429,192.58	$2,212.33	$79.45	13,497	5,402
2024 Total	**497**	**3,743**	**$15,017,556.84**	**$4,012.17**	**$132.24**	**276,591**	**113,559**
Fiscal Year 2025							
FFS	273	2,406	$10,269,843.03	$4,268.43	$141.69	184,010	72,482
Aetna	83	593	$2,266,281.91	$3,821.72	$133.16	42,704	17,019
Humana	103	675	$3,959,876.45	$5,866.48	$203.97	48,534	19,414
OCH	109	757	$3,019,157.63	$3,988.32	$137.02	56,889	22,035
2025 Total	**503**	**4,431**	**$19,515,159.02**	**$4,404.23**	**$149.03**	**332,137**	**130,950**
% Change	**1.20%**	**18.40%**	**29.90%**	**9.80%**	**12.70%**	**20.10%**	**15.30%**
Change	**6**	**688**	**$4,497,602.18**	**$392.06**	**$16.79**	**55,546**	**17,391**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Pulmonary Hypertension Medications: Pharmacy Claims (All Plans)



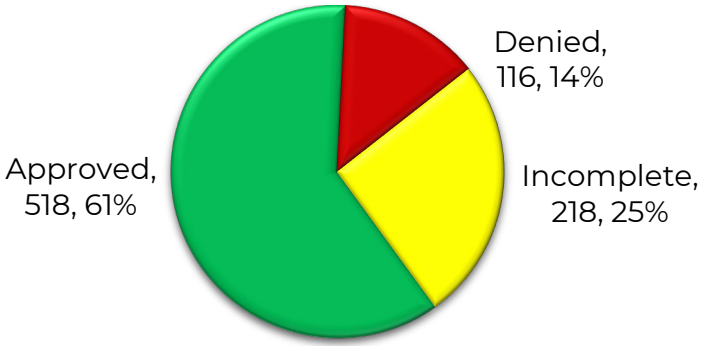
Top Prescriber Specialties of Pulmonary Hypertension Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Pulmonary Hypertension Medications

There were 852 prior authorization requests submitted for pulmonary hypertension medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	399	63%	192	30%	40	6%	**631**
Aetna	33	53%	17	27%	12	19%	**62**
Humana	37	58%	0	0%	27	42%	**64**
OCH	49	52%	9	9%	37	39%	**95**
Total	**518**	**61%**	**218**	**25%**	**116**	**14%**	**852**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5]

Anticipated Patent Expiration(s):

- Veletri® (epoprostenol injection): March 2027
- Tracleer® (bosentan tablet for oral suspension): December 2027
- Tyvaso® (treprostinil inhalation solution): December 2028
- Remodulin® (treprostinil injection): March 2029
- Opsumit® (macitentan tablet): April 2029
- Opsynvi® (macitentan/tadalafil tablet): April 2029
- Orenitram® (treprostinil tablet): August 2031
- Letairis® (ambrisentan tablet): October 2031
- Adempas® (riociguat tablet): February 2034
- Tyvaso DPI® (treprostinil powder for inhalation): April 2035
- Uptravi® (selexipag tablet): December 2036
- Yutrepia™ (treprostinil powder for inhalation): May 2037
- Liqrev® (sildenafil oral suspension): December 2038
- Tadliq® (tadalafil oral suspension): December 2038

New U.S. Food and Drug Administration (FDA) Approval(s) and Label Update(s):

- **April 2025:** The FDA determined that the Risk Evaluation and Mitigation Strategies (REMS) program for the macitentan-containing products, Opsynvi® and Opsumit®, was no longer necessary to ensure the benefits of use outweigh the risk of embryo-fetal toxicity. This decision was supported by the evaluation of long-term human fetal outcomes of those exposed to the endothelial receptor antagonist (ERA) class from 2001 to 2024. The FDA concluded that *Boxed Warnings* in the labeling were sufficient to convey the potential safety risks of fetal harm.
- **May 2025:** The FDA approved the prostacyclin dry-powder formulation, Yutrepia™ (treprostinil powder for inhalation), for the treatment of adults with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) to improve exercise tolerability.

- **October 2025:** The FDA approved an update to the package labeling for Winrevair™ (sotatercept-csrk) based on data from the Phase 3 ZENITH trial. The labeling now describes the specific clinically worsening events for which Winrevair™ is indicated to reduce the risk of hospitalization for PAH, lung transplantation, and death.

Pipeline:

- **Seralutinib:** Seralutinib is an investigational small molecule delivered via a dry powder inhaler (DPI) that is being evaluated in a Phase 3 clinical trial for the treatment of PAH. An additional trial evaluating seralutinib for PH-ILD is currently recruiting participants. Seralutinib works by inhibiting platelet-derived growth factor (PDGRF), colony-stimulating factor 1 receptor (CSF1R), and mast/stem cell growth factor receptor kit (c-KIT), which are key receptors in the underlying pathophysiology of PAH and PH-ILD.

Yutrepia™ (Treprostinil Powder for Inhalation) Product Summary[6,7]

Therapeutic Class: Prostacyclin mimetic

Indication(s): Treatment of PAH and PH-ILD to improve exercise tolerability

How Supplied: 26.5mcg, 53mcg, 79.5mcg, and 106mcg capsules containing powder for inhalation

Dosing and Administration:

- Yutrepia™ capsules should only be administered via inhalation and used only with the supplied inhaler.
- For treprostinil-naïve patients, initial dosing should be 26.5mcg 3 to 5 times per day, with each dose delivered in 2 breaths, based on patient response.
- See full *Prescribing Information* for initial dosing in patients transitioning from treprostinil inhalation solution.
- In treprostinil-naïve patients and those transitioning from treprostinil inhalation solution, the initial dose can be titrated by 26.5mcg per dose each week as tolerated; target maintenance dosing is 79.5 to 106mcg 4 times daily.
- Doses above 848mcg per day have not been studied in patients with PAH.

Efficacy: Yutrepia™ was approved by the FDA through the 505(b)(2) regulatory pathway. The safety and tolerability of Yutrepia™ were evaluated in INSPIRE a Phase 3, open-label, multicenter trial that included patients naïve to treprostinil and those transitioning from nebulized treprostinil.

Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days	Cost Per Year
Yutrepia™ (treprostinil inh pow) 106mcg	**$228.38**	**$25,578.56***	**$332,521.28**
Tyvaso DPI® (treprostinil inh pow) 64mcg	$226.00	$25,312.00⁺	$329,056.00
Tyvaso® (treprostinil inh sol) 1.74mg/2.9mL	$288.74	$23,445.69ᵅ	$304,793.97
Remodulin® (treprostinil inj) 10mg/mL	$544.80	$15,254.40ᵝ	$198,307.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DPI = dry powder inhaler; inh = inhalation, inj = injection, pow = powder, sol = solution
Unit = capsule; cartridge, mL
*Cost per 28 days is based on the upper limit of the target dose range of 106mcg inhaled 4 times daily.
⁺Cost per 28 days is based on the upper limit of the target dose range of 64mcg inhaled 4 times daily.
ᵅCost per 28 days is based on use of 1 ampule per day divided 4 times daily.
ᵝCost per 28 days is based on the upper limit of the target dose range of 80ng/kg/min by continuous intravenous or subcutaneous infusion for an 80kg patient

Recommendations

The College of Pharmacy Recommends the prior authorization of Yutrepia™ (treprostinil powder for inhalation) with criteria similar to Tyvaso DPI® (treprostinil powder for inhalation) and updating the Tyvaso DPI® criteria for clarity (changes shown in red):

Tyvaso DPI® (Treprostinil Powder for Inhalation) and Yutrepia™ (Treprostinil Powder for Inhalation) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Pulmonary arterial hypertension (PAH); or
    b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and
        i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. For a diagnosis of PAH:
    a. Member must have previous failed trials of at least 1 of each of the following categories or have a contraindication to use of all alternatives:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
4. A patient-specific, clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and
5. For a diagnosis of PH-ILD, a patient-specific, clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.

The College of Pharmacy also recommends updating the Opsynvi® (macitentan) and Opsumit® (macitentan/tadalafil) approval criteria based on the discontinuation of the REMS program (changes shown in red):

Opsumit® (Macitentan) and Opsynvi® (Macitentan/Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Requests for Opsynvi® will also require a patient-specific, clinically significant reason why the member cannot use Opsumit® in combination with generic sildenafil or tadalafil; and
5. ~~Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program or the Macitentan-Containing Products REMS program; and~~
6. Female members of reproductive potential must have a negative pregnancy test prior to initiation of Opsumit® or Opsynvi® and, if pregnancy occurs during therapy, Opsumit® or Opsynvi® must be discontinued immediately; and
7. A quantity limit of 30 tablets per 30 days will apply.

Lastly, the College of Pharmacy recommends updating the Uptravi® (selexipag) and Winrevair™ (sotatercept-csrk) based on clinical practice (changes shown in red):

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. ~~Member must be 18 years of age or older; and~~
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination) or have a contraindication to use of all alternatives:
   a. Adcirca® (tadalafil), Adempas® (riociguat), or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
4. Medical supervision by a pulmonary specialist or cardiologist; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and

6. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

Winrevair™ (Sotatercept-csrk) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. ~~Member must be 18 years of age or older; and~~
3. Member is currently taking PAH medications from at least 2 of the following categories for ≥90 days or has a contraindication to use of all alternatives:
   a. Phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil, tadalafil) or soluble guanylate cyclase stimulator (e.g., riociguat); or
   b. Endothelin-receptor antagonist (e.g., ambrisentan, bosentan); or
   c. Prostacyclin analogue or receptor agonist (e.g., epoprostenol, treprostinil); and
4. Prescriber must verify that Winrevair™ will be used concurrently with member's current PAH therapies; and
5. Medical supervision by a pulmonary specialist and/or cardiologist; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the preparation, subcutaneous (sub-Q) administration, and proper storage of Winrevair™; and
7. Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and
8. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 4 months after the last dose; and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. A quantity limit of 1 kit every 3 weeks will apply.
    a. Members requiring (2) 45mg or (2) 60mg vials based on their body weight will not be approved for multiple 1-vial kits but should use the 2-vial kits to achieve the dose required.

Utilization Details of Pulmonary Hypertension Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS						
TADLIQ SUS 20MG/5ML	1,154	167	$1,428,159.56	$1,237.57	6.91	7.32%
SILDENAFIL TAB 20MG	813	192	$14,042.39	$17.27	4.23	0.07%
TADALAFIL TAB 20MG	598	85	$12,762.54	$21.34	7.04	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SILDENAFIL SUS 10MG/ML	51	9	$5,677.68	$111.33	5.67	0.03%
SUBTOTAL	**2,616**	**453**	**$1,460,642.17**	**$558.35**	**5.77**	**7.48%**
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						
AMBRISENTAN TAB 10MG	489	69	$395,227.41	$808.24	7.09	2.03%
OPSUMIT TAB 10MG	310	40	$3,454,322.14	$11,142.97	7.75	17.70%
AMBRISENTAN TAB 5MG	69	11	$62,507.84	$905.91	6.27	0.32%
TRACLEER TAB 32MG	56	6	$635,869.47	$11,354.81	9.33	3.26%
BOSENTAN TAB 125MG	39	9	$7,942.32	$203.65	4.33	0.04%
BOSENTAN TAB 62.5MG	33	6	$10,589.17	$320.88	5.5	0.05%
SUBTOTAL	**996**	**141**	**$4,566,458.35**	**$4,584.80**	**7.06**	**23.40%**
PROSTACYCLIN VASODILATORS						
ORENITRAM TAB 1MG	72	16	$709,812.95	$9,858.51	4.5	3.64%
ORENITRAM TAB 5MG	56	8	$1,346,585.32	$24,046.17	7	6.90%
TYVASO DPI POW 64MCG	52	6	$1,234,765.86	$23,745.50	8.67	6.33%
ORENITRAM TAB 0.25MG	42	12	$77,900.36	$1,854.77	3.5	0.40%
REMODULIN INJ 5MG/ML	39	9	$497,582.29	$12,758.52	4.33	2.55%
REMODULIN INJ 10MG/ML	38	5	$539,095.68	$14,186.73	7.6	2.76%
ORENITRAM TAB 2.5MG	36	9	$412,067.09	$11,446.31	4	2.11%
UPTRAVI TAB 1,600MCG	35	6	$803,167.73	$22,947.65	5.83	4.12%
UPTRAVI TAB 1,400MCG	32	4	$741,424.42	$23,169.51	8	3.80%
UPTRAVI TAB 1,200MCG	27	4	$626,213.96	$23,193.11	6.75	3.21%
UPTRAVI TAB 200MCG	26	15	$746,791.53	$28,722.75	1.73	3.83%
REMODULIN INJ 2.5MG/ML	26	4	$296,826.31	$11,416.40	6.5	1.52%
TYVASO RF KIT SOL 0.6MG/ML	23	4	$498,359.97	$21,667.82	5.75	2.55%
UPTRAVI TAB 600MCG	20	2	$463,785.76	$23,189.29	10	2.38%
UPTRAVI TAB 1000MCG	20	4	$461,190.67	$23,059.53	5	2.36%
ORENITRAM TAB 0.125MG	16	7	$7,118.30	$444.89	2.29	0.04%
UPTRAVI PACK TAB 200/800MCG	12	10	$415,779.91	$34,648.33	1.2	2.13%
EPOPROSTENOL INJ 1.5MG	12	1	$32,172.92	$2,681.08	12	0.16%
TYVASO DPI POW 48MCG	10	1	$235,554.00	$23,555.40	10	1.21%
UPTRAVI TAB 400MCG	8	2	$169,243.87	$21,155.48	4	0.87%
TYVASO DPI POW 16MCG	7	1	$167,901.86	$23,985.98	7	0.86%
TYVASO DPI POW 16/32/48MCG	7	6	$162,472.66	$23,210.38	1.17	0.83%
REMODULIN INJ 1MG/ML	6	4	$5,797.04	$966.17	1.5	0.03%
UPTRAVI TAB 800MCG	5	4	$100,149.73	$20,029.95	1.25	0.51%
TYVASO ST KIT SOL 0.6MG/ML	4	4	$80,388.01	$20,097.00	1	0.41%
ORENITRAM TAB MONTH 2	4	4	$15,473.78	$3,868.45	1	0.08%
ORENITRAM TAB MONTH 1	4	4	$6,080.12	$1,520.03	1	0.03%
TREPROSTINIL INJ 2.5MG/ML	4	2	$28,462.64	$7,115.66	2	0.15%
ORENITRAM TAB MONTH 3	2	2	$12,695.32	$6,347.66	1	0.07%
VELETRI INJ 1.5MG	2	1	$3,880.82	$1,940.41	2	0.02%
TREPROSTINIL INJ 1MG/ML	1	1	$6,219.10	$6,219.10	1	0.03%
SUBTOTAL	**648**	**162**	**$10,904,959.98**	**$16,828.64**	**4**	**55.88%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ACTIVIN SIGNALING INHIBITORS						
WINREVAIR INJ 45MG	76	21	$1,380,842.66	$18,168.98	3.62	7.07%
WINREVAIR INJ 60MG	11	2	$98,919.87	$8,992.72	5.5	0.51%
SUBTOTAL	**87**	**23**	**$1,479,762.53**	**$17,008.76**	**3.78**	**7.58%**
SOLUBLE GUANYLATE CYCLASE (sGC) STIMULATORS						
ADEMPAS TAB 2.5MG	31	6	$402,688.55	$12,989.95	5.17	2.06%
ADEMPAS TAB 1.5MG	3	3	$42,088.53	$14,029.51	1	0.22%
ADEMPAS TAB 2MG	1	1	$14,121.61	$14,121.61	1	0.07%
ADEMPAS TAB 0.5MG	7	2	$98,574.97	$14,082.14	3.5	0.51%
ADEMPAS TAB 1MG	8	3	$111,853.68	$13,981.71	2.67	0.57%
SUBTOTAL	**50**	**15**	**$669,327.34**	**$13,386.55**	**3.33**	**3.43%**
ERA/PDE-5 COMBINATION PRODUCTS						
OPSYNVI TAB 10-40MG	34	5	$434,008.65	$12,764.96	6.8	2.22%
SUBTOTAL	**34**	**5**	**$434,008.65**	**$12,764.96**	**6.8**	**2.22%**
TOTAL	**4,431**	**503***	**$19,515,159.02**	**$4,404.23**	**8.81**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DPI = dry powder inhaler; INJ = injection; POW = powder; RF = refill; SOL = solution; ST = starter; SUS = suspension; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[3] Liquidia. U.S. FDA Approves Liquidia's Yutrepia™ (Treprostinil) Inhalation Powder for Patients with Pulmonary Arterial Hypertension (PAH) and Pulmonary Hypertensions Associated with Interstitial Lung Disease (PH-ILD). Available online at: https://liquidia.com/news-releases/news-release-details/us-fda-approves-liquidias-yutrepiatm-treprostinil-inhalation. Issued 05/23/2025. Last accessed 01/20/2026.
[4] Merck. U.S. FDA Approves Updated Indication for Winrevair™ (Sotatercept-csrk) in Adults with Pulmonary Arterial Hypertension (PAH WHO Group 1 Pulmonary Hypertension) Based on Phase 3 ZENITH Study. Available online at: https://www.merck.com/news/u-s-fda-approves-updated-indication-for-winrevair-sotatercept-csrk-in-adults-with-pulmonary-arterial-hypertension-pah-who-group-1-pulmonary-hypertension-based-on-phase-3-zenith-study/. Issued 10/27/2025. Last accessed 01/20/2026.
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[7] Liquidia. U.S. FDA Approves Liquidia's YUTREPIA™ (treprostinil) Inhalation Powder for Patients with Pulmonary Arterial Hypertension (PAH) and Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD). Available online at: https://liquidia.com/news-releases/news-release-details/us-fda-approves-liquidias-yutrepiatm-treprostinil-inhalation. Issued 05/23/2025. Last accessed 01/27/2026.

Appendix AA

Fiscal Year 2025 Annual Review of Crenessity (Crinecerfont)

Oklahoma Health Care Authority
February 2026

Current Prior Authorization Criteria

Crenessity® (Crinecerfont) Approval Criteria:

1. An FDA approved indication as adjunctive treatment to glucocorticoid replacement to control androgens in members with classic congenital adrenal hyperplasia (CAH); and
2. A diagnosis of classic CAH due to 21-hydroxylase deficiency (21OHD) must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
    a. Elevated 17-hydroxyprogesterone (17-OHP); or
    b. Elevated 17-OHP following a cosyntropin stimulation test; or
    c. Genetic testing identifying biallelic pathogenic variants in the CYP21A2 gene; or
    d. Positive newborn screening with confirmatory second-tier testing; or
    e. Submitted historical documentation confirming the diagnosis; and
3. Member must be 4 years of age or older and weigh ≥10kg; and
    a. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
4. Crenessity® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. Prescriber must verify that member will continue glucocorticoid replacement therapy concomitantly with Crenessity® and the member will be monitored for signs of acute adrenal insufficiency or adrenal crisis; and
6. For the oral solution, members weighing ≥55kg (or ≥20kg if on concomitant CYP3A4 inducers) will require a patient-specific, clinically significant reason why the capsule formulation cannot be used; and
7. A quantity limit of 60 tablets or 60mLs per 30 days will apply; and
    a. For members who require increased doses above 100mg twice daily, a quantity limit override may be approved with documentation that the member is taking a strong or moderate CYP3A4 inducer (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Crenessity®; and

8. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents that the member is responding well to therapy as indicated by a decrease in glucocorticoid daily dose from baseline or a decrease in serum androstenedione levels from baseline. Subsequent approvals will be for 1 year.

Utilization of Crenessity® (Crinecerfont): Fiscal Year 2025

Fiscal Year 2025 Utilization: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	2	3	$95,866.73	$31,955.58	$1,065.19	150	90
Aetna	1	2	$76,688.82	$38,344.41	$1,278.15	120	60
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2025 Total	**3**	**5**	**$172,555.55**	**$34,511.11**	**$1,150.37**	**270**	**150**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Please note: There were no paid pharmacy claims for Crenessity® during fiscal year 2024 to allow for a fiscal year comparison.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Crenessity® (Crinecerfont): Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing Crenessity® (crinecerfont), detailed demographic information could not be provided.

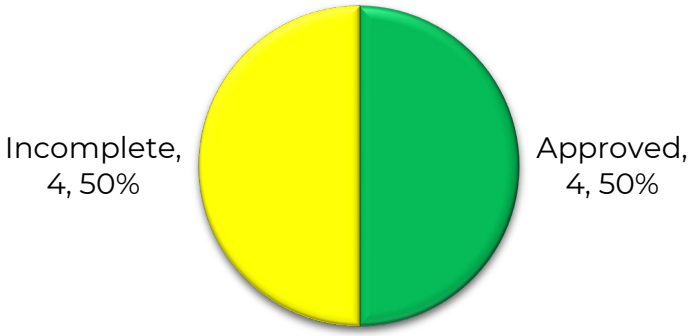
Top Prescriber Specialties of Crenessity® (Crinecerfont) by Number of Claims: Pharmacy Claims (All Plans)

- The only prescriber specialty listed on paid claims for Crenessity® (crinecerfont) during fiscal year 2025 was pediatric endocrinologist.

Prior Authorization of Crenessity® (Crinecerfont)

There were 8 prior authorization requests submitted for Crenessity® (crinecerfont) during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	2	40%	3	60%	0	0%	**5**
Aetna	1	50%	1	50%	0	0%	**2**
Humana	1	100%	0	0%	0	0%	**1**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**4**	**50%**	**4**	**50%**	**0**	**0%**	**8**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Crenessity® (crinecerfont): June 2041

Pipeline:

- **Atumelnant:** Atumelnant is an investigational oral adrenocorticotropic hormone (ACTH) receptor antagonist being studied for the treatment of classic congenital adrenal hyperplasia (CAH) and ACTH-dependent Cushing's syndrome. In the TouCAHn Phase 2 trial, treatment with atumelnant resulted in rapid, sustained lowering of androstenedione (A4) in all 8 patients who completed the fourth cohort. Seven out of these 8 patients continued to maintain lower A4 after glucocorticoid doses were reduced to physiologic levels. A Phase 3 trial is currently ongoing.

Recommendations

The College of Pharmacy does not recommend any changes to the current Crenessity® (crinecerfont) prior authorization criteria at this time.

Utilization Details of Crenessity® (Crinecerfont): Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CRENESSITY SOL 50MG/ML	3	2	$95,866.73	$31,955.58	1.5	55.56%
CRENESSITY CAP 100MG	2	1	$76,688.82	$38,344.41	2	44.44%
TOTAL	**5**	**3***	**$172,555.55**	**$34,511.11**	**1.67**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 01/2026. Last accessed 01/20/2026.
[2] Crinetics Pharmaceuticals. Crinetics Announces Strong Palsonify™ Launch Execution and Positive Results for Concurrent Androstenedione Lowering and Glucocorticoid Dose Reduction in Phase 2 Trial of Atumelnant for Congenital Adrenal Hyperplasia. Available online at: https://crinetics.com/crinetics-announces-strong-palsonify-launch-execution-and-positive-results-for-concurrent-androstenedione-lowering-and-glucocorticoid-dose-reduction-in-phase-2-trial-of-atumelnant-for-congenital-adren/. Issued 01/05/2026. Last accessed 01/20/2026.

Appendix AB

Fiscal Year 2025 Annual Review of Kebilidi™ (Eladocagene Exuparvovec-tneq)

Oklahoma Health Care Authority
February 2026

Current Prior Authorization Criteria

Kebilidi™ (Eladocagene Exuparvovec-tneq) Approval Criteria:

1. An FDA approved diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency; and
2. Diagnosis must be confirmed by
    a. Genetic testing confirming biallelic pathogenic or likely pathogenic mutations in the *DDC* gene (results of genetic testing must be submitted); and
    b. Functional confirmation with measured diagnostic variations in AADC enzyme activity in plasma and/or levels of neurotransmitters in cerebrospinal fluid (CSF) (results of testing must be submitted); and
3. Member must be 16 months of age or older; and
4. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to Kebilidi™ administration; and
5. Must be prescribed by a neurologist, neurosurgeon, or a specialist with expertise in the treatment of AADC deficiency; and
6. Prescriber must verify the member has confirmed skull maturity as assessed by neuroimaging; and
7. Must be administered by intraputaminal infusion in a medical center that specializes in stereotactic neurosurgery in addition to the preparation and infusion of Kebilidi™; and
8. Must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment, and the facility must be capable of adhering to the storage, handling, and preparation requirements as described in the package labeling; and
9. Must only be administered using an FDA-authorized cannula for intraparenchymal infusion (e.g., ClearPoint® SmartFlow® Neuro Cannula); and
10. Approvals will be for 1 treatment per member per lifetime.

Utilization of Kebilidi™ (Eladocagene Exuparvovec-tneq): Fiscal Year 2025

There was no SoonerCare utilization of Kebilidi™ (eladocagene exuparvovec-tneq) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Prior Authorization of Kebilidi™ (Eladocagene Exuparvovec-tneq)

There were no prior authorization requests submitted for Kebilidi™ (eladocagene exuparvovec-tneq) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Recommendations

The College of Pharmacy does not recommend any changes to the current Kebilidi™ (eladocagene exuparvovec-tneq) prior authorization criteria at this time.

Appendix AC

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates*

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: January 12, 2026

FDA Approves First Treatment for Children With Menkes Disease

The FDA approved Zycubo® (copper histidinate) injection as the first treatment for Menkes disease in pediatric patients.

Menkes disease is a neurodegenerative disorder caused by a genetic defect that impairs a child's ability to absorb copper. The disease is characterized by seizures, failure to gain weight and grow, developmental delays, and intellectual disability. It leads to abnormalities of the vascular system, bladder, bowel, bones, muscles, and nervous system. Children with classical Menkes (90% of those with the disease) begin to develop symptoms in infancy and typically do not live past 3 years. It affects approximately 1 in every 100,000-250,000 live births worldwide and is more common in boys.

Zycubo® is a copper replacement therapy given by subcutaneous (sub-Q) injection. It delivers copper in a form that bypasses the genetic defect in intestinal absorption, allowing the body to better use the mineral.

The FDA evaluated Zycubo® in 2 open-label, single-arm clinical trials in pediatric patients treated for up to 3 years. Overall survival was assessed by comparing treated patients to untreated patients from contemporaneous external control groups. The analysis included 66 treated patients and 17 untreated patients, most of whom were from the United States.

Children who began treatment within 4 weeks of birth had a 78% reduction in the risk of death compared with untreated patients. Nearly half of early-treated patients survived beyond 6 years, and some survived more than 12 years. No patients in the untreated control group survived beyond 6 years. Children who started treatment later than 4 weeks after birth also experienced a substantial survival benefit.

The most common side effects reported with Zycubo® included infections, respiratory problems, seizures, vomiting, fever, anemia and injection site reactions. Because copper can accumulate in the body, patients receiving Zycubo® should be closely monitored for potential toxicity.

This application received Priority Review, Fast Track Designation, Breakthrough Therapy Designation, and Orphan Drug Designation. The FDA approved Zycubo® for Sentynl Therapeutics.

FDA NEWS RELEASE

For Immediate Release: January 12, 2026

FDA Issues Guidance on Modernizing Statistical Methods for Clinical Trials

The FDA published draft guidance designed to facilitate the use of Bayesian methodologies in clinical trials of drugs and biologics, helping drug developers make better use of available data, conduct more efficient clinical trials, and deliver safe and effective treatments to patients sooner.

Bayesian approaches use a different framework from traditional statistical approaches. In a Bayesian analysis, data from a study are combined with relevant prior information to form a new distribution that can be used for inference and to draw conclusions about safety and efficacy.

Examples of Bayesian calculations used in various ways in clinical trials can include:

- Determining futility or success earlier in adaptive trials.
- Informing design elements like dose selection in subsequent trials.
- Incorporating information from other sources, such as previous clinical study data, real-world evidence, and external or nonconcurrent controls.
- Facilitating subgroup analyses.
- Supporting primary inference in a trial.

The guidance provides recommendations on the appropriate use of Bayesian methods, with an emphasis on the use of these methods to support primary inference. Bayesian methods may be especially valuable for sponsors targeting rare or pediatric indications, where patient populations are smaller.

The publication of this guidance — *Use of Bayesian Methodology in Clinical Trials of Drugs and Biologics Guidance for Industry* — is intended to satisfy the FDA's commitment in the Prescription Drug User Fee Act (PDUFA) VII. As part of the sixth reauthorization of the PDUFA, the FDA and industry agreed to performance goals around enhancing the capacity to review complex innovative trial designs, including a commitment to publish draft guidance on the use of Bayesian methodology in clinical trials of drugs and biological products (see PDUFA VII Performance Goals Letter, Section I.L.4.f).

The FDA is seeking public comment on the draft guidance, titled *Use of Bayesian Methodology in Clinical Trials of Drugs and Biologics; Draft Guidance for Industry*.

FDA NEWS RELEASE

For Immediate Release: January 11, 2026

FDA Increases Flexibility on Requirements for Cell and Gene Therapies to Advance Innovation

The FDA announced it is sharing information about the agency's flexible approach to overseeing chemistry, manufacturing and control (CMC) requirements for cell and gene therapies (CGT). The agency's more flexible approach has been, and is expected to continue to be, helpful in expediting

product development and will help guide the FDA's evaluation of development strategies in preparation for a Biologics License Application (BLA) submission.

Over the last decade, the FDA's Center for Biologics Evaluation and Research (CBER) has approved close to 50 CGTs. The transformative potential of these therapies has captured the imagination of the patient community and ignited product development.

CBER has historically had similar CMC expectations across products, including small-batch products such as CGTs. CGTs are inherently complex biologic products, often individualized for patients, and may need sophisticated manufacturing under particular time constraints. CBER has leveraged its growing experience with CGT products to identify and implement regulatory flexibilities allowed under FDA's regulations that accommodate the unique characteristics of these innovative therapies, while maintaining rigorous quality standards through appropriate control measures. While there is a long history of making concerted efforts to help sponsors meet standards to assure product safety, purity and potency, the application of flexibilities has not always been fully clear to stakeholders.

Given the rapid scientific developments witnessed during the decade, it is a high priority for both the agency and the administration to remove barriers and perceived misconceptions that stand in the way of expedited product development. These flexibilities will enable progress while not compromising or undermining the FDA's ability to assure safety, purity and potency of a product, or weaken the FDA's dependency on understanding the benefits and risks of both the specific therapy and the disease context.

In June, the FDA hosted a Cell and Gene Therapy Roundtable, bringing together leading experts to discuss advancing the field of cell and gene therapies for patients and innovators.

Current Drug Shortages Index (as of January 28, 2026):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***

Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***

Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***