OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
December 10, 2025
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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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 – December 10, 2025

DATE: December 3, 2025

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 December 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 Program Update – Appendix C

Action Item – SoonerCare Maintenance Drug List – Appendix D

Action Item – Vote to Prior Authorize Brinsupri™ (Brensocatib) – Appendix E

Action Item – 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 – Appendix F

Action Item – Vote to Prior Authorize Forzinity™ (Elamipretide) – Appendix G

Action Item – Vote to Prior Authorize Rhapsido® (Remibrutinib) – Appendix H

Action Item – Vote to Prior Authorize Harliku™ (Nitisinone), Orfadin® (Nitisinone), Nityr® (Nitisinone), and Sephience™ (Sepiapterin) and Update the Approval Criteria for the Amino Acid Disorder Medications – Appendix I

Action Item – Vote to Prior Authorize Anzupgo® (Delgocitinib 2% Cream) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications – Appendix J

Action Item – Vote to Prior Authorize Omlyclo® (Omalizumab-igec) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications – Appendix K

Action Item – Vote to Prior Authorize Boruzu® (Bortezomib) and Lynozyfic™ (Linvoseltamab-gcpt) and Update the Approval Criteria for the Multiple Myeloma Medications – Appendix L

Action Item – Annual Review of Skysona® (Elivaldogene Autotemcel) – Appendix M

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) – Appendix N

Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Imaavy™ (Nipocalimab-aahu) – Appendix O

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) – Appendix P

Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib) – Appendix Q

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) – Appendix R

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 – Appendix S

Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution) – Appendix T

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – December 10, 2025 @ 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. November 12, 2025 DUR Board Meeting Minutes
   B. November 12, 2025 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 November 2025
   B. Medication Coverage Activity for November 2025

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

5. **Academic Detailing Program Update – See Appendix C**
   A. Background
   B. Current Topics: Co-Prescribing Opioid Medications with Benzodiazepines (BZD) and Naloxone
   C. Prescriber Mailings and Results: Co-Prescribing Opioid Medications with BZD and Naloxone
   D. Summary

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

6. **Action Item – SoonerCare Maintenance Drug List – See Appendix D**
   1. Introduction
   2. SoonerCare Maintenance Drug List

3. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Brinsupri™ (Brensocatib) – See Appendix E**

A. Market News and Updates
B. Brinsupri™ (Brensocatib) Product Summary
C. College of Pharmacy Recommendations

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

8. **Action Item – 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 – See Appendix F**

A. Market News and Updates
B. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Forzinity™ (Elamipretide) – See Appendix G**

A. Market News and Updates
B. Forzinity™ (Elamipretide) Product Summary
C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Rhapsido® (Remibrutinib) – See Appendix H**

A. Market News and Updates
B. Rhapsido® (Remibrutinib) Product Summary
C. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Harliku™ (Nitisinone), Orfadin® (Nitisinone), Nityr® (Nitisinone), and Sephience™ (Sepiapterin) and Update the Approval Criteria for the Amino Acid Disorder Medications – See Appendix I**

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:

12. **Action Item – Vote to Prior Authorize Anzupgo® (Delgocitinib 2% Cream) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications – See Appendix J**
    A. Market News and Updates
    B. Anzupgo® (Delgocitinib 2% Cream) Product Summary
    C. Cost Comparisons
    D. College of Pharmacy Recommendations

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

13. **Action Item – Vote to Prior Authorize Omlyclo® (Omalizumab-igec) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance 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 Boruzu® (Bortezomib) and Lynozyfic™ (Linvoseltamab-gcpt) and Update the Approval Criteria for the Multiple Myeloma Medications – See Appendix L**
    A. Market News and Updates
    B. Lynozyfic™ (Linvoseltamab-gcpt) Product Summary
    C. Cost Comparison: Bortezomib Products
    D. College of Pharmacy Recommendations

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

15. **Action Item – Annual Review of Skysona® (Elivaldogene Autotemcel) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Skysona® (Elivaldogene Autotemcel)
    C. Prior Authorization of Skysona® (Elivaldogene Autotemcel)
    D. Market New and Updates
    E. College of Pharmacy Recommendations

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

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) – See Appendix N**
    A. Current Prior Authorization Criteria
    B. Utilization of Skin Cancer Medications
    C. Prior Authorization of Skin Cancer Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Skin Cancer Medications

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

17. **Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Imaavy™ (Nipocalimab-aahu) – See Appendix O**

A. Current Prior Authorization Criteria
B. Utilization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents
C. Prior Authorization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents
D. Market News and Updates
E. Imaavy™ (Nipocalimab-aahu) Product Summary
F. Cost Comparisons
G. College of Pharmacy Recommendations
H. Utilization Details of Complement Inhibitors and Miscellaneous Immunomodulatory Agents

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

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) – See Appendix P**

A. Introduction
B. Cost Comparisons
C. College of Pharmacy Recommendations

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

19. **Annual Review of Thrombocytopenia Medications and 30-Day Notice to Prior Authorize Doptelet® Sprinkle (Avatrombopag) and Wayrilz™ (Rilzabrutinib) – See Appendix Q**

A. Current Prior Authorization Criteria
B. Utilization of Thrombocytopenia Medications
C. Prior Authorization of Thrombocytopenia Medications
D. Market News and Updates
E. Walyrilz™ (Rilzabrutinib) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Thrombocytopenia Medications

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

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) – See Appendix R**

A. Current Prior Authorization Criteria
B. Utilization of Muscle Relaxant Medications
C. Prior Authorization of Muscle Relaxant Medications
D. Market News and Updates
E. Product Summaries
F. Carisoprodol Products Cost Comparison
G. College of Pharmacy Recommendations
H. Utilization Details of Muscle Relaxant Medications

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

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 – See Appendix S**

A. Current Prior Authorization Criteria
B. Market News and Updates
C. Product Summaries
D. Estimation of Savings
E. College of Pharmacy Recommendations

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

22. **Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Escitalopram 15mg Capsule and Raldesy™ (Trazodone Oral Solution) – See Appendix T**

A. Current Prior Authorization Criteria
B. Utilization of Antidepressants
C. Prior Authorization of Antidepressants
D. Market News and Updates
E. Cost Comparisons
F. College of Pharmacy Recommendations
G. Utilization Details of Antidepressants

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

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

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

24. Future Business* (Upcoming Product and Class Reviews)
No live DUR Board Meeting is scheduled for January 2026. January 2026 will be a packet-only meeting.

A. Adiposity-Based Chronic Disease (ABCD) Medications
B. Antihyperlipidemics
C. Antihypertensive Medications
D. Gastrointestinal (GI) Cancer Medications
E. Non-Malignant Solid Tumor Medications
F. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
G. Ophthalmic Antibiotic Medications

*Future product and class reviews subject to change.

25.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 NOVEMBER 12, 2025

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP		X
Kenneth Foster, MHS, PA-C	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	
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): Joshua Goalden	X	

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	
Travis Dennis, J.D.; Deputy General Counsel	X	
Gentry Kincade, J.D.; Deputy General Counsel		X

Gwendolyn Maxey, J.D.; Deputy General Counsel		X
Melissa Miller, State Medicaid Director		X
Conner Mulvaney, J.D.; Deputy General Counsel		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer		X
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Sharon Smith, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Lynn Kaye, Indivior	Sam Brantman, Incyte
Brandon Ross, Merck	Melissa Abbott, Galderma
Carla McSpadden, Galderma	Deidra Williams, Humana
Eardie Curry, Genentech	Bret Milovac, Leo Pharma
Kristen Winters, Centene	Bryan Steffan, Boehringer
Carmen Hinton, Emergent BioSolutions	Lee Stout, Chiesi
Irene Chung, Aetna	Christopher Filds, Abeona Therapeutics
Adriana Sanchez, Bridge Bio	Jay Milton, Bayer
Andrew Delgado, Bristol Myers Squibb	Mike Thiem, Incyte
Jennifer Lauper, Bristol Myers Squibb	Michael Sullivan, Amgen
Valerie Willard, Glaukos	Pam Storey, PTC Therapeutics
Melanie Kitto, Biocryst	Laura Cordell, Sanofi
Michael Pericozzi, Sanofi	Andy Berg, Concis Labs
John Suelzer, Leo Pharma	David Miley, Teva
Lauren Warn, PTC Therapeutics	Christine Dube, AstraZeneca
Jennifer Tamburo, AstraZeneca	Lindsey Walter, Novartis
Tina Hartmann, Arcutis	LaShaun Coleman, Gene
Ginger Papesh, Novo Nordisk	Gary Parenteau, Dexcom
Jason Dickerson, Jazz Pharma	Anthony Duca, Incyte

PRESENT FOR PUBLIC COMMENT:	
Sam Brantman, Incyte	Carla McSpadden, Galderma

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.14 SAM BRANTMAN

2B: AGENDA ITEM NO. 14 CARLA MCSPADDEN

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MEETING MINUTES**

3A: OCTOBER 8, 2025 DUR MINUTES

Materials included in agenda packet; presented by Dr. Haymore

Dr. Kupiec moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **APPROVAL OF 2026 DUR BOARD MEETING DATES**

Materials included in agenda packet; presented by Dr. Haymore
Mr. Foster moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 5: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT**

5A: PHARMACY HELPDESK ACTIVITY FOR OCTOBER 2025
5B: MEDICATION COVERAGE ACTIVITY FOR OCTOBER 2025

Non-presentation item; materials included in agenda packet by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **HEPATITIS C PROGRAM UPDATE**

6A: BACKGROUND
6B: RESULTS OF CLAIMS ANALYSIS
6C: CONCLUSIONS

Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE ELIQUIS® (APIXABAN) TABLET FOR ORAL SUSPENSION AND ELIQUIS® SPRINKLE (APIXABAN) CAPSULE FOR ORAL SUSPENSION AND UPDATE THE APPROVAL CRITERIA FOR THE ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS**

7A: MARKET NEWS AND UPDATES
7B: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE AVTOZMA® (TOCILIZUMAB-ANOH), IMULDOSA® (USTEKINUMAB-SRLF), OTEZLA XR™ [APREMILAST EXTENDED-RELEASE (ER)], STARJEMZA™ (USTEKINUMAB-HMNY), STEQEYMA® (USTEKINUMAB-STBA), AND YESINTEK™ (USTEKINUMAB-KFCE) AND UPDATE THE APPROVAL CRITERIA FOR THE TARGETED IMMUNOMODULATOR AGENTS**

8A: MARKET NEWS AND UPDATES
8B: COST COMPARISON: CURRENTLY AVAILABLE SUBCUTANEOUS (SUB-Q) USTEKINUMAB PRODUCTS
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF MULTIPLE MYELOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BORUZU® (BORTEZOMIB) AND LYNOZYFIC™ (LINVOSELTAMAB-GCPT)**

9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF MULTIPLE MYELOMA MEDICATIONS
9C: PRIOR AUTHORIZATION OF MULTIPLE MYELOMA MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: LYNOZYFIC™ (LINVOSELTAMAB-GCPT) PRODUCT SUMMARY
9F: COST COMPARISON: BORTEZOMIB PRODUCTS

9G: COLLEGE OF PHARMACY RECOMMENDATIONS
9H: UTILIZATION DETAILS OF MULTIPLE MYELOMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 10: ANNUAL REVIEW OF BONE DENSITY REGULATORS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BILDYOS® (DENOSUMAB-NXXP), BILPREVDA® (DENOSUMAB-NXXP), BOMYNTRA® (DENOSUMAB-BNHT), CONEXXENCE® (DENOSUMAB-BNHT), OSENVELT® (DENOSUMAB-BMWO), AND STOBOCLO® (DENOSUMAB-BMWO)
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF BONE DENSITY REGULATORS
10C: PRIOR AUTHORIZATION OF BONE DENSITY REGULATORS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF BONE DENSITY REGULATORS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 11: 30-DAY NOTICE TO PRIOR AUTHORIZE FORZINITY™ (ELAMIPRETIDE)
11A: INTRODUCTION
11B: FORZINITY™ (ELAMIPRETIDE) PRODUCT SUMMARY
11C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 12: ANNUAL REVIEW OF AMINO ACID DISORDER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HARLIKU™ (NITISINONE), ORFADIN® (NITISONE), NITYR® (NITISINONE), AND SEPHIENCE™ (SEPIAPTERIN)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF AMINO ACID DISORDER MEDICATIONS
12C: PRIOR AUTHORIZATION OF AMINO ACID DISORDER MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: PRODUCT SUMMARIES
12F: COST COMPARISON: PHENYLKETONURIA (PKU) PRODUCTS
12G: COLLEGE OF PHARMACY RECOMMENDATIONS
12H: UTILIZATION DETAILS OF AMINO ACID DISORDER MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 13: 30-DAY NOTICE TO PRIOR AUTHORIZE BRINSUPRI™ (BRENSOCATIB)
13A: INTRODUCTION
13B: BRINSUPRI™ (BRENSOCATIB) PRODUCT SUMMARY
13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ATOPIC DERMATITIS (AD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ANZUPGO® (DELGOCITINIB 2% CREAM)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA

14B: UTILIZATION OF AD MEDICATIONS
14C: PRIOR AUTHORIZATION OF AD MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: ANZUPGO® (DELGOCITINIB 2% CREAM) PRODUCT SUMMARY
14F: COST COMPARISONS
14G: COLLEGE OF PHARMACY RECOMMENDATIONS
14H: UTILIZATION DETAILS OF AD MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 15: ANNUAL REVIEW OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE OMLYCLO® (OMALIZUMAB-IGEC)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
15C: PRIOR AUTHORIZATION OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 16: 60-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
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: MARKET NEWS AND UPDATES
16C: PRODUCT SUMMARIES
16D: ESTIMATION OF SAVINGS
16E: 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. 17: 30-DAY NOTICE TO PRIOR AUTHORIZE RHAPSIDO® (REMIBRUTINIB)
17A: INTRODUCTION
17B: RHAPSIDO® (REMIBRUTINIB) PRODUCT SUMMARY
17C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 18: 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. 19: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
19A: ANTIDEPRESSANTS
19B: COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

19C: IMMUNE GLOBULIN INTRAVENOUS AND SUBCUTANEOUS PRODUCTS
19D: LYSOSOMAL STORAGE DISEASE MEDICATIONS
19E: SKIN CANCER MEDICATIONS
19F: THROMBOCYTOPENIA MEDICATIONS
*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 20:</u> NOMINATION AND APPROVAL OF DUR BOARD OFFICERS
20A: NOMINATION AND APPROVAL OF CHAIR
Dr. Kupiec nominated Dr. Haymore to remain Chair; seconded by Dr. Weakley
ACTION: MOTION CARRIED
20B: NOMINATION AND APPROVAL OF VICE CHAIR
Dr. Haymore nominated Dr. Patatanian to remain Vice Chair; seconded by Dr. Kupiec
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 21:</u> ADJOURNMENT
The meeting was adjourned at 6:04pm.

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

Memorandum

Date: November 14, 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 November 12, 2025

Recommendation 1: Approval of 2026 Drug Utilization Review (DUR) Board Meeting Dates

MOTION CARRIED by unanimous approval.

DUR Board meetings are held the second Wednesday of every month at 4:00pm at the Oklahoma Health Care Authority:

- January 14, 2026
- February 11, 2026
- March 11, 2026
- April 8, 2026
- May 13, 2026
- June 10, 2026
- July 8, 2026
- August 12, 2026
- September 9, 2026
- October 14, 2026
- November 12, 2026*
  *Scheduled for Thursday, November 12, 2026, due to the Veterans' Day holiday on Wednesday, November 11, 2026
- December 9, 2026

Recommendation 2: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 3: Hepatitis C Program Update

NO ACTION REQUIRED.

Recommendation 4: Vote to Prior Authorize Eliquis® (Apixaban) Tablet for Oral Suspension and Eliquis® Sprinkle (Apixaban) Capsule for Oral Suspension and Update the Approval Criteria for the Anticoagulants and Platelet Aggregation Inhibitors

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends coverage of Eliquis® (apixaban) tablet for oral suspension and Eliquis® Sprinkle (apixaban) capsule for oral suspension with an age restriction with the following criteria (shown in red):

Eliquis® (Apixaban) Tablet for Oral Suspension and Eliquis® Sprinkle (Apixaban) Capsule for Oral Suspension Approval Criteria:

1. Eliquis® tablet for oral suspension and Eliquis® Sprinkle capsule for oral suspension will not require prior authorization for members 10 years of age or younger. For members 11 years of age or older, a patient-specific, clinically significant reason why the member cannot use Eliquis® tablets must be provided; and
2. Clinical exceptions for the age restriction may be considered for approval (e.g., documented dysphagia, weight-based dose cannot be achieved with the tablet formulation).

Additionally, the College of Pharmacy recommends removing the prior authorization of Aggrenox® (aspirin/dipyridamole extended-release), making Brilinta® (ticagrelor) 60mg tablets brand preferred, and removing the brand preferred status from Pradaxa® (dabigatran) capsules based on net costs (changes shown in red):

~~**Aggrenox® (Aspirin/Dipyridamole Extended-Release) Approval Criteria:**~~

~~1. An FDA approved indication for the prophylaxis of recurrent thromboembolic stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis; and~~
~~2. Member must be 18 years of age or older; and~~
~~3. A patient-specific, clinically significant reason why the member cannot use immediate-release dipyridamole and over-the-counter (OTC) aspirin in place of Aggrenox® must be provided; and~~
~~4. A quantity limit of 60 capsules for a 30-day supply will apply.~~

Brilinta® (Ticagrelor) Approval Criteria:

1. The first 365 days of therapy with generic Brilinta® 90mg twice daily does not require prior authorization; and
2. After the first 365 days, a patient-specific, clinically significant reason for continuing the 90mg twice daily dosage will need to be provided or the member should be switched to the 60mg twice daily dosage; and
3. Brilinta® 60mg tablet is brand preferred. Requests for generic ticagrelor 60mg tablets will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. Approvals will be for the duration of 1 year.

Pradaxa® (Dabigatran) Approval Criteria:

1. Pradaxa® (dabigatran) capsules require the following:
    a. An FDA approved indication of 1 of the following:
        i. Non-valvular atrial fibrillation; or
        ii. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) after treatment with a parenteral anticoagulant for 5 to 10 days; or
        iii. To reduce the risk of recurrent DVT or PE in members who have been previously treated; or
        iv. For the prophylaxis of DVT and PE in members who have undergone hip replacement surgery; or
        v. Treatment of venous thromboembolic events (VTE) in pediatric members 8 to 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; or
        vi. To reduce the risk of recurrent VTE in pediatric members 8 to 18 years of age who have been previously treated.
    b. A patient-specific, clinically significant reason why the member cannot use Eliquis® (apixaban) and Xarelto® (rivaroxaban) must be provided. ~~; and~~
    ~~c. Requests for generic dabigatran capsules will require a patient-specific, clinically significant reason why brand name Pradaxa® cannot be used.~~
2. Pradaxa® (dabigatran) oral pellets require the following:
    a. An FDA approved indication of 1 of the following:
        i. Treatment of VTE in members who have been treated with a parenteral anticoagulant for at least 5 days; or
        ii. To reduce the risk of recurrent VTE in members who have been previously treated; and
    b. Member must be 3 months of age or older; and
    c. Members older than 7 years of age require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
    d. A patient-specific, clinically significant reason why the member cannot use Xarelto® (rivaroxaban) oral suspension must be provided.

Recommendation 5: Vote to Prior Authorize Avtozma® (Tocilizumab-anoh), Imuldosa® (Ustekinumab-srlf), Otezla XR™ [Apremilast Extended-Release (ER)], Starjemza™ (Ustekinumab-hmny), Steqeyma® (Ustekinumab-stba), and Yesintek™ (Ustekinumab-kfce) and Update the Approval Criteria for the Targeted Immunomodulator Agents

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following additions and changes to the Targeted Immunomodulator Agents 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 Imuldosa® (ustekinumab-srlf), Starjemza™ (ustekinumab-hmny), branded Steqeyma® (ustekinumab-stba), and Yesintek™ (ustekinumab-kfce) into Tier-2 based on net costs; and
2. Moving branded Pyzchiva® (ustekinumab-ttwe) and branded Selarsdi™ (ustekinumab-aekn) from the Special PA Tier to Tier-2 and updating the ustekinumab approval criteria based on net costs; and
3. Prior authorization and placement of Avtozma® (tocilizumab-anoh) and Otezla XR™ (apremilast ER) into the Special PA Tier; and
4. Placement of Gamifant® (emapalumab-lzsg) into the Special PA Tier and updating the approval criteria for Gamifant® based on the recent FDA approved indication; and
5. Updating the approval criteria for Bimzelx® (bimekizumab-bkzx) and Rinvoq® (upadacitinib) based on recent FDA approved indications; and
6. Indicating that Hadlima™ (adalimumab-bwwd) and Tyenne® (tocilizumab-aazg) are preferred only for the branded formulations, similar to Humira® (adalimumab), and placing the unbranded Humira® (adalimumab), Hadlima™ (adalimumab-bwwd), and Tyenne® (tocilizumab-aazg) products into the Special PA Tier; and
7. Moving unbranded Hyrimoz® (adalimumab-adaz), unbranded Hulio® (adalimumab-fkjp), and branded Simlandi® (adalimumab-ryvk) to Tier-2 and updating the adalimumab approval criteria based on net costs and based on current FDA approved indications for HS and uveitis; and
    a. Note: These changes are to be implemented on 01/01/2026; and
8. Moving unbranded Remicade® (infliximab) from Tier-3 to Tier-2 and updating the infliximab approval criteria based on net cost; and
9. Updating the rituximab and tocilizumab approval criteria based on the current FDA approved indications for the biosimilar products; and
10. Updating the Entyvio® (vedolizumab) approval criteria based on net cost and currently available Tier-2 options for CD and UC.

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
6-mercaptopurine	adalimumab (Humira®)+± **- Branded Only**	abatacept (Orencia®, Orencia® ClickJect™)¤	**adalimumab (Humira®)+± - Unbranded Only**
azathioprine	**adalimumab-adaz (Hyrimoz®)+± - Unbranded Only**	certolizumab pegol (Cimzia®)	adalimumab-aacf (Idacio®)+±
hydroxychloroquine	adalimumab-aqvh (Yusimry®)+±	deucravacitinib (Sotyktu®)	adalimumab-aaty (Yuflyma®)+±
leflunomide	adalimumab-bwwd (Hadlima™)+± **- Branded Only**	golimumab (Simponi®, Simponi Aria®)	adalimumab-adaz (Hyrimoz®)+± **- Branded Only**
mesalamine	**adalimumab-fkjp (Hulio®)+± - Unbranded Only**	infliximab (Remicade®)± **- Branded Only**	adalimumab-adbm (Cyltezo®)+±
methotrexate	**adalimumab-ryvk (Simlandi®)+± - Branded Only**	infliximab-abda (Renflexis®)±	adalimumab-afzb (Abrilada™)+±
minocycline	anakinra (Kineret®)	infliximab-axxq (Avsola®)±	adalimumab-atto (Amjevita®)+±
NSAIDs	apremilast (Otezla®)ß	sarilumab (Kevzara®)§	**adalimumab-bwwd (Hadlima™)+± - Unbranded Only**
oral corticosteroids	etanercept (Enbrel®)±	tocilizumab-aazg (Tyenne®)± **- Branded Only**	adalimumab-fkjp (Hulio®)+± **- Branded Only**
sulfasalazine	**infliximab (Remicade®)± - Unbranded Only**	tofacitinib (Xeljanz®, Xeljanz® XR, Xeljanz® oral solution)**	adalimumab-ryvk (Simlandi®)+± **- Unbranded Only**
topical corticosteroids	infliximab-dyyb (Inflectra®)±	vedolizumab intravenous (IV) (Entyvio®)**	anifrolumab-fnia (Saphnelo®)**
	rituximab (Rituxan®)~±		**apremilast ER (Otezla XR™)ß**
	rituximab-abbs (Truxima®)±		avacopan (Tavneos®)**
	rituximab-arrx (Riabni®)±		baricitinib (Olumiant®)€
	rituximab-pvvr (Ruxience®)±		belimumab (Benlysta®)**
	ustekinumab-aekn (Selarsdi™)± - Branded Only		bimekizumab-bkzx (Bimzelx®)Δ
	ustekinumab-hmny (Starjemza™)±		brodalumab (Siliq®)**
	ustekinumab-kfce (Yesintek™)±		canakinumab (Ilaris®)¥
	ustekinumab-srlf (Imuldosa®)±		deuruxolitinib (Leqselvi™)€

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
	ustekinumab-stba (Steqeyma®)± - Branded Only		**emapalumab-lzsg (Gamifant®)****
	ustekinumab-ttwe (Pyzchiva®)± - Branded Only		etanercept-szzs (Erelzi®)±
			etanercept-ykro (Eticovo®)±
			etrasimod (Velsipity®)
			guselkumab (Tremfya®)
			infliximab-dyyb (Zymfentra®)±
			ixekizumab (Taltz®)
			mirikizumab-mrkz (Omvoh®)
			rilonacept (Arcalyst®)**
			risankizumab-rzaa (Skyrizi®)
			ritlecitinib (Litfulo®)€
			secukinumab (Cosentyx®)Δ
			spesolimab-sbzo (Spevigo®)**
			tildrakizumab-asmn (Ilumya®)
			tocilizumab (Actemra®)π±
			tocilizumab-aazg (Tyenne®)± - Unbranded Only
			tocilizumab-anoh (Avtozma®)±
			tocilizumab-bavi (Tofidence™)±
			upadacitinib (Rinvoq®, Rinvoq® LQ)#
			ustekinumab (Stelara®)±
			ustekinumab-aauz (Otulfi®)±
			ustekinumab-aekn (Selarsdi™)± **- Unbranded Only**
			ustekinumab-auub (Wezlana™)±
			ustekinumab-stba (Steqeyma®)± - Unbranded Only
			vedolizumab subcutaneous (sub-Q) (Entyvio®)**
			voclosporin (Lupkynis®)**

DMARDs = disease modifying anti-rheumatic drugs; **ER = extended-release;** NSAIDs = nonsteroidal anti-inflammatory drugs

*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). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to participate in supplemental rebates.
±Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.
+Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.
ß Unique criteria applies for a diagnosis of Behçet's disease (BD).
¥Unique criteria applies for a diagnosis of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor-associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), familial Mediterranean fever (FMF), systemic juvenile idiopathic arthritis (SJIA), adult-onset Still's disease (AOSD), or gout flare.
~Unique criteria applies for a diagnosis of pemphigus vulgaris (PV). Unique criteria applies for a diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).
πUnique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS), and systemic sclerosis-associated interstitial lung disease (SSc-ILD).
¤Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.
#Unique criteria applies for **Rinvoq® LQ** or for a diagnosis of atopic dermatitis (AD) or **giant cell arteritis (GCA)**.
€Unique criteria applies for a diagnosis of alopecia areata.
§Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).
ΔUnique criteria applies for a diagnosis of hidradenitis suppurativa (HS).
**Unique criteria applies to this medication for approval.

Abrilada™ (Adalimumab-afzb), Amjevita® (Adalimumab-atto), Cyltezo® (Adalimumab-adbm), Unbranded Hadlima™ (Adalimumab-bwwd), Branded Hulio® (Adalimumab-fkjp), Unbranded Humira® (Adalimumab), Branded Hyrimoz® (Adalimumab-adaz), Idacio® (Adalimumab-aacf), Unbranded Simlandi® (Adalimumab-ryvk), and Yuflyma® (Adalimumab-aaty) Approval Criteria:

1. For a diagnosis of hidradenitis suppurativa (HS) or uveitis, the member must meet the unique adalimumab approval criteria for those indications; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason why the member cannot use ~~Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry® (adalimumab-aqvh)~~ a preferred Tier-2 adalimumab product 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.

Abrilada™ (Adalimumab-afzb), Amjevita® (Adalimumab-atto), Cyltezo® (Adalimumab-adbm), Hadlima™ (Adalimumab-bwwd), Hulio® (Adalimumab-fkjp), Humira® (Adalimumab), Hyrimoz® (Adalimumab-adaz), Idacio® (Adalimumab-aacf), Simlandi® (Adalimumab-ryvk), Yuflyma® (Adalimumab-aaty), and Yusimry® (Adalimumab-aqvh) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
4. Previous failure of at least 2 of the following categories:
    a. Topical or systemic antibiotics; or
    b. Oral or intralesional corticosteroids; or
    c. Dapsone; or
    d. Cyclosporine; or
    e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
    f. Finasteride; or
    g. Surgery; and
5. For Special Prior Authorization (PA) adalimumab products, a patient-specific, clinically significant reason why the member cannot use a preferred Tier-2 adalimumab product 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.

Abrilada™ (Adalimumab-afzb), Amjevita® (Adalimumab-atto), Cyltezo® (Adalimumab-adbm), Hadlima™ (Adalimumab-bwwd), Hulio® (Adalimumab-fkjp), Humira® (Adalimumab), Hyrimoz® (Adalimumab-adaz), Idacio® (Adalimumab-aacf), Simlandi® (Adalimumab-ryvk), Yuflyma® (Adalimumab-aaty), and Yusimry® (Adalimumab-aqvh) Approval Criteria [Noninfectious Intermediate and Posterior Uveitis or Panuveitis Diagnosis]:

1. Diagnosis of noninfectious intermediate uveitis, posterior uveitis, or panuveitis in members 2 years of age and older; and
2. A failed trial with a corticosteroid injection or systemic corticosteroid in which member has had an inadequate response; or
3. A patient-specific, clinically significant reason why a trial of corticosteroid treatment is inappropriate for the member must be provided; and
4. For Special Prior Authorization (PA) adalimumab products, a patient-specific, clinically significant reason why the member cannot use a preferred Tier-2 adalimumab product 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.

Actemra® (Tocilizumab), Avtozma® (Tocilizumab-anoh), ~~and~~ Tofidence™ (Tocilizumab-bavi), and Unbranded Tyenne® (Tocilizumab-aazg) Approval Criteria:

1. For a diagnosis of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS), giant cell arteritis (GCA), or systemic sclerosis-associated interstitial lung disease (SSc-ILD), the member must meet the unique tocilizumab approval criteria for those indications; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason why the member cannot use branded Tyenne® (tocilizumab-aazg) 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.

Actemra® (Tocilizumab), Avtozma® (Tocilizumab-anoh), and Tyenne® (Tocilizumab-aazg) Approval Criteria [Chimeric Antigen Receptor (CAR) T Cell-Induced Cytokine Release Syndrome (CRS) Diagnosis]:

1. An FDA approved diagnosis of CAR T cell-induced CRS; and
2. Requests for Actemra®, Avtozma®, or unbranded Tyenne® will require a patient-specific, clinically significant reason why the member cannot use branded Tyenne®. 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.

Actemra® (Tocilizumab), Avtozma® (Tocilizumab-anoh), Tofidence™ (Tocilizumab-bavi), and Tyenne® (Tocilizumab-aazg) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. History of erythrocyte sedimentation rate (ESR) of ≥30mm/hr or a history of C-reactive protein (CRP) ≥1mg/dL; and
4. Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and
5. Must be taken in combination with a tapering course of corticosteroids upon initiation; and
6. Member must have baseline liver enzymes, absolute neutrophil count (ANC), lipid panel, and platelet count and verification that they are acceptable to prescriber; and
7. Member must not have severe hepatic impairment; and

8. Should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
9. Requests for Actemra®, Avtozma®, ~~or~~ Tofidence™, or unbranded Tyenne® will require a patient-specific, clinically significant reason why the member cannot use branded Tyenne®. 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
10. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Avsola® (Infliximab-axxq), Branded Remicade® (Infliximab), and Renflexis® (Infliximab-abda) Approval Criteria:

1. Member must meet Tier-3 trial requirements; and
2. A patient-specific, clinically significant reason why the member cannot use Inflectra® (infliximab-dyyb) and unbranded Remicade® (infliximab) 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.

Bimzelx® (Bimekizumab-bkzx) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
4. Previous failure of at least 2 of the following categories:
    a. Topical or systemic antibiotics; or
    b. Oral or intralesional corticosteroids; or
    c. Dapsone; or
    d. Cyclosporine; or
    e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
    f. Finasteride; or
    g. Surgery; and
5. Previous failure of a preferred Tier-2 adalimumab product for at least 12 weeks at recommended dosing (or documented intolerance); and
6. A patient-specific, clinically significant reason why the member cannot use Cosentyx® (secukinumab) must be provided.

Cosentyx® (Secukinumab) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and

3. Member must have at least ~~5~~ 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
4. Previous failure of at least 2 of the following categories:
    a. Topical or systemic antibiotics; or
    b. Oral or intralesional corticosteroids; or
    c. Dapsone; or
    d. Cyclosporine; or
    e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
    f. Finasteride; or
    g. Surgery; and
5. Previous failure of ~~Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry® (adalimumab-aqvh)~~ a preferred Tier-2 adalimumab product for at least 12 weeks at recommended dosing (or documented intolerance).

Entyvio® (Vedolizumab) Subcutaneous (Sub-Q) Formulation Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. ~~An FDA approved diagnosis of moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); and~~
3. ~~Member must be 18 years of age or older; and~~
4. ~~A minimum of a 4 week trial of a Tier-2 tumor necrosis factor (TNF) blocker medications indicated for the treatment of CD or UC that did not yield adequate relief of symptoms or resulted in intolerable adverse effects. Current Tier-2 medications include the following:~~
    ~~a. CD: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or~~
    ~~b. UC: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or~~
5. ~~Prior stabilization on the medication documented within the last 100 days; and~~
6. For Entyvio® sub-Q administration, member must have received at least 2 initial intravenous (IV) doses of Entyvio®; and
    a. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue to use the IV formulation must be provided; and
7. A quantity limit of ~~300mg every 8 weeks will apply for the IV formulation and~~ 108mg every 2 weeks will apply for the sub-Q formulation~~. Approvals will be granted for titration quantities required for initial dosing~~; and
8. Initial approvals will be for the duration of 14 weeks as Entyvio® should be discontinued in patients who do not show evidence of therapeutic benefit by week 14.

Gamifant® (Emapalumab-lzsg) Approval Criteria [Hemophagocytic Lymphohistiocytosis (HLH)/ Macrophage Activation Syndrome (MAS) in Still's Disease Diagnosis]:

1. An FDA approved indication for the treatment of adult and pediatric members with HLH/MAS in Still's Disease; and
2. Member must have a confirmed or suspected diagnosis of systemic juvenile idiopathic arthritis (sJIA) or adult-onset Still's disease (AOSD); and
3. Member must have active MAS confirmed by ferritin >684ng/mL and at least 2 of the following:
   a. Platelet count ≤181 x 10^9/L; or
   b. Aspartate aminotransferase (AST) >48U/L; or
   c. Triglycerides >156mg/dL; or
   d. Fibrinogen levels ≤360mg/dL; and
4. Member meets 1 of the following:
   a. Member has had an inadequate response or intolerance to high-dose intravenous (IV) glucocorticoids; or
   b. Member has recurrent MAS; and
5. Must be prescribed by, or in consultation with, a rheumatologist, immunologist, or other specialist with expertise in the treatment of HLH/MAS; and
6. Prescriber must verify member has received or will receive prophylaxis for herpes zoster, *Pneumocystis jirovecii,* and fungal infection(s), if appropriate; and
7. Prescriber must verify member will be monitored for tuberculosis (TB), herpes zoster, adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) as clinically indicated; and
8. 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
9. Approvals will be for the duration of 6 months with reauthorization granted if the prescriber documents the member is responding well to treatment, no unacceptable toxicity has occurred, and the member requires continued treatment for HLH/MAS.

Otezla XR™ [Apremilast Extended-Release (ER)] Approval Criteria:

1. For a diagnosis of Behçet's disease (BD), the member must meet the unique apremilast approval criteria for that indication; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue using the immediate-release formulation of apremilast must be provided.

Otezla® (Apremilast) and Otezla XR™ [Apremilast Extended-Release (ER)] Approval Criteria [Behçet's Disease (BD) Diagnosis]:

1. An FDA approved indication for the treatment of oral ulcers associated with BD; and
2. Member must have had oral ulcers at least 3 times in the last 12 month period; and
3. Member must have had a 2 week trial of the following that resulted in inadequate efficacy or intolerable adverse effects (or be contraindicated for the member):
   a. Topical corticosteroids (applied topically to the mouth); and
   b. Colchicine; and
4. For Otezla XR™, a patient-specific, clinically significant reason (beyond convenience) why the member cannot continue using the immediate-release formulation of apremilast must be provided; and
5. Quantity limits according to package labeling will apply.

Otulfi® (Ustekinumab-aauz), Unbranded Pyzchiva® (Ustekinumab-ttwe), Unbranded Selarsdi™ (Ustekinumab-aekn), Stelara® (Ustekinumab), Unbranded Steqeyma® (Ustekinumab-stba), and Wezlana™ (Ustekinumab-auub) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use ~~Stelara® (ustekinumab)~~ Imuldosa® (ustekinumab-srlf), branded Pyzchiva® (ustekinumab-ttwe), branded Selarsdi™ (ustekinumab-aekn), Starjemza™ (ustekinumab-hmny), branded Steqeyma® (ustekinumab-stba), and Yesintek™ (ustekinumab-kfce) 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
3. Additionally, initial and continuation requests for branded Stelara® will require a patient-specific, clinically significant reason why unbranded Stelara® cannot be used.

Riabni® (Rituximab-arrx), Rituxan® (Rituximab), Ruxience® (Rituximab-pvvr), and Truxima® (Rituximab-abbs) Approval Criteria [Granulomatosis with Polyangiitis (GPA, Wegener's Granulomatosis) or Microscopic Polyangiitis (MPA) Diagnosis]:

1. An FDA approved diagnosis of GPA or MPA in adult and pediatric members 2 years of age and older; and
2. ~~Rituxan®~~ Must be used in combination with corticosteroids; and
3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Riabni® (Rituximab-arrx), Rituxan® (Rituximab), Ruxience® (Rituximab-pvvr), and Truxima® (Rituximab-abbs) Approval Criteria [Pemphigus Vulgaris (PV) Diagnosis]:

1. Diagnosis of moderate-to-severe PV; and
2. ~~Rituxan®~~ Must be used in combination with a tapering course of corticosteroids; and
3. Initial approvals will be for (2) 1,000mg intravenous (IV) infusions separated by 2 weeks and a 500mg IV infusion at month 12. Subsequent approvals may be authorized based on 6-month evaluations or upon relapse no sooner than 16 weeks after the previous infusion.

Rinvoq® (Upadacitinib) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. History of erythrocyte sedimentation rate (ESR) of ≥30mm/hr or a history of C-reactive protein (CRP) ≥1mg/dL; and
4. Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and
5. Must be taken in combination with a tapering course of corticosteroids upon initiation; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling; and
7. A trial of branded Tyenne® (tocilizumab-aazg) used in combination with a tapering course of corticosteroids or a patient-specific, clinically significant reason why the member cannot use branded Tyenne® must be provided; and
8. Approvals will be for a dose of 15mg once daily and a quantity limit of 30 tablets per 30 days will apply.

Recommendation 6: Fiscal Year 2025 Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Boruzu® (Bortezomib) and Lynozyfic™ (Linvoseltamab-gcpt)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 7: Fiscal Year 2025 Annual Review of Bone Density Regulators and 30-Day Notice to Prior Authorize Bildyos® (Denosumab-nxxp), Bilprevda® (Denosumab-nxxp), Bomyntra® (Denosumab-bnht), Conexxence® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), and Stoboclo® (Denosumab-bmwo)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 8: 30-Day Notice to Prior Authorize Forzinity™ (Elamipretide)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 9: Fiscal Year 2025 Annual Review of Amino Acid Disorder Medications and 30-Day Notice to Prior Authorize Harliku™ (Nitisinone), Orfadin® (Nitisinone), Nityr® (Nitisinone), and Sephience™ (Sepiapterin)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 10: 30-Day Notice to Prior Authorize Brinsupri™ (Brensocatib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 11: Fiscal Year 2025 Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Anzupgo® (Delgocitinib 2% Cream)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 12: Fiscal Year 2025 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Omlyclo® (Omalizumab-igec)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 13: 60-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 14: 30-Day Notice to Prior Authorize Rhapsido® (Remibrutinib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER 2025.

Recommendation 15: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 16: Future Business

NO ACTION REQUIRED.

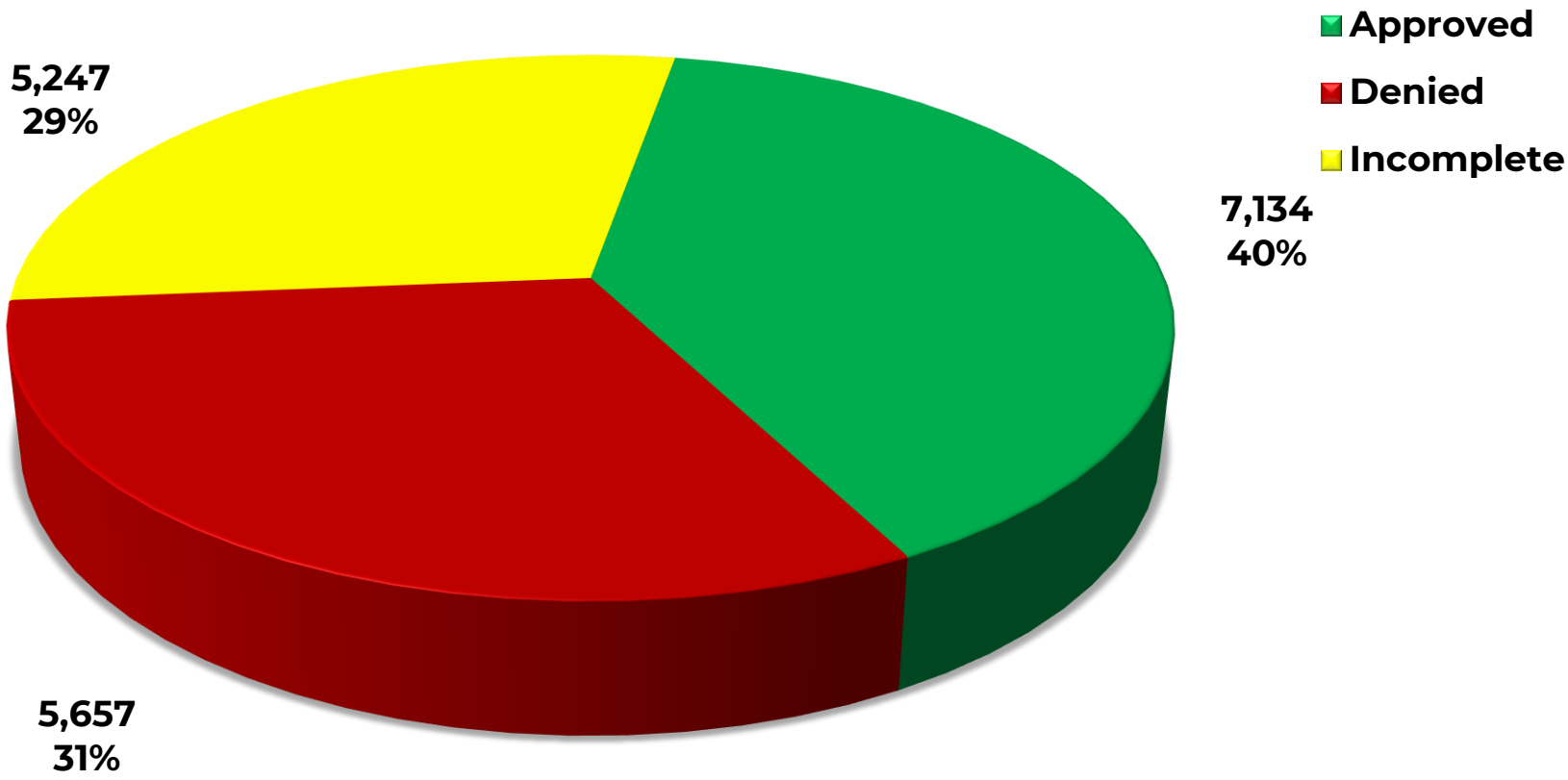
Recommendation 17: Nomination of DUR Board Officers

MOTION(S) CARRIED by unanimous approval.

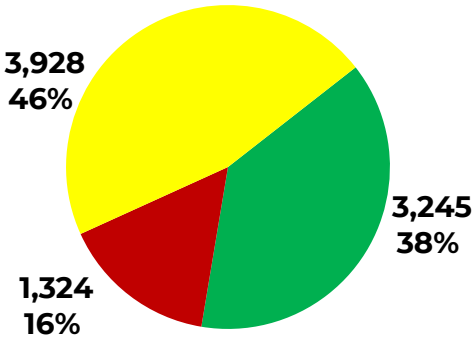
- Dr. Haymore nominated and confirmed as chair.
- Dr. Patatanian nominated and confirmed as vice chair.

Appendix B

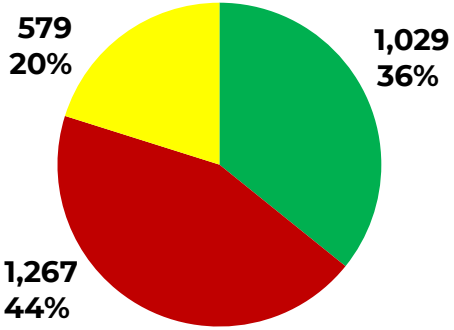
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: NOVEMBER 2025



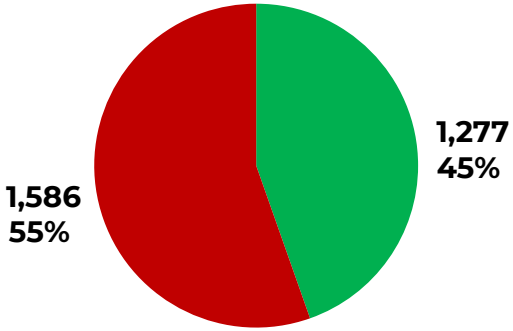
SoonerCare FFS



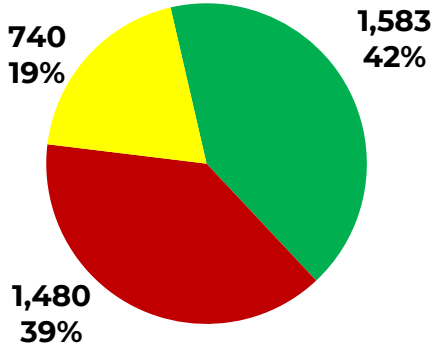
SoonerSelect Aetna



SoonerSelect Humana

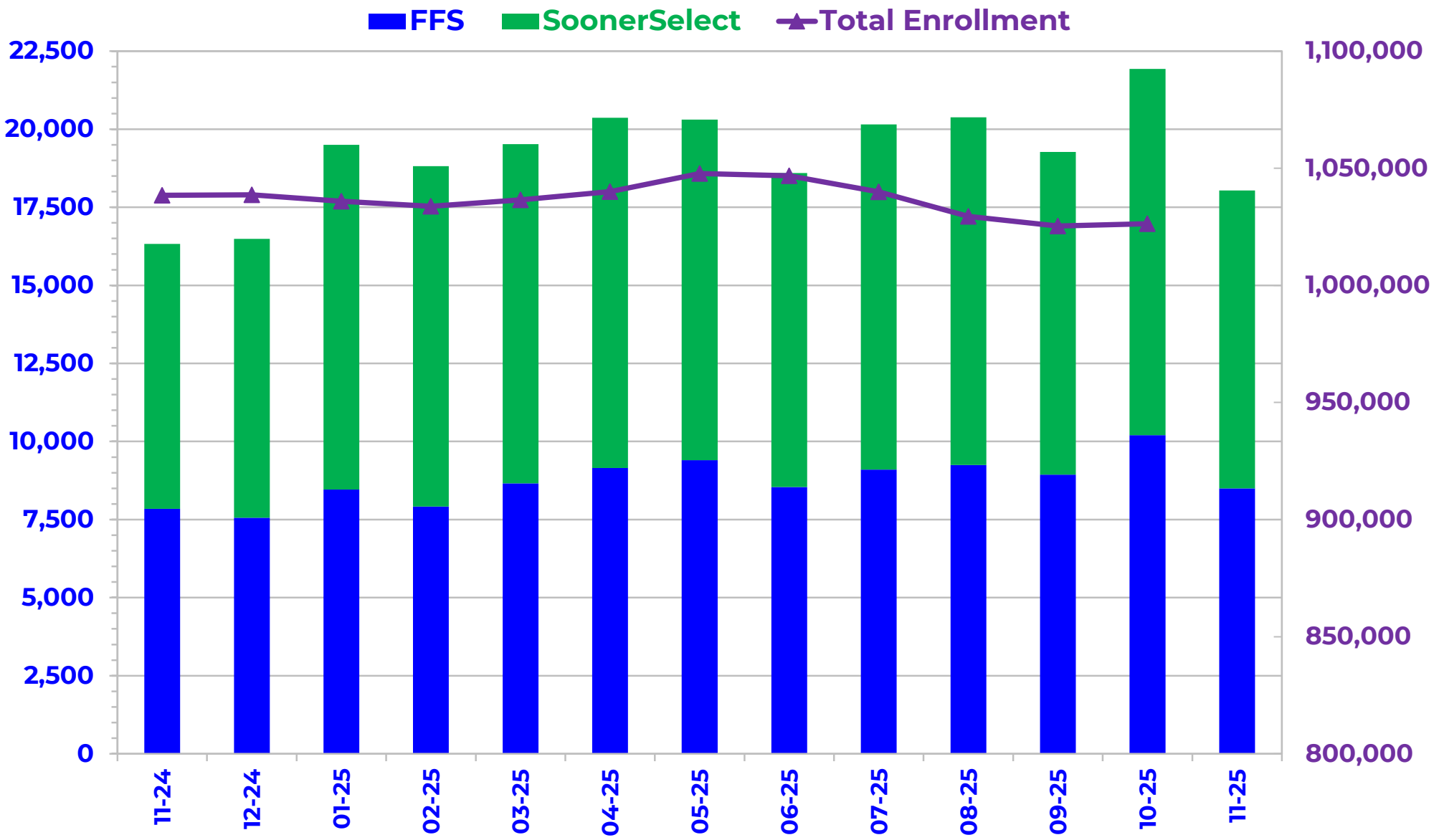


SoonerSelect OK Complete Health



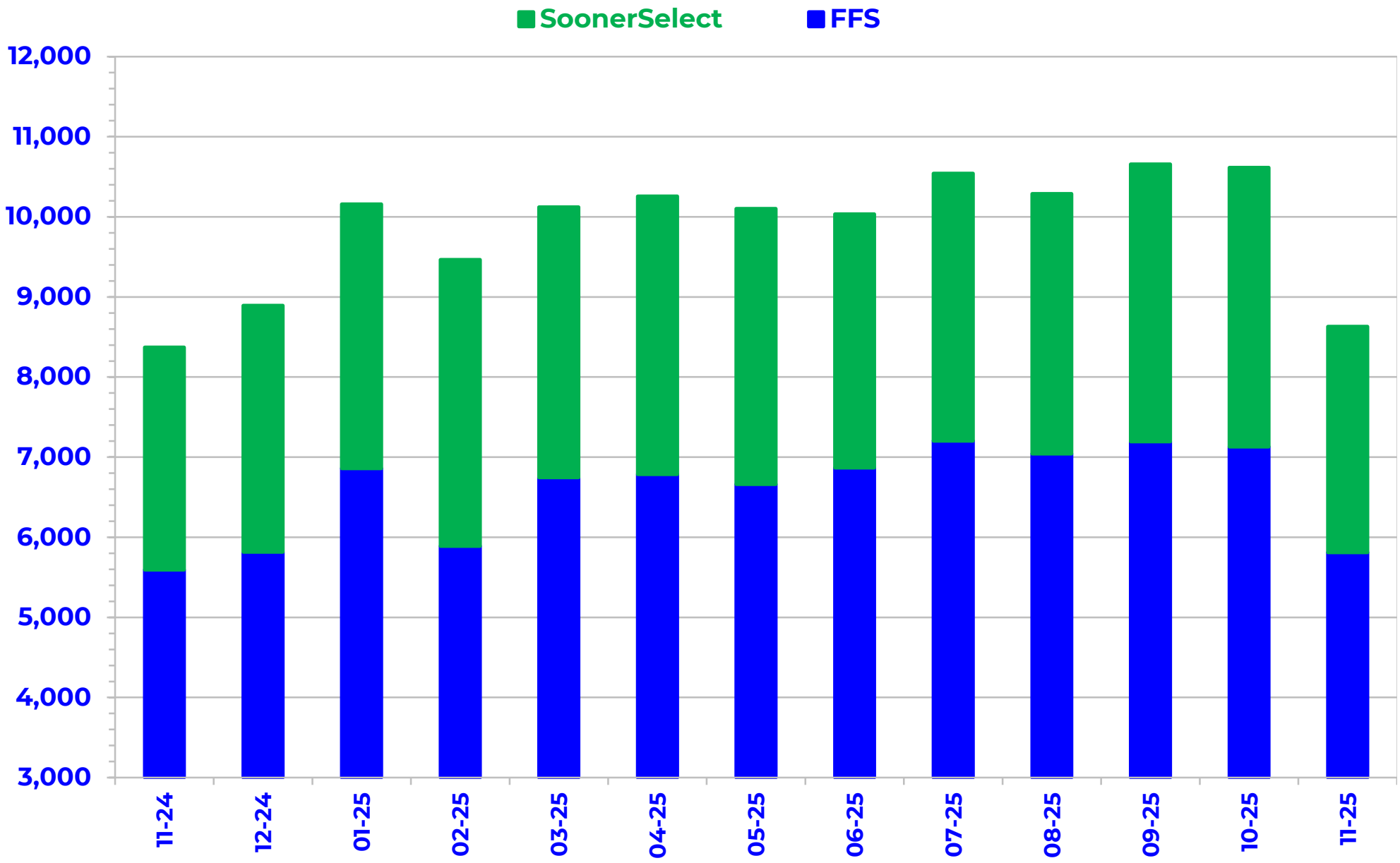
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: NOVEMBER 2024 – NOVEMBER 2025



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: NOVEMBER 2024 – NOVEMBER 2025



SoonerCare FFS Prior Authorization Activity

11/1/2025 Through 11/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	7	1	3	3	201
Amphetamines	749	348	58	343	350
Analgesics - Anti-Inflammatory	200	80	26	94	296
Analgesics - Nonnarcotic	7	0	0	7	0
Analgesics - Opioid	275	137	23	115	135
Androgens - Anabolic	70	13	17	40	356
Antacids	2	1	0	1	0
Anthelmintics	9	0	0	9	0
Anti-Infective Agents - Misc.	29	2	13	14	185
Anti-Obesity Agents	108	8	80	20	149
Antianxiety Agents	25	1	3	21	360
Antiasthmatic and Bronchodilator Agents	475	103	79	293	520
Antibiotics	28	11	2	15	233
Anticoagulants	17	0	3	14	0
Anticonvulsants	194	103	5	86	377
Antidepressants	201	62	26	113	433
Antidiabetics	1,218	389	236	593	374
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antidotes and Specific Antagonists	6	5	0	1	357
Antiemetics	18	3	2	13	159
Antifungals	9	2	0	7	130
Antihistamines	20	2	6	12	359
Antihyperlipidemics	50	17	10	23	365
Antihypertensives	25	6	4	15	558
Antimyasthenic/Cholinergic Agents	5	1	2	2	361
Antineoplastics and Adjunctive Therapies	165	102	12	51	182
Antiparkinson and Related Therapy Agents	2	1	0	1	1091
Antipsychotics/Antimanic Agents	285	113	24	148	382
Antivirals	35	12	4	19	47
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	197	123	10	64	957
Beta Blockers	8	4	0	4	906
Calcium Channel Blockers	10	1	3	6	1091
Cardiovascular Agents - Misc.	103	51	10	42	352
Contraceptives	15	8	2	5	359
Corticosteroids	12	5	3	4	149
Dermatologicals	466	130	140	196	246
Diagnostic Products	62	25	3	34	192
Dietary Products/Dietary Management Products	1	0	1	0	0
Digestive Aids	6	3	1	2	360
Diuretics	17	7	1	9	750
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	9	0	3	6	0
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	183	84	27	72	237

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogens	2	0	0	2	0
Gastrointestinal Agents - Misc.	277	84	61	132	242
Genitourinary Agents - Misc.	4	1	1	2	355
Gout Agents	5	2	2	1	360
Hematological Agents - Misc.	17	6	0	11	258
Hematopoietic Agents	41	16	11	14	114
Histamine H3-receptor Antagonist/Inverse Agonists	3	1	0	2	363
Hypnotics/Sedatives/Sleep Disorder Agents	52	7	6	39	175
Laxatives	20	6	3	11	127
Medical Devices and Supplies	266	49	58	159	262
Migraine Products	412	100	97	215	224
Minerals and Electrolytes	6	2	1	3	190
Miscellaneous Therapeutic Classes	71	22	9	40	342
Multivitamins	6	5	0	1	355
Musculoskeletal Therapy Agents	29	6	5	18	186
Nasal Agents - Systemic and Topical	16	0	5	11	0
Neuromuscular Agents	62	34	13	15	227
Nutrients	1	1	0	0	361
Ophthalmic Agents	64	15	10	39	76
Other*	46	17	4	25	171
Otic Agents	27	4	4	19	24
Pharmaceutical Adjuvants	2	2	0	0	273
Progestins	4	0	2	2	0
Psychotherapeutic and Neurological Agents - Misc.	233	74	40	119	226
Respiratory Agents - Misc.	28	18	3	7	338
Stimulants - Misc.	223	105	12	106	352
Thyroid Agents	5	0	2	3	0
Ulcer Drugs/Antispasmodics/Anticholinergics	64	8	18	38	781
Urinary Antispasmodics	46	7	11	28	568
Vaccines	1	0	0	1	0
Vaginal and Related Products	2	0	0	2	0
Vitamins	30	3	22	5	206
Total	**7,389**	**2,559**	**1,242**	**3,588**	

Overrides					
Brand	18	7	0	11	539
Compound	18	14	0	4	12
Cumulative Early Refill	1	1	0	0	180
Diabetic Supplies	1	1	0	0	6
Dosage Change	176	155	1	20	16
Ingredient Duplication	2	2	0	0	100
Lost/Broken Rx	60	53	1	6	34
MAT Override	16	10	0	6	89
NDC vs Age	153	91	29	33	474
NDC vs Sex	6	4	2	0	359

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Nursing Home Issue	100	77	5	18	15
Opioid MME Limit	90	14	6	70	176
Opioid Quantity	19	8	1	10	130
Other	40	32	0	8	44
Quantity vs Days Supply	330	180	28	122	346
STBS/STBSM	14	9	1	4	122
Step Therapy Exception	17	2	6	9	725
Stolen	6	4	2	0	16
Third Brand Request	40	21	0	19	31
Wrong D.S. on Previous Rx	1	1	0	0	25
Overrides Total	**1,108**	**686**	**82**	**340**	
Total Regular PAs + Overrides	**8,497**	**3,245**	**1,324**	**3,928**	

Denial Reasons	
Unable to verify required trials.	3,353
Does not meet established criteria.	1,346
Lack required information to process request.	541
Other PA Activity	
Duplicate Requests	1,046
Letters	36,809
No Process	4
Helpdesk Initiated Prior Authorizations	323
PAs Missing Information	278
Pharmacotherapy	51
Changes to Existing PAs	557

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

SoonerSelect Aetna Prior Authorization Activity

11/1/2025 Through 11/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amebicides	1	1	0	0	30
Amphetamines	205	129	61	15	384
Analgesics - Anti-Inflammatory	142	89	24	29	473
Analgesics - Nonnarcotic	23	1	4	18	61
Analgesics - Opioid	110	55	37	18	206
Androgens - Anabolic	46	7	38	1	511
Anorectal and Related Products	1	0	0	1	0
Anthelmintics	7	1	6	0	30
Antianginal Agents	2	0	0	2	0
Antianxiety Agents	19	7	5	7	269
Antiasthmatic and Bronchodilator Agents	131	32	78	21	369
Antibiotics	11	1	0	10	99
Anticoagulants	1	0	0	1	0
Anticonvulsants	37	14	14	9	410
Antidepressants	140	42	67	31	543
Antidiabetics	441	142	240	59	366
Antidotes and Specific Antagonists	8	0	0	8	0
Antiemetics	26	3	2	21	253
Antifungals	1	0	1	0	0
Antihistamines	15	3	10	2	543
Antihyperlipidemics	35	2	22	11	365
Antihypertensives	13	2	1	10	365
Anti-Infective Agents - Misc.	4	1	0	3	30
Antineoplastics and Adjunctive Therapies	12	5	1	6	299
Anti-Obesity Agents	92	3	78	11	70
Antiparkinson and Related Therapy Agents	3	1	1	1	1096
Antipsychotics/Antimanic Agents	107	32	51	24	410
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	61	43	17	1	721
Beta Blockers	13	1	1	11	365
Calcium Channel Blockers	9	0	3	6	0
Cardiovascular Agents - Misc.	38	13	16	9	421
Chemicals	1	1	0	0	10
Contraceptives	10	1	5	4	365
Corticosteroids	24	13	2	9	273
Dermatologicals	245	108	97	40	237
Diagnostic Products	32	20	7	5	419
Dietary Products/Dietary Management Products	2	1	0	1	92
Digestive Aids	2	2	0	0	365
Diuretics	9	3	1	5	365
Endocrine and Metabolic Agents - Misc.	26	11	14	1	346
Estrogens	10	4	4	2	547
Gastrointestinal Agents - Misc.	92	37	48	7	329
General Anesthetics	16	0	0	16	0
Genitourinary Agents - Misc.	2	2	0	0	273
Gout Agents	4	1	2	1	365
Hematological Agents - Misc.	1	1	0	0	181
Hematopoietic Agents	8	3	3	2	365
Hypnotics/Sedatives/Sleep Disorder Agents	28	2	17	9	273

*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	14	2	9	3	365
Local Anesthetics-Parenteral	16	0	0	16	0
Medical Devices and Supplies	76	20	34	22	355
Migraine Products	153	45	100	8	204
Minerals and Electrolytes	6	3	0	3	365
Miscellaneous Therapeutic Classes	21	20	1	0	318
Multivitamins	3	1	1	1	365
Musculoskeletal Therapy Agents	37	7	13	17	70
Nasal Agents - Systemic and Topical	6	0	2	4	0
Neuromuscular Agents	18	5	3	10	253
Ophthalmic Agents	22	10	9	3	391
Other	10	4	2	4	364
Otic Agents	9	1	8	0	30
Passive Immunizing and Treatment Agents	3	1	0	2	365
Progestins	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	28	14	14	0	372
Respiratory Agents - Misc.	6	3	1	2	638
Stimulants - Misc.	82	41	31	10	411
Thyroid Agents	1	0	0	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	48	7	20	21	283
Urinary Antispasmodics	16	2	13	1	365
Vaccines	2	2	0	0	105
Vaginal and Related Products	2	0	0	2	0
Vitamins	29	1	28	0	365
****Total**	**2,875**	**1,029**	**1,267**	**579**	

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

Overrides					
Other	657	78	0	579	339
Quantity Level Limit	20	20	0	0	447
Step Therapy Met	3	3	0	0	142
Overrides Total	**680**	**101**	**0**	**579**	

Denial Reason	
Benefit	71
Experimental/Investigational	124
Lack Required Infomation to Process Request	82
Medical Necessity	990
Other PA Activity	
Duplicate Requests	20
Letters	3,634
No Process	200
Changes to existing PAs	0
Helpdesk initiated PA	2
PAs missing info	6

*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

11/1/2025 Through 11/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	5	2	3	0	137
Amphetamines	2	0	2	0	0
Analgesics - Anti-Inflammatory	74	57	17	0	327
Analgesics - Nonnarcotic	1	0	1	0	0
Analgesics - Opioid	46	27	19	0	261
Androgens - Anabolic	44	14	30	0	214
Anthelmintics	5	2	3	0	365
Antiasthmatic and Bronchodilator Agents	83	42	41	0	245
Antibiotics	6	2	4	0	365
Anticonvulsants	12	8	4	0	443
Antidepressants	64	36	28	0	259
Antidiabetics	215	75	140	0	285
Antidotes and Specific Antagonists	1	1	0	0	365
Antiemetics	5	2	3	0	22
Antifungals	3	1	2	0	365
Antihyperlipidemics	17	5	12	0	248
Antineoplastics and Adjunctive Therapies	37	34	3	0	245
Anti-Obesity Agents	46	4	42	0	22
Antiparkinson and Related Therapy Agents	1	1	0	0	365
Antipsychotics/Antimanic Agents	4	2	2	0	183
Antivirals	7	5	2	0	154
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	9	4	5	0	365
Beta Blockers	4	0	4	0	0
Cardiovascular Agents - Misc.	17	7	10	0	404
Contraceptives	38	26	12	0	272
Corticosteroids	7	1	6	0	273
Dermatologicals	144	62	82	0	223
Diagnostic Products	16	7	9	0	305
Digestive Aids	2	1	1	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	1	1	0	183
Endocrine and Metabolic Agents - Misc.	44	19	25	0	236
Estrogens	1	0	1	0	0
Gastrointestinal Agents - Misc.	70	41	29	0	262
Gout Agents	2	0	2	0	0
Hematological Agents - Misc.	1	1	0	0	365
Hematopoietic Agents	8	3	5	0	341
Histamine H3-Receptor Antagonist/Inverse Agonists	1	1	0	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	7	0	7	0	0
Laxatives	2	0	2	0	0
Medical Devices and Supplies	7	5	2	0	334
Migraine Products	136	82	54	0	210
Miscellaneous Therapeutic Classes	11	9	2	0	456
Multivitamins	1	1	0	0	365
Musculoskeletal Therapy Agents	19	7	12	0	293
Nasal Agents - Systemic and Topical	1	0	1	0	0
Neuromuscular Agents	18	13	5	0	256
Nutrients	1	1	0	0	92
Ophthalmic Agents	15	6	9	0	263

*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
Other	15	6	9	0	188
Otic Agents	1	0	1	0	0
Psychotherapeutic and Neurological Agents - Misc.	20	16	4	0	295
Respiratory Agents - Misc.	3	3	0	0	365
Stimulants - Misc.	10	4	6	0	372
Ulcer Drugs/Antispasmodics/Anticholinergics	15	5	10	0	229
Urinary Antispasmodics	13	3	10	0	260
Vitamins	36	1	35	0	365
Total	**1,375**	**656**	**719**	**0**	
Overrides					
Ingredient Duplication	137	68	69	0	153
NDC vs Age	362	242	120	0	251
Opioid MME Limit	3	2	1	0	243
Opioid Quantity	5	5	0	0	511
Other	138	53	85	0	131
Quantity vs Days Supply	201	124	77	0	242
STBS/STBSM	381	4	377	0	6
Step Therapy Exception	261	123	138	0	176
Overrides Total	**1,488**	**621**	**867**	**0**	
Total Regular PAs + Overrides	**2,863**	**1,277**	**1,586**	**0**	
Denial Reasons					
Benefit					651
Medical Necessity					935

*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

11/1/2025 Through 11/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	3	1	1	1	365
Amphetamines	424	186	151	87	677
Analgesics - Anti-Inflammatory	113	52	31	30	750
Analgesics - Nonnarcotic	14	1	12	1	14
Analgesics - Opioid	260	82	130	48	330
Androgens - Anabolic	58	10	34	14	652
Anorectal and Related Products	4	0	0	4	0
Anorexiants Non-Amphetamine	3	0	0	3	0
Anthelmintics	5	0	5	0	0
Antianxiety Agents	15	2	9	4	365
Antiasthmatic and Bronchodilator Agents	182	58	100	24	481
Antibiotics	19	9	7	3	294
Anticoagulants	3	3	0	0	45
Anticonvulsants	69	24	35	10	569
Antidepressants	127	48	55	24	781
Antidiabetics	556	262	201	93	669
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antiemetics	8	3	3	2	47
Antifungals	5	2	2	1	202
Antihistamines	11	4	4	3	365
Antihyperlipidemics	19	7	9	3	532
Antihypertensives	5	2	3	0	1,096
Anti-Infective Agents - Misc.	14	3	2	9	365
Antineoplastics and Adjunctive Therapies	41	28	5	8	484
Anti-Obesity Agents	109	5	51	53	446
Antipsychotics/Antimanic Agents	120	54	40	26	599
Antivirals	12	3	5	4	167
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	127	83	26	18	646
Beta Blockers	8	5	1	2	114
Calcium Channel Blockers	8	7	1	0	443
Cardiovascular Agents - Misc.	28	15	9	4	663
Contraceptives	17	7	7	3	343
Corticosteroids	3	0	1	2	0
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	331	127	130	74	444
Diagnostic Products	56	32	18	6	452
Dietary Products/Dietary Management Products	1	0	1	0	0
Digestive Aids	1	1	0	0	365
Diuretics	2	1	1	0	365
Endocrine and Metabolic Agents - Misc.	53	18	29	6	547
Estrogens	7	1	4	2	365
Gastrointestinal Agents - Misc.	119	46	59	14	647
Genitourinary Agents - Misc.	1	0	0	1	0
Gout Agents	1	0	0	1	0
Hematological Agents - Misc.	6	2	4	0	730
Hematopoietic Agents	24	8	10	6	231
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	28	16	9	3	244

*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	8	4	2	2	261
Medical Devices and Supplies	119	78	25	16	757
Migraine Products	181	70	93	18	727
Minerals and Electrolytes	3	1	1	1	181
Miscellaneous Therapeutic Classes	18	11	3	4	328
Multivitamins	3	2	1	0	730
Musculoskeletal Therapy Agents	28	8	15	5	155
Nasal Agents - Systemic and Topical	4	0	4	0	0
Neuromuscular Agents	15	9	2	4	253
Ophthalmic Agents	20	5	13	2	281
Other	32	12	8	12	746
Otic Agents	12	2	6	4	365
Passive Immunizing and Treatment Agents	2	0	1	1	0
Progestins	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	36	10	16	10	769
Respiratory Agents - Misc.	7	5	2	0	1,096
Stimulants - Misc.	216	125	45	46	503
Thyroid Agents	12	8	2	2	276
Ulcer Drugs/Antispasmodics/Anticholinergics	44	10	28	6	415
Urinary Antispasmodics	14	4	4	6	153
Vaccines	1	0	1	0	0
Vaginal and Related Products	1	0	1	0	0
Vasopressors	2	0	2	0	0
Vitamins	1	1	0	0	365
****Total**	**3,803**	**1,583**	**1,480**	**740**	

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

Denial Reasons	
Medical Necessity	1,479
Benefit	1

*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
December 2025

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 providers 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. 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) coverage criteria

To date, AD services have been provided to over 1,200 health care providers and/or their administrative staff. Future AD services will be delivered to providers whose SoonerCare members' fee-for-service (FFS) 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 $3,413,207 through December 2024. This amount is inclusive of all federal and supplemental rebates for the analysis periods following AD on the treatment of the following for 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

Current Topics: Co-Prescribing Opioid Medications with Benzodiazepines (BZD) and Naloxone[4,5,6,7,8,9,10]

The State Unintentional Drug Overdose Reporting System (SUDORS) sponsored by the Centers for Disease Control and Prevention (CDC) reported drug overdose data from 43 jurisdictions (42 U.S. states and the District of Columbia) for calendar year 2024. The SUDORS database collects information from death certificates, coroner or medical examiner reports, and postmortem toxicology reports to provide information on the number of overdose-related deaths and the medications involved. Of the 43 jurisdictions included for calendar year 2024, it was reported that over 53,336 overdose deaths occurred overall, of which 1,196 occurred in Oklahoma.

According to the CDC, approximately 50% of overdose deaths in Oklahoma involved at least 1 opioid with illegally made fentanyls, the most commonly involved opioids with almost 4% of overdose deaths involving only prescription opioids (no other opioids or stimulants). Potential bystanders were present in over 35% of Oklahoma overdose deaths as recorded by a medical examiner or coroner report. However, of those deaths with a potential bystander present, no response was provided in 50% of the deaths. A person was considered a potential bystander if they were 11 years of age or older, physically nearby either during or shortly preceding the overdose, and potentially had an opportunity to intervene or respond to the overdose. The reasons for bystander nonresponse included:

- Was unaware of substance use; or
- Did not recognize signs of overdose; or

- Was using substances or alcohol; or
- Was not close enough to provide aid.

The 2022 CDC guidelines for prescribing opioids for pain recommend the following patients taking opioids should be prescribed naloxone:

- Prescribed high-dose opioids (i.e., ≥50 morphine milligram equivalents (MME)/day)
- Concomitant use with BZD
- With sleep-disordered breathing (e.g., sleep apnea)
- History of substance use disorder
- History of drug overdose
- At risk of returning to a high dose for which they have lost tolerance (e.g., incarceration or recently leaving a rehab facility)

According to national trends, only 1 naloxone prescription is written for every 70 high-dose opioid prescriptions. It is difficult to determine which patients taking opioid medications are at risk for accidental overdose, so it is recommended that ideally, all patients on opioids be prescribed naloxone.

In accordance with the Centers for Medicare and Medicaid Services (CMS), OHCA is monitoring and managing the concomitant utilization of BZDs and opioids through AD. In 2016, the U.S. Food & Drug Administration (FDA) issued a Boxed Warning about the risks associated with taking opioids and BZDs together, highlighting the potential for serious side effects. SoonerCare does not currently restrict concomitant use of these medications; however, there is increasing evidence to suggest that this combination could increase the risk of adverse effects.

The 2022 CDC opioid prescribing guidelines recommend using particular caution when prescribing an opioid and a BZD concurrently. The benefits and risks should be assessed and discussed with the patient to determine if starting or continuing treatment would be beneficial or would place that patient at increased risk of adverse effects.

According to a report from the National Institute on Drug Abuse (NIDA), BZDs were implicated in over 10,000 of the over 105,000 overdose deaths recorded in 2023. Among these BZD-related deaths, co-prescribed opioids were involved in approximately 9,000 cases.

Provider Mailings and Results: Co-Prescribing Opioid Medications with BZD and Naloxone

PMC, OHCA, and OSDH are working to improve the safety of Oklahomans with harm reduction strategies related to opioid use by providing educational outreach concerning the concurrent use of opioids and BZD and co-prescribing of naloxone in SoonerCare members [fee-for-service (FFS)

pharmacy benefit]. Additional members covered by one of the managed care SoonerSelect plans may be impacted.

Opioid-AD services were delivered by the PMC-AD pharmacist. In total, 29 providers at this time have accepted the offer of AD. Opioid and naloxone prescribing patterns were shared with providers on request. Opioid-AD was delivered through in-person visits, phone calls, and Zoom meetings.

Co-Prescribing Opioid Medications with BZD

In March 2025, 238 providers received an educational outreach letter addressing the concurrent prescribing of an opioid and BZD based on paid claims from September 1, 2024 to February 28, 2025 with the following selection criteria:

- Paid claims for a BZD and an opioid during the same 30-day period.

In some cases, the concomitant prescribing is shared across multiple providers. If one provider wrote a prescription for an opioid and a different provider wrote for a BZD, both providers received a letter. In September 2025, 218 providers received a letter based on paid claims from March 1, 2025 to August 31, 2025 based on the above criteria.

Contact has been attempted with all providers who received an educational outreach letter who had 3 or more FFS members who have concurrent prescriptions of an opioid and BZD, and AD has been completed with 16 providers to date. Before AD, these providers had an average of 5 members with concurrent prescriptions with a range of 3 to 9 members. After AD, these providers had an average of 3 members with a range of 0 to 9 members, which represents a decrease of 35 total members. Member counts and the percentage change are represented in Table 1.

Table 1: Changes in Opioid-BZD AD Outcomes

AD Providers (N=16)				
Provider	**Pre-AD**	**Post-AD**	**Change‡**	**% Change***
A	3	0	**-3**	**100%**
B	7	4	**-3**	**42.86%**
C	6	7	**1**	**-16.67%**
D	4	0	**-4**	**100%**
E	3	0	**-3**	**100%**
F	3	2	**-1**	**33.33%**
G	8	4	**-4**	**50.00%**
H	3	2	**-1**	**33.33%**
I	5	4	**-1**	**20.00%**
J	3	0	**-3**	**100%**
K	9	9	**0**	**0.00%**
L	7	3	**-4**	**57.14%**
M	3	2	**-1**	**33.33%**
N	6	2	**-4**	**66.67%**
O	3	1	**-2**	**66.67%**

P	5	3	**-2**	**40.00%**
Total	**78**	**43**	**-35**	**51.67%**

BZD = Benzodiazepine; AD = Academic detailing; N = Number of providers
* Positive indicates improvement
‡ Negative indicates improvement

Co-Prescribing Opioid Medications with Naloxone

In August 2025, 264 providers received an educational outreach letter addressing the potential lack of naloxone dispensing based on paid claims from May 1, 2024 to April 30, 2025 with the following selection criteria:

- ≥1 high-dose opioid prescription(s) (i.e., ≥50 MME/day), irrespective of treatment length, lacking a paid claim for naloxone; or
- ≥1 opioid medication(s) lasting ≥30 days, irrespective of dose, lacking a paid claim for naloxone.

Contact has been attempted with all providers who received an educational outreach letter for lack of co-prescribing naloxone with opioid medications for FFS members, and AD has been completed with 13 providers to date. Before AD, these providers had an average of 10.02% paid claims of naloxone in 12 months with a range of 0 to 33%. After AD, these providers had an average of 28.62% paid claims of naloxone in 5 months with a range of 14 to 50%, representing a total increase of 18.60% of naloxone paid claims. The percentage of naloxone paid claims for providers that have received AD and providers that have not received AD are included in Table 2.

Table 2: Changes In Naloxone AD Outcomes				
AD Providers (N=13)				
Prescribing Patterns*	**Pre-AD**	**Post-AD**	**Change**	**% Change**
Naloxone Claims (AD)	10.02%	28.62%	**18.60%**	**185.62%**
Naloxone Claims (non-AD)	12.86%	4.46%	**-8.40%**	**-65.31%**

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

Summary

As demonstrated in the results, it is shown that providing AD to providers increased the endpoint of more naloxone prescriptions and fewer members with concurrent opioid and BZD prescriptions. This data does not reflect members who obtained naloxone from other sources, which could include the following:

- Over-the-counter (OTC) products
- Provided in provider's office
- OK I'm Ready – mail order provided by the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS)

The Opioid AD project is ongoing, and providers who have not responded will continue to be contacted, as the data shows that there have been positive

impacts with prescribing practices. The goal is to increase safety and reduce harm related to opioid use for our SoonerCare members.

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Appendix D

SoonerCare Maintenance Drug List

Oklahoma Health Care Authority
December 2025

Introduction[1]

Most adult SoonerCare members are limited to 6 prescriptions each month; therefore, prescribing for and dispensing 90-day supplies of chronic maintenance medications will help members who are on multiple medications obtain the maintenance medications necessary. Dispensing 90-day supplies of chronic maintenance medications has been shown to increase medication adherence and persistence, compared to dispensing 30-day supplies. Additionally, 90-day supplies will reduce the SoonerCare member's financial burden as they will pay the same copay for a 90-day supply as they would for a 30-day supply.

In November 2019, the Oklahoma Health Care Authority (OHCA) Board voted to update the current policy and rules regarding dispensing limitations. Previously, medications could only be dispensed and reimbursed by SoonerCare up to a 34-day supply or if the quantity did not exceed 100 units. The updated OHCA policy and rules state the following regarding dispensing limitations and a maintenance drug list (317:30-5-77.1):

> "Prescription quantities shall be limited to a 34-day supply, except in the following situations:
> 1. The Drug Utilization Review (DUR) Board has recommended a different day supply or quantity limit based on published medical data, including the manufacturer's package insert; or
> 2. The product is included on the Maintenance List of medications which are exempted from this limit and may be dispensed up to a 90-day supply; or
> 3. The manufacturer of the drug recommends a dispensing quantity less than a 34-day supply….".
>
> "The DUR Board shall develop a Maintenance List of medications which are used in general practice on a continuing basis. These drugs shall be made available through the Vendor Drug Program in quantities up to a 90-day supply when approved by the prescriber. The DUR Board shall review the Maintenance List at least annually."

The DUR Board recommended and voted on categories of medications for inclusion on the maintenance drug list in December 2019, and the SoonerCare Maintenance Drug List was implemented in January 2020. The

purpose of this report is to provide the DUR Board with the current maintenance drug list for review, which is to be maintained by the DUR Board. Medications included in the maintenance drug list allow a 90-day supply of medications in the claims processing system without the need for an override. Action by the DUR Board is not required unless changes are recommended to the current maintenance drug list.

SoonerCare Maintenance Drug List

The current SoonerCare Maintenance Drug List is available on the OHCA website (https://oklahoma.gov/ohca/rx) and includes the following categories of medications:

- Alzheimer's Medications
- Anticonvulsants
- Antidepressants/Anxiolytics
- 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
- Glaucoma Medications
- Hyperlipidemia Medications
- Non-Controlled Attention-Deficit/Hyperactivity Disorder (ADHD) Medications
- Parkinson's Medications
- Thyroid Medications

Please note that not all medications in each category can be processed for a 90-day supply.

Recommendations

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

[1] Taitel M, Fensterheim L, Kirkham H, et al. Medication Days' Supply, Adherence, Wastage, and Cost Among Chronic Patients in Medicaid. *MMRR* 2012; 2(3):E1-E13. doi: 10.5600/mmrr.002.03.a04.

Appendix E

Vote to Prior Authorize Brinsupri™ (Brensocatib)

Oklahoma Health Care Authority
December 2025

Market News and Updates[1]

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

- **August 2025:** The FDA approved Brinsupri™ (brensocatib) for the treatment of non-cystic fibrosis bronchiectasis (NCFB) in patients 12 years of age and older. Brinsupri™ is the first FDA approved treatment for NCFB.

Brinsupri™ (Brensocatib) Product Summary[2,3,4]

Therapeutic Class: Dipeptidyl peptidase-1 (DPP-1) inhibitor

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

How Supplied: 10mg and 25mg oral tablet

Dosing and Administration:

- Recommended dose is 10mg or 25mg once daily with or without food

Efficacy: Brinsupri™ was studied in 2 randomized, double-blind, placebo-controlled trials, ASPEN and WILLOW, comparing Brinsupri™ to placebo.

- Key Inclusion Criteria:
  - ASPEN: 12 years of age or older
  - WILLOW: 18 years of age or older
  - Clinical history consistent with NCFB (i.e., cough, chronic sputum production, and/or recurrent respiratory infections) that is confirmed by chest CT scan
  - History of pulmonary exacerbation(s) defined by the need for antibiotic prescription for the signs and symptoms of respiratory infections in the past 12 months
    - ASPEN: ≥1 pulmonary exacerbation for adolescents or ≥2 pulmonary exacerbations for adults
    - WILLOW: ≥2 pulmonary exacerbations
- Key Exclusion Criteria:
  - A primary diagnosis of chronic obstructive pulmonary disease (COPD) or asthma
  - Bronchiectasis due to cystic fibrosis (CF)
- Intervention(s): Patients were randomized 1:1:1 (2:2:1 in adolescents) to receive brensocatib 10mg or 25mg or placebo once daily

- Primary Endpoint(s):
  - ASPEN: Annualized rate of pulmonary exacerbations over 52-week treatment period
  - WILLOW: Time to first pulmonary exacerbation over 24-week treatment period
  - Pulmonary exacerbations were defined as ≥3 of the following major symptoms over 48 hours resulting in a health care provider's decision to prescribe systemic antibiotics: increased cough, increased sputum volume or change in sputum consistency, increased sputum purulence, increased breathlessness, decreased exercise tolerance, fatigue and/or malaise, and hemoptysis.
- Results:
  - ASPEN:
    - Annualized rate of pulmonary exacerbation was 1.02 for the 10mg group vs. 1.29 for placebo [treatment difference: 0.79; 95% confidence interval (CI): 0.68, 0.92; adjusted P=0.04] and 1.04 for the 25mg group vs. 1.29 for placebo (treatment difference: 0.81; 95% CI: 0.69, 0.94; adjusted P=0.005)
  - WILLOW:
    - The median time to the first exacerbation was 189 days in the placebo group, but because of the low number of exacerbations in the 2 brensocatib groups, the median time to the first exacerbation could not be estimated in those groups. The 25th percentile of the time to the first exacerbation was 67 days in the placebo group, 134 days in the 10mg brensocatib group, and 96 days in the 25mg brensocatib group.
    - The adjusted hazard ratio in the comparison of Brinsupri™ vs. placebo was 0.58 (95% CI: 0.35, 0.95; P=0.03) in the 10mg group and 0.62 (95% CI: 0.38, 0.99; P=0.046) in the 25mg group.

Cost: The Wholesale Acquisition Cost (WAC) of Brinsupri™ (brensocatib) is $244.44 per tablet, regardless of strength. This would result in an estimated cost of $7,333.20 per month or $87,998.40 per year based on recommended dosing.

Recommendations

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.

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[1] Insmed. FDA Approves Brinsupri™ (Brensocatib) as the First and Only Treatment for Non-Cystic Fibrosis Bronchiectasis, a Serious, Chronic Lung Disease. Available online at: https://investor.insmed.com/2025-08-12-FDA-Approves-BRINSUPRI-TM-brensocatib-as-the-First-and-Only-Treatment-for-Non-Cystic-Fibrosis-Bronchiectasis,-a-Serious,-Chronic-Lung-Disease. Issued 08/12/2025. Last accessed 11/19/2025.

[2] Brinsupri™ (Brensocatib) Prescribing Information. Insmed. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217673s000lbl.pdf. Last revised 08/2025. Last accessed 11/19/2025.

[3] Chalmers J, Burgel P, Daley C, et al. Phase 3 Trial of the DPP-1 Inhibitor Brensocatib in Bronchiectasis. *N Engl J Med* 2025; 392: 1569-81. doi: 10.1056/NEJMoa2411664.

[4] Chalmers J, Haworth C, Metersky M, et al. Phase 2 Trial of the DPP-1 Inhibitor Brensocatib in Bronchiectasis. *N Eng J Med* 2020; 383: 2127-37. doi: 10.1056/NEJMoa2021713.

Appendix F

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

Oklahoma Health Care Authority
December 2025

Market News and Updates[1,2,3]

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

- **March 2025:** The FDA approved Stoboclo® (denosumab-bmwo) and Osenvelt® (denosumab-bmwo) as biosimilars to Prolia® (denosumab) and Xgeva® (denosumab), respectively, for the same indications currently approved for the reference products.
- **March 2025:** The FDA approved Conexxence® (denosumab-bnht) and Bomyntra® (denosumab-bnht) as biosimilars to Prolia® and Xgeva®, respectively, for the same indications currently approved for the reference products.
- **September 2025:** The FDA approved Bildyos® (denosumab-nxxp) and Bilprevda® (denosumab-nxxp) as biosimilars to Prolia® and Xgeva®, respectively, for the same indications currently approved for the reference products.

Recommendations

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**
		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.

[1] Celltrion. Celltrion Receives U.S. FDA Approval for Stoboclo® (Denosumab-bmwo) and Osenvelt® (Denosumab-bmwo) Biosimilars Referencing Prolia® and Xgeva®. Available online at: https://www.celltrion.com/en-us/company/media-center/press-release/3768. Issued 03/04/2025. Last accessed 11/25/2025.

[2] Fresenius Kabi. Fresenius Kabi Receives FDA Approval for Their Denosumab Biosimilars and Secures Global Settlement Agreement. Available online at: https://www.fresenius-kabi.com/us/news-and-events/fda-approval-denosumab-and-secures-global-settlement-agreement. Issued 03/27/2025. Last accessed 11/25/2025.

[3] Henlius. U.S. Food and Drug Administration (FDA) Approves Henlius and Organon's Bildyos® (Denosumab-nxxp) and Bilprevda® (Denosumab-nxxp), Biosimilars to Prolia® (Denosumab) and Xgeva® (Denosumab), Respectively. *PRNewswire.* Available online: https://www.prnewswire.com/apac/news-releases/us-food-and-drug-administration-fda-approves-henlius-and-organons-bildyos-denosumab-nxxp-and-bilprevda-denosumab-nxxp-biosimilars-to-prolia-denosumab-and-xgeva-denosumab-respectively-302543830.html. Issued 09/02/2025. Last accessed 11/25/2025.

Appendix G

Vote to Prior Authorize Forzinity™ (Elamipretide)

Oklahoma Health Care Authority
December 2025

Market News and Updates[1]

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

- **September 2025:** The FDA granted accelerated approval to Forzinity™ (elamipretide) to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30kg.

Forzinity™ (Elamipretide) Product Summary[2,3,4]

Therapeutic Class: Mitochondrial cardiolipin binder

Indication(s): To improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30kg

- This indication is approved under accelerated approval based on an improvement in knee extensor muscle strength, an intermediate clinical endpoint. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: 280mg/3.5mL solution in single-patient-use vials

Dosing and Administration:

- The recommended dosage in patients weighing ≥30kg is 40mg subcutaneously (sub-Q) once daily.
- The dosage should be reduced to 20mg sub-Q once daily for patients with an estimated glomerular filtration rate (eGFR) <30mL/minute who are not on dialysis.
- There is insufficient information to recommend a dosage regimen in adults with eGFR <30mL/minute who are on dialysis.

Efficacy: The efficacy of Forzinity™ was based primarily on a Phase 2/3, randomized, double-blind, placebo-controlled, crossover study (TAZPOWER) and its 192-week open-label, single-arm extension period. The randomized portion of the trial enrolled 12 patients with Barth syndrome who were randomized 1:1 to 1 of 2 sequence groups: 12 weeks of daily elamipretide in period 1 followed by 12 weeks of placebo in period 2, or vice versa. Following the randomized portion, 10 patients entered the open-label extension period and 8 of those participated through 168 weeks during the extension period.

- Key Inclusion Criteria:
  - Molecularly confirmed diagnosis of Barth syndrome (e.g., presence of a pathogenic genetic variant in the *TAFAZZIN* gene)
- Primary Endpoint(s) at Week 12:
  - Distance walked during the 6-minute walk test (6MWT)
  - Total fatigue score on the Barth Syndrome Symptom Assessment (BTHS-SA)
- Results:
  - Elamipretide was not superior to placebo for either primary endpoint.
- Change from Baseline in Knee Extensor Muscle Strength:
  - During the extension period, increases in knee extensor muscle strength (as measured by handheld dynamometry) were observed. At baseline, prior to the randomized trial, the median muscle strength was 124 newtons. At week 168, the median muscle strength had increased by 63 newtons.

Cost: The Wholesale Acquisition Cost (WAC) of Forzinity™ is $4,360.27 per milliliter or $15,260.95 per vial. This would result in an estimated cost of $61,043.78 per 28 days or $793,569.14 per year based on the recommended dose of 40mg once daily.

Recommendations

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.

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[1] Stealth BioTherapeutics, Inc. Stealth BioTherapeutics Announces FDA Accelerated Approval of Forzinity™ (Elamipretide) Injection, the First Therapy for Progressive and Life-Limiting Ultra-Rare Genetic Disease Barth Syndrome. Available online at: https://stealthbt.com/stealth-biotherapeutics-announces-fda-accelerated-approval-of-forzinity-elamipretide-hcl-the-first-therapy-for-progressive-and-life-limiting-ultra-rare-genetic-disease-barth-syndrome/. Issued 09/19/2025. Last accessed 11/13/2025.

[2] Forzinity™ (Elamipretide) Prescribing Information. Stealth BioTherapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf. Last revised 09/2025. Last accessed 11/13/2025.

[3] Thompson WR, Hornby B, Manuel R, et al. A Phase 2/3 Randomized Clinical Trial Followed by an Open-Label Extension to Evaluate the Effectiveness of Elamipretide in Barth Syndrome, a Genetic Disorder of Mitochondrial Cardiolipin Metabolism. *Genet Med* 2021; 23(3):471-478. doi: 10.1038/s41436-020-01006-8.

[4] Thompson WR, Manual R, Abbruscato A, et al. Long-Term Efficacy and Safety of Elamipretide in Patients with Barth Syndrome: 168-Week Open-Label Extension Results of TAZPOWER. *Genet Med* 2024; 26(7):101138. doi: 10.1016/j.gim.2024.101138.

Appendix H

Vote to Prior Authorize Rhapsido® (Remibrutinib)

Oklahoma Health Care Authority
December 2025

Market News and Updates[1]

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

- **September 2025:** The FDA approved Rhapsido® (remibrutinib) for the treatment of adults with chronic spontaneous urticaria (CSU) who remain symptomatic despite histamine-1 (H1) antihistamine treatment. Rhapsido® is the first Bruton's tyrosine kinase (BTK) inhibitor for CSU.

Rhapsido® (Remibrutinib) Product Summary[2,3]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of CSU in adult patients who remain symptomatic despite H1 antihistamine treatment

- **Limitation(s) of Use:** Not indicated for other forms of urticaria.

How Supplied: 25mg oral tablet

Dosing and Administration:

- The recommended dose is 25mg twice daily with or without food.
- Rhapsido® should be swallowed whole and not split, crushed, or chewed.
- Rhapsido® should be interrupted for 3 to 7 days pre- and post-surgery.

Efficacy: Rhapsido® was studied in 2 randomized, double-blind, placebo-controlled trials, REMIX-1 and REMIX-2, in adults with CSU.

- Key Inclusion Criteria:
  - Diagnosis of CSU inadequately controlled by second generation H1 antihistamines as defined by the presence of itch and hives for ≥6 consecutive weeks
  - Weekly urticaria activity score (UAS) ≥16, a weekly itch severity score (ISS7) ≥6, and a weekly hives severity score (HSS7) ≥6 for 7 days prior to randomization
- Intervention(s): Patients were randomized 2:1 to Rhapsido® 25mg or placebo twice daily.
- Primary Endpoint(s): The co-primary endpoints were absolute change from baseline in ISS7 and HSS7 at week 12.
  - The ISS7 (range 0 to 21) was defined as the sum of the daily itch severity scores (range 0 to 3) recorded over a 7-day period.

- The HSS7 (range 0 to 21) was defined as the sum of the daily hive severity scores (range 0 to 3) recorded over a 7-day period.

- Results:
  - REMIX-1:
    - Change from baseline in ISS7 was -9.52 in the Rhapsido® group vs. -6.89 in the placebo group [treatment difference: -2.63; 95% confidence interval (CI): -3.70, -1.56; P<0.001]
    - Change from baseline in HSS7 was -10.47 in the Rhapsido® group vs. -6.86 in the placebo group (treatment difference: -3.61; 95% CI: -4.85, -2.36; P<0.001)
  - REMIX-2:
    - Change from baseline in ISS7 was -8.95 in the Rhapsido® group vs. -5.72 in the placebo group (treatment difference: -3.23; 95% CI: -4.29, -2.16; P<0.001)
    - Change from baseline in HSS7 was -10.47 in the Rhapsido® group vs. -6.00 in the placebo group (treatment difference: -4.47; 95% CI: -5.71, -3.23; P<0.001)

Cost Comparison:

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Rhapsido® (remibrutinib) 25mg tablet	**$75.35**	**$4,521.00***	**$54,252.00**
Dupixent® (dupilumab) 300mg/2mL	$962.05	$3,848.20⁺	$50,026.60
Xolair® (mepolizumab) 300mg/2mL	$1,337.88	$2,675.76^	$34,784.88

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), Specialty Pharmaceutical Acquisition Cost (SPAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet or mL
*Cost per month based on the maximum FDA approved dosing of 25mg twice daily
⁺Cost per month based on the maximum FDA approved maintenance dosing of 300mg every 2 weeks
^Cost per month based on the maximum FDA approved dosing of 300mg every 4 weeks

Recommendations

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.

[1] Novartis. Novartis Receives FDA Approval for Rhapsido® (Remibrutinib), the Only Oral, Targeted BTKi Treatment for Chronic Spontaneous Urticaria (CSU). Available online at: https://www.novartis.com/us-en/news/media-releases/novartis-receives-fda-approval-rhapsido-remibrutinib-only-oral-targeted-btki-treatment-chronic-spontaneous-urticaria-csu. Issued 09/30/2025. Last accessed 11/19/2025.
[2] Rhapsido® (Remibrutinib) Prescribing Information. Novartis. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218436s000lbl.pdf. Last revised 09/2025. Last accessed 11/19/2025.
[3] Mertz M, Gimenez-Arnau A, Hide M, et al. Remibrutinib in Chronic Spontaneous Urticaria. *N Engl J Med* 2025; 392: 984-994. doi: 10.1056/NEJMoa2408792.

Appendix I

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

Oklahoma Health Care Authority
December 2025

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

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

- **January 2002:** The FDA approved Orfadin® (nitisinone) for the treatment of hereditary tyrosinemia type 1 (HT-1). Additionally, generic nitisinone capsules were first FDA approved in 2019 and are currently available.
- **July 2017:** The FDA approved Nityr® (nitisinone), a tablet formulation of nitisinone, for the treatment of HT-1.
- **April 2025:** The FDA approved Zelvysia™ (sapropterin) powder for oral solution, which is a branded generic of Kuvan® (sapropterin).
- **June 2025:** The FDA approved Harliku™ (nitisinone) for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU). Harliku™ was approved through a Supplemental New Drug Application (sNDA) under Nityr®, and there is no difference between the products except Nityr® is available in higher strengths.
- **July 2025:** The FDA approved Sephience™ (sepiapterin) for the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU).

Guideline Update(s):

- **January 2025:** Updated guidelines for the diagnosis and management of phenylalanine hydroxylase (PAH) deficiency (also known as PKU and HPA) were published by the American College of Medical Genetics and Genomics (ACMG). Some of the key recommendations included:
  - Treatment for PAH deficiency should be lifelong for individuals with untreated phenylalanine levels >360micromol/L.
  - Blood phenylalanine should be maintained to ≤360micromol/L for life in individuals with PAH deficiency because it is associated with higher IQ levels.
  - Achieving phenylalanine levels ≤360micromol/L before conception is strongly recommended to prevent pregnancy complications and negative outcomes for the offspring.

- Genetic testing for *PAH* variants is recommended at birth to confirm diagnosis and guide therapy.
- Treatment success should not only be measured by blood phenylalanine levels but also by the ability of individuals with a PAH deficiency to consume more natural protein and improve clinical symptoms.

Harliku™ (Nitisinone) Product Summary[8,9,10]

Therapeutic Class: Hydroxy-phenylpyruvate dioxygenase inhibitor

Indication(s): Reduction of urine HGA in adult patients with AKU

How Supplied: 2mg tablet

Dosing and Administration:

- The recommended Harliku™ dose is 2mg by mouth once daily.

Efficacy: The safety and efficacy of Harliku™ were studied in an open-label, single-center, randomized, no-treatment controlled trial in 40 adult patients diagnosed with AKU. Patients could not be masked in the trial because their urine color revealed whether or not they were receiving nitisinone.

- Key Inclusion Criteria:
  - 30 to 80 years of age
  - Diagnosis of AKU based upon urinary HGA excretion >0.4g/24 hour
  - At least 1 hip joint remaining
  - Some evidence of hip involvement (e.g., pain or decreased range of motion)
- Intervention: 20 patients received no treatment and 20 patients received nitisinone 2mg orally once daily
- Outcome: Mean urine HGA excretion
- Results:
  - The mean HGA excretion in the no treatment group was 5.80 grams per day at baseline and stayed at that level for the duration of the study (range: 4.60-6.47 grams per day).
  - The mean HGA excretion in the nitisinone treated group decreased from 5.1 grams per day at baseline to 125mg per day by the 4th month and ranged from 113mg to 203mg per day for the remainder of the trial.
  - Overall, nitisinone reduced urinary HGA excretion by >95%.

Orfadin® (Nitisinone) Product Summary[11]

Therapeutic Class: Hydroxy-phenylpyruvate dioxygenase inhibitor

Indication(s): Treatment of adult and pediatric patients with HT-1 in combination with dietary restriction of tyrosine and phenylalanine

How Supplied:

- 2mg, 5mg, 10mg, 20mg capsules
- 4mg/mL oral suspension

Dosing and Administration:

- The recommended starting dosage is 0.5mg/kg orally twice daily.
- In patients 5 years of age and older who have undetectable serum and urine succinylacetone concentrations after a minimum of 4 weeks on a stable dose of nitisinone, the total daily dose may be given once daily.
- The dose should be titrated based on biochemical and/or clinical response, as described in the *Prescribing Information*.
- The maximum total daily dosage is 2mg/kg orally.
- Dietary restriction of tyrosine and phenylalanine should be maintained when taking Orfadin®.
- The capsules should be taken 1 hour before or 2 hours after a meal.
- For patients with difficulty swallowing the capsules and who are intolerant to the oral suspension, the capsules may be opened and the contents suspended in a small amount of water, formula, or apple sauce immediately before use.
- The oral suspension can be taken without regard to meals.

Efficacy: The safety and efficacy of Orfadin® were studied in 207 patients with HT-1 in an open-label, uncontrolled trial.

- Key Inclusion Criteria:
  - 0 to 22 years of age
  - Diagnosis of HT-1 based on the presence of succinylacetone in the urine or plasma
- Intervention: All patients were treated with Orfadin® for 22 months; doses were titrated based on clinical response.
- Outcome: Comparison of survival to historical controls
- Results:
  - For patients presenting with HT-1 prior to 2 months of age who were treated with dietary restriction and nitisinone, 2- and 4-year survival probabilities were 88% and 88%, respectively. Data from historical controls showed that patients presenting with HT-1 prior to 2 months of age and treated with dietary restriction alone had 2- and 4-year survival probabilities of 29% and 29%, respectively.
  - For patients presenting with HT-1 between 2 months and 6 months of age who were treated with dietary restriction and nitisinone, 2- and 4-year survival probabilities were 94% and 94%, respectively. Data for historical controls showed that patients presenting with HT-1 between 2 months and 6 months of age treated with dietary

restriction alone had 2- and 4-year survival probabilities of 74% and 60%, respectively.

Nityr® (Nitisinone) Product Summary[12]

Therapeutic Class: Hydroxy-phenylpyruvate dioxygenase inhibitor

Indication(s): Treatment of adult and pediatric patients with HT-1 in combination with dietary restriction of tyrosine and phenylalanine

How Supplied: 2mg, 5mg, 10mg tablets

Dosing and Administration:

- The recommended starting dosage is 0.5 mg/kg administered orally twice daily.
- Nityr® may be administered with or without food.
- Dietary restriction of tyrosine and phenylalanine should be maintained when administering Nityr®.
- The recommended maintenance dosage of Nityr® in patients 5 years of age and older who have undetectable serum and urine succinylacetone concentrations after a minimum of 4 weeks on a stable dosage of nitisinone, is 1 to 2mg/kg once daily.
- The dose should be titrated based on biochemical and/or clinical response, as described in the *Prescribing Information*.
- For patients who have difficulty swallowing intact tablets, Nityr® tablets may be disintegrated in water and administered using an oral syringe.
- For patients who can swallow semi-solid foods, Nityr® tablets can be crushed and mixed with applesauce.

Efficacy: The safety and efficacy of Nityr® in patients with HT-1 were based on the studies of Orfadin®, another oral formulation of nitisinone.

Cost Comparison: Nitisinone Products

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Harliku™ (nitisinone) 2mg tablet	**$1,485.10**	**$44,553.00**	**$534,636.00**
Nityr® (nitisinone) 2mg tablet	**$89.29**	**$2,678.70**	**$32,144.40**
nitisinone 2mg capsule (generic Orfadin®)	**$72.66**	**$2,179.80**	**$26,157.60**

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 = tablet or capsule
*Cost per 30 days is based on the recommended 2mg daily dose for the reduction of urine HGA in adult patients with AKU.

Sephience™ (Sepiapterin) Product Summary[13,14]

Therapeutic Class: Phenylalanine hydroxylase activator

Indication(s): Treatment of HPA in adult and pediatric patients 1 month of age and older with sepiapterin-responsive PKU

How Supplied: 250mg or 1,000mg sepiapterin as yellow to orange powder in a unit-dose packet

Dosing and Administration:

- Patients treated with Sephience™ should be on a dietary protein and a phenylalanine restricted diet.
- Treatment with Sephience™ should be directed by a physician knowledgeable in the management of PKU.
- Phenylalanine levels should be obtained before initiating treatment with Sephience™ and patients should undergo regular dietary assessments by their health care provider.
- Sephience™ should be administered orally once daily with food.
- The recommended starting dose of Sephience™ is based on the patient's age:
  - Younger than 6 months: 7.5mg/kg per day
  - 6 months to younger than 1 year: 15mg/kg per day
  - 1 year to younger than 2 years: 30mg/kg per day
  - 2 years and older: 60mg/kg per day
- See full *Prescribing Information* for preparation and administration instructions.
- After initiating treatment with Sephience™, in patients younger than 2 years of age, blood phenylalanine levels should be checked within 2 weeks, and the dose should be titrated based on response to a maximum daily dose of 60mg/kg.
- Sephience™ should be discontinued in all patients whose blood phenylalanine levels do not decrease after 2 weeks of treatment at the maximum daily dose of 60mg/kg.

Efficacy: The safety and efficacy of Sephience™ were supported by the Phase 3 APHENITY trial (Part 1 and Part 2).

- <u>Key Inclusion Criteria:</u>
  - Clinical diagnosis of PKU with HPA documented by past medical history of at least 2 blood phenylalanine measurements ≥600micromol/L
  - Uncontrolled blood phenylalanine ≥360micromol/L on current therapy anytime during screening and uncontrolled blood phenylalanine level ≥360micromol/L on current therapy when taking the average of the 3 most recent phenylalanine levels from the participant's medical history (inclusive of the screening value)
  - Willing to continue current diet without changing it through the study

- Key Exclusion Criteria:
  - Confirmed diagnosis of a primary BH4 deficiency
  - Concomitant treatment or unwillingness to washout treatment with sapropterin dihydrochloride or pegvaliase-pqpz
- Intervention:
  - Part 1: 157 patients received Sephience™, dose based on age and weight, once daily for 14 days.
  - Part 2: After a 2-week washout period from Part 1, 98 patients age 2 years or older who had a ≥30% reduction in phenylalanine level with Sephience™ in Part 1 were randomized in a double-blind fashion to receive Sephience™ or placebo for 6 weeks.
- Outcome:
  - Part 1: 66% of patients had ≥30% reduction in phenylalanine level after 2 weeks.
  - Part 2:
    - The Sephience™ treated group had a baseline mean phenylalanine level of 646.1micromol/L and after weeks 5 to 6, the mean phenylalanine level was 236micromol/L compared to the placebo group, which had a baseline mean phenylalanine level of 654micromol/L and after weeks 5 to 6, the mean phenylalanine level was 637.9micromol/L.
    - The treatment difference in adjusted mean percent change in blood phenylalanine from baseline to weeks 5 and 6 was -64.2% [95% confidence interval (CI): -74.1%, -54.4%].

Cost Comparison: PKU Products

Product	Cost Per 30 days	Cost Per Year
Sephience™ (sepiapterin) 250mg & 1,000mg pak	**$67,500.00***	**$810,000.00**
Zelvysia™ (sapropterin) 500mg pak	**$16,329.60±**	**$195,955.20**
Kuvan® (sapropterin) 500mg pak	$18,900.00±	$226,800.00
sapropterin dihydrochloride (generic) 500mg pak	$12,240.00±	$146,880.00

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).
pak = packet
*Cost per 30 days is based on the FDA approved maximum dose of 60mg/kg per day for a 75kg patient.
±Cost per 30 days is based on the FDA approved maximum dose of 20mg/kg for a 75kg patient.

Recommendations

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).

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Appendix J

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

Oklahoma Health Care Authority
December 2025

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

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

- **December 2024:** The FDA approved Nemluvio® (nemolizumab-ilto) for a new indication for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe AD in combination with topical corticosteroids (TCS) and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
- **May 2025:** The FDA approved Zoryve® (roflumilast 0.3% foam) for a new indication for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.
- **July 2025:** The FDA approved Anzupgo® (delgocitinib 2% cream) for the topical treatment of moderate-to-severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom TCS are not advisable.
- **September 2025:** The FDA approved Opzelura® (ruxolitinib 1.5% cream) for an age expansion down to 2 years of age for the topical short-term and non-continuous chronic treatment of mild-to-moderate AD in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not controlled with topical prescription therapies or when those therapies are not advisable. Previously, Opzelura® was approved for this indication in patients 12 years of age and older.
- **October 2025:** The FDA approved Zoryve® (roflumilast 0.05% cream) for the topical treatment of mild-to-moderate AD in pediatric patients 2 to 5 years of age. This represents an age expansion and a new formulation for Zoryve®. Previously, only Zoryve® 0.15% cream was FDA approved for the treatment of mild-to-moderate AD, but only in patients 6 years of age and older.

Guideline Update(s):

- **American Academy of Dermatology (AAD) Focused Update:**
  - In 2025, the AAD published a focused update to their guidelines for the management of AD in adults. This update provides recommendations for 4 newer FDA approved topical and systemic therapies that have been approved since the AAD's previous guideline updates for topical therapies (from 2023) and

phototherapy and systemic therapies (from 2024). The new recommendations made include:

- Strong recommendations (based on high certainty of evidence) in favor of tapinarof cream and lebrikizumab for adults with moderate-to-severe AD
- Strong recommendation (based on high certainty of evidence) in favor of nemolizumab with concomitant topical therapy for adults with moderate-to-severe AD
- Strong recommendation (based on high certainty of evidence) in favor of roflumilast 0.15% cream for adults with mild-to-moderate AD

Anzupgo® (Delgocitinib 2% Cream) Product Summary[7,8]

Therapeutic Class: Janus kinase (JAK) inhibitor

Indication(s): Topical treatment of moderate to severe CHE in adults who have had an inadequate response to, or for whom TCS are not advisable

- **Limitation(s) of Use:** Use of Anzupgo® in combination with other JAK inhibitors or potent immunosuppressants is not recommended.

How Supplied: 2% cream (containing 20mg of delgocitinib per gram) in 30- and 60-gram tubes

Dosing and Administration:

- A thin layer of Anzupgo® should be applied twice daily to the affected areas only on the hands and wrists. Anzupgo® is not for oral, ophthalmic, or intravaginal use.
- The amount of medication used should not exceed 30 grams per 2 weeks or 60 grams per month.
- Prior to applying Anzupgo®, the affected areas should be cleaned and dried.

Efficacy: The efficacy of Anzupgo® was assessed primarily in 2 Phase 3 studies (DELTA 1 and DELTA 2) which were randomized, double-blind, vehicle-controlled studies. The studies enrolled a total of 960 adult patients with moderate to severe CHE with a history of inadequate response to TCS, or for whom TCS were not advisable. In both studies, patients were randomized to apply Anzupgo® or vehicle twice daily to affected areas on the hands and wrists for 16 weeks.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Diagnosis of CHE (e.g., hand eczema has persisted for >3 months or returned twice or more within the past 12 months)

- Disease is moderate to severe [e.g., Investigator's Global Assessment for chronic hand eczema (IGA-CHE) score of 3 or 4 at baseline on a scale from 0-4]
- Hand Eczema Symptom Diary (HESD) itch score (weekly average) ≥4 points at baseline on a scale from 0-10
- Documented recent history of inadequate response to treatment with TCS or for whom TCS are documented to be otherwise medically inadvisable (e.g., due to important side effects or safety risks)

- Primary Endpoint(s):
  - Proportion of patients achieving an IGA-CHE score of 0 ("clear skin") or 1 ("almost clear skin") and at least a 2-point improvement from baseline at week 16
- Results:
  - DELTA 1: Achieved by 20% of patients who received Anzupgo® vs. 10% of patients who received vehicle [treatment difference: 10%; 95% confidence interval (CI): 4%, 16%]
  - DELTA 2: Achieved by 29% of patients who received Anzupgo® vs. 7% of patients who received vehicle (treatment difference: 22%; 95% CI: 16%, 29%)

Cost Comparison: Injectable Products

Product	Cost Per Pen	Cost Per 1st 16 Weeks*	Cost Per Year+
Ebglyss® (lebrikizumab-lbkz) 250mg/2mL	$3,500.00	$35,000.00	$66,500.00
Nemluvio® (nemolizumab-ilto) 30mg	$4,240.00	$21,200.00	$59,360.00
Adbry® (tralokinumab-ldrm) 300mg/2mL	$2,034.69	$18,312.21	$54,936.63
Dupixent® (dupilumab) 300mg/2mL	$1,920.48	$17,284.32	$51,852.96

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 first 16 weeks based on the initial FDA approved dosing for AD for each product, including required loading doses.
+Cost per year based on the initial year of treatment, including required loading doses and the maximum maintenance dosing of 30mg every 4 weeks (for Nemluvio®), 250mg every 4 weeks (for Ebglyss™) or 300mg every 2 weeks (for Adbry® and Dupixent®).

Cost Comparison: Topical Products

Product	Cost Per Gram	Cost Per Tube	Cost Per Year*
Anzupgo® (delgocitinib 2% cream) 30g tube	$66.20	$1,986.00	$23,832.00
Vtama® (tapinarof 1% cream) 60g tube	$24.08	$1,444.80	$17,366.40
Zoryve® (roflumilast 0.05% cream) 60g tube	$16.09	$965.40	$11,584.80
Zoryve® (roflumilast 0.15% cream) 60g tube	$14.79	$887.4	$10,648.80
Eucrisa® (crisaborole 2% ointment) 60g tube	$12.65	$759.00	$9,108.00
Opzelura® (ruxolitinib 1.5% cream) 60g tube	$33.48	$2,008.80	$8,035.20
pimecrolimus 1% cream 60g tube	$2.99	$179.40	$717.60
tacrolimus 0.03% ointment 60g tube	$0.84	$50.40	$201.60
triamcinolone 0.1% ointment 80g tube	$0.04	$3.20	$38.40
triamcinolone 0.1% cream 80g tube	$0.03	$2.40	$28.80

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).
*Cost per year is based on the use of 1 tube per month for all products except Opzelura®, pimecrolimus, and tacrolimus which are based on the use of 1 tube every 3 months as these products are only FDA approved for the short-term and non-continuous chronic treatment of atopic dermatitis.

Recommendations

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.~~

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[5] Arcutis Biotherapeutics, Inc. FDA Approves Arcutis' Zoryve® (Roflumilast) Cream 0.05% for the Treatment of Atopic Dermatitis in Children Ages 2 to 5. Available online at: https://www.arcutis.com/fda-approves-arcutis-zoryve-roflumilast-cream-0-05-for-the-treatment-of-atopic-dermatitis-in-children-ages-2-to-5/. Issued 10/06/2025. Last accessed 11/25/2025.

[6] Davis DM, Frazer-Green L, Alikhan A, et al. Focused Update: Guidelines of Care for the Management of Atopic Dermatitis in Adults. *J Am Acad Dermatol* 2025; 93(3): 745.e1-745.e7. doi: 10.1016/j.jaad.2025.05.1386.

[7] Anzupgo® (Delgocitinib) Prescribing Information. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219155s000lbl.pdf. Last revised 07/2025. Last accessed 11/25/2025.

[8] Bissonnette R, Warren RB, Pinter A, et al. Efficacy and Safety of Delgocitinib Cream in Adults with Moderate to Severe Chronic Hand Eczema (DELTA 1 and DELTA 2): Results from Multicentre, Randomised, Controlled, Double-Blind, Phase 3 Trials. *Lancet* 2024; 404(10451):461-473. doi: 10.1016/S0140-6736(24)01027-4.

Appendix K

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

Oklahoma Health Care Authority
December 2025

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 Omlyclo® (omalizumab-igec) as the first and only interchangeable biosimilar to Xolair® (omalizumab) for the treatment of all 4 different Xolair® indications.
- **April 2025:** The FDA approved a New Drug Application (NDA) for umeclidinium/vilanterol as an authorized unbranded generic of Anoro® Ellipta® (umeclidinium/vilanterol).
- **April 2025:** The FDA approved Dupixent® (dupilumab) for a new indication for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite histamine-1 (H1) antihistamine treatment.
- **May 2025:** The FDA approved Nucala (mepolizumab) for a new indication as an add-on maintenance treatment for adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
- **June 2025:** The FDA approved Dupixent® (dupilumab) for a new indication for the treatment of adult patients with bullous pemphigoid (BP). BP is an autoimmune subepidermal blistering disorder that presents with tense bullae and severe itching and is most prevalent in patients 60 years of age or older. Dupixent® (dupilumab) is the first FDA approved medication for this indication. Currently, the most commonly used therapies are systemic oral corticosteroids (OCS) to induce remission. Additionally, to minimize OCS exposure, topical corticosteroids and adjuvant steroid-sparing agents (e.g., doxycycline, methotrexate, azathioprine, mycophenolate, dapsone) are also used.
- **July 2025:** The FDA approved an NDA for fluticasone furoate as an authorized unbranded generic of Arnuity® Ellipta® (fluticasone furoate).
- **October 2025:** The FDA approved Tezspire® (tezepelumab-ekko) for a new indication of add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP) in adult and pediatric patients 12 years of age and older.

Guideline Update(s):

- **American College of Gastroenterology (ACG) Guideline Update:** The ACG released an update to the 2013 guideline for the diagnosis and management of eosinophilic esophagitis (EoE). Some notable updates include:
  - Proton-pump inhibitors (PPIs) are now positioned as a treatment of EoE over diagnostic criterion. Previously, a failed trial of a PPI was required before a definitive diagnosis of EoE could be established.
    - EoE is diagnosed with the following 3 criteria: symptoms of esophageal dysfunction; at least 15 eosinophils per high-power field (eos/hpf) on esophageal biopsy; and an evaluation for non-EoE disorders that cause or potentially contribute to esophageal eosinophilia.
  - High-dose PPIs and swallowed respiratory corticosteroids are still recommended as treatment options for EoE.
  - Dupilumab treatment is suggested as a treatment for EoE in patients 1 year of age or older who are non-responsive or intolerant to PPI therapy. Additionally, it is advised that providers use dupilumab as step-up therapy in difficult-to-treat patients.
- **Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guideline Update:** The GOLD guidelines have been updated for 2025 and now include new recommendations for dupilumab and ensifentrine in their treatment algorithms. This treatment algorithm can be applied to any patient already taking maintenance treatment(s) regardless of the GOLD group allocated at treatment initiation.
  - For patients with persistent breathlessness or exercise limitations on bronchodilator monotherapy, the use of 2 long-acting bronchodilators is recommended. If the addition of a second long-acting bronchodilator does not improve symptoms, the addition of ensifentrine can be considered.
  - In patients treated with a LABA/long-acting muscarinic agonist (LAMA)/ICS who still have exacerbations and have eosinophils ≥300 cells/mcL and symptoms of chronic bronchitis, dupilumab can be considered.

Recommendations

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 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:

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.

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Appendix L

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

Oklahoma Health Care Authority
December 2025

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

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

- **August 2024:** The FDA approved Boruzu® (bortezomib) for the treatment of adult patients with multiple myeloma or mantle cell lymphoma. Boruzu® is a new formulation of bortezomib that does not have to be reconstituted. It is available as a 3.5mg/1.4mL solution in a single-dose vial (SDV). Boruzu® is approved for the same indications as Velcade® (bortezomib), which is available as generic formulations from several manufacturers.
- **June 2025:** The FDA announced the removal of the Risk Evaluation and Mitigation Strategies (REMS) programs for all currently approved Bispecific B-cell maturation antigen (BCMA)- and CD19-directed autologous chimeric antigen receptor (CAR) T-cell immunotherapies, including Abecma® (idecabtagene vicleucel) and Carvykti® (ciltacabtagene autoleucel). The FDA determined that the REMS were no longer necessary to ensure that the benefits of these therapies outweigh their risks and to minimize the burden on the health care delivery system.
- **July 2025:** The FDA approved Lynozyfic™ (linvoseltamab-gcpt) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- **October 2025:** The FDA added a new *Boxed Warning* for Carvykti® (ciltacabtagene autoleucel) regarding the risk of immune effector cell-associated enterocolitis (IEC-EC), including fatal or life-threatening reactions, which have occurred following treatment with Carvykti®. The FDA determined that the overall benefits of Carvykti® continue to outweigh the potential risks, including an overall survival benefit in patients treated with Carvykti® for its approved use.
- **October 2025:** The FDA approved Blenrep (belantamab mafodotin-blmf), in combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 2 prior lines of therapy, including a

proteasome inhibitor and an immunomodulatory agent. Blenrep was previously granted accelerated approval by the FDA in 2020 as a single agent for the treatment of relapsed or refractory multiple myeloma in patients who had received at least 4 prior lines of therapy; however, that indication was withdrawn by the FDA in 2023 because the confirmatory trial did not meet its primary endpoint to demonstrate superior progression-free survival.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for multiple myeloma allow for the use of:
  - Darzalex® (daratumumab) and Darzalex Faspro® (daratumumab/ hyaluronidase-fihj) in relapsed/refractory light chain amyloidosis:
    - In combination with lenalidomide and dexamethasone; or
    - In combination with venetoclax for patients with t(11;14) translocation
  - Darzalex® and Darzalex Faspro® in smoldering myeloma diagnosis as a single agent
  - Darzalex® and Darzalex Faspro® in multiple myeloma:
    - In combination with carfilzomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for autologous stem cell transplant (ASCT); or
    - In combination with venetoclax and dexamethasone for patients with t(11:14) translocation; or
    - As maintenance therapy as a single agent or in combination with lenalidomide for stable or responsive disease after primary therapy or hematopoietic stem cell transplant (HSCT)
  - Ninlaro® (ixazomib) in symptomatic multiple myeloma and as a single agent for maintenance therapy following response to primary myeloma therapy in transplant candidates or following HSCT
  - Sarclisa® (isatuximab-irfc) as primary therapy in combination with carfilzomib, lenalidomide, and dexamethasone for transplant eligible patients or in combination with lenalidomide and dexamethasone for transplant deferred or in patients when transplant is not indicated
  - Talvey® (talquetamab-tgvs) in combination with Tecvayli® (teclistamab-cgyv) in patients who have received at least 3 prior lines of therapy
  - Xpovio® (selinexor) in combination with daratumumab and dexamethasone in patients who have failed at least 1 prior therapy

Lynozyfic™ (Linvoseltamab-gcpt) Product Summary[8]

Therapeutic Class: BCMA-directed CD3 T-cell engager

Indication(s):

- Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
    - This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

How Supplied:

- 5mg/2.5mL (2mg/mL) solution in an SDV
- 200mg/10mL (20mg/mL) solution in an SDV

Dosing and Administration:

- Lynozyfic™ should be administered intravenously (IV) according to the step-up schedule to reduce the incidence and severity of cytokine release syndrome (CRS).
- Patients should be hospitalized for 24 hours after administration of the first and second step-up doses.
- The recommended dosage includes:
    - Step-Up Dosing: 5mg on day 1 + 25mg on day 8 + 200mg on day 15
    - Weekly Dosing: 200mg weekly from week 4 to week 13 for 10 doses
    - Biweekly Dosing: 200mg at week 14 and every 2 weeks thereafter
    - Every 4 Week Dosing: 200mg every 4 weeks for patients who achieved and maintained a very good partial response (VGPR) or better at or after week 24 and received at least 17 doses of 200mg
- Dosing should be continued until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) of Lynozyfic™ is $470 per 5mg SDV and $18,800 per 200mg SDV. This would result in an estimated cost of $322,420 for 24 weeks of treatment for a member who received step-up dosing plus 17 doses of 200mg.

Cost Comparison: Bortezomib Products

Product	Cost Per 0.1mg	Cost Per Dose*	Cost Per Tx Course+
Boruzu® (bortezomib) (J9054) 3.5mg/1.4mL SDV	**$26.15**	**$915.25**	**$47,593.00**
bortezomib (Velcade® generic) (J9041) 3.5mg SDV	$2.87	$100.45	$5,223.40

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS).
*Cost per dose based on 1.3mg/m^2 for a member with a body surface area (BSA) of 1.73m^2 (requiring 1 3.5mg vial per dose)
+Cost per treatment course based on 9 cycles and a total of 52 bortezomib doses.
SDV = single-dose vial; Tx = treatment

Recommendations

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 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.

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[1] Amneal Pharmaceuticals, Inc. and Shilpa Medicare Limited. Amneal and Shilpa Announce U.S. FDA Approval of Boruzu®, the First Ready-to-Use Version of Bortezomib for Subcutaneous Administration. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-and-Shilpa-Announce-U.S.-FDA-Approval-of-BORUZU-the-First-Ready-to-Use-Version-of-Bortezomib-for-subcutaneous-administration/default.aspx. Issued 09/05/2024. Last accessed 11/13/2025.

[2] U.S. Food and Drug Administration (FDA). FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor (CAR) T cell Immunotherapies. Available online at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor. Issued 06/26/2025. Last accessed 11/13/2025.

[3] U.S. FDA. FDA Grants Accelerated Approval to Linvoseltamab-gcpt for Relapsed or Refractory Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-linvoseltamab-gcpt-relapsed-or-refractory-multiple-myeloma. Issued 07/02/2025. Last accessed 11/13/2025.

[4] U.S. FDA. FDA Approves Labeling Changes that Include a Boxed Warning for Immune Effector Cell-Associated Enterocolitis Following Treatment with Ciltacabtagene Autoleucel (Carvykti®, Janssen Biotech, Inc.). Available online at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-labeling-changes-include-boxed-warning-immune-effector-cell-associated-enterocolitis. Issued 10/10/2025. Last accessed 11/13/2025.

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[6] U.S. FDA. FDA Granted Accelerated Approval to Belantamab Mafodotin-blmf for Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-granted-accelerated-approval-belantamab-mafodotin-blmf-multiple-myeloma. Last revised 03/07/2024. Last accessed 11/13/2025.

[7] National Comprehensive Cancer Network (NCCN). Multiple Myeloma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Last revised 11/03/2025. Last accessed 11/13/2025.

[8] Lynozyfic™ (Linvoseltamab-gcpt) Prescribing Information. Regeneron Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761400s000lbl.pdf. Last revised 07/2025. Last accessed 11/13/2025.

Appendix M

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

Oklahoma Health Care Authority
December 2025

Current Prior Authorization Criteria

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 month 6 and month 12 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.

Utilization of Skysona® (Elivaldogene Autotemcel): Fiscal Year 2025

There was no SoonerCare utilization of Skysona® (elivaldogene autotemcel) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Prior Authorization of Skysona® (Elivaldogene Autotemcel)

There were no prior authorization requests submitted for Skysona® (elivaldogene autotemcel) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Market News and Updates[1,2]

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

- **October 2025:** The FDA approved required labeling changes for Skysona® (elivaldogene autotemcel) regarding the increased risk of hematological malignancy following treatment with Skysona®. At the time of approval, hematologic malignancy was identified as a serious risk with 3 out of 67 patients treated reporting myelodysplastic syndrome (MDS); however, since its FDA approval, 7 additional clinical trial participants have been diagnosed with hematologic malignances. The FDA recommended updating the *Boxed Warning*, *Indications and Usage*, *Warnings and Precautions*, and *Adverse Reactions*. Most notably, the FDA recommended Skysona® should be restricted to patients without an available human leukocyte antigen (HLA)-matched allogeneic hematopoietic stem cell (allo-HSC) donor. Additionally, the

monitoring parameters were updated to recommend monitoring after treatment with Skysona® for hematologic malignancy via complete blood count (with differential) at least every 3 months and via integration site analysis or other testing for evidence of clonal expansion and predominance at least twice in the first year and then annually.

Recommendations

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.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves Required Labeling Changes for Increased Risk of Hematological Malignancy Following Treatment with Skysona®. Available online at: https://www.fda.gov/vaccines-blood-biologics/fda-approves-required-labeling-changes-increased-risk-hematologic-malignancy-following-treatment. Issued 08/07/2025. Last accessed 11/12/2025.

[2] Skysona® (Elivaldogene Autotemcel) Prescribing Information. Bluebird Bio, Inc. Available online at: https://www.genetixbiotx.com/-/media/bluebirdbio/Corporate%20COM/Files/Skysona/SKYSONA_Prescribing_Information.pdf. Last Revised 08/2025. Last accessed 11/12/2025.

Appendix N

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)

Oklahoma Health Care Authority
December 2025

Current Prior Authorization Criteria

Utilization data for Tecentriq® (atezolizumab) and Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs) and approval criteria for indications other than skin cancer can be found in the May 2025 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the lung cancer medications.

Bavencio® (Avelumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic MCC; and
2. Member must be 12 years of age or older.

Bavencio® (Avelumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Used as first-line treatment; and
3. Used in combination with axitinib.

Bavencio® (Avelumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Disease has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; or
3. Used as maintenance therapy for members not progressing on a first-line platinum-containing regimen.

Braftovi® (Encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic CRC; and
2. *BRAF* V600E mutation positive; and
3. Used in combination with cetuximab or panitumumab; and
4. Disease must have progressed following adjuvant therapy within 12 months; or

5. Used following progression of any line of metastatic therapy.

Braftovi® (Encorafenib) Approval Criteria [Melanoma Diagnosis]:
1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
3. Used in combination with binimetinib.

Braftovi® (Encorafenib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of metastatic NSCLC; and
2. *BRAF* V600E mutation; and
3. Used in combination with binimetinib.

Cotellic® (Cobimetinib) Approval Criteria [Histiocytic Neoplasm Diagnosis]:
1. Diagnosis of a histiocytic neoplasm; and
2. Member must be 18 years of age or older; and
3. Used as a single agent.

Cotellic® (Cobimetinib) Approval Criteria [Melanoma Diagnosis]:
1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Cobimetinib is not indicated for wild-type *BRAF* melanoma; and
3. Member meets 1 of the following:
    a. Used as first-line therapy in combination with vemurafenib; or
    b. Used as second-line therapy or subsequent therapy with vemurafenib.

Erivedge® (Vismodegib) 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.

Hepzato Kit™ (Melphalan) Approval Criteria [Uveal Melanoma Diagnosis]:
1. Diagnosis of metastatic uveal melanoma; and
2. Presence of hepatic metastases affecting <50% of the liver; and
3. No other extrahepatic metastases; or
4. Presence of extrahepatic metastases limited to the bone, lymph nodes, subcutaneous tissue, and/or lung that is amenable to resection or radiation.

Imlygic® (Talimogene Laherparepvec) Approval Criteria [Melanoma Diagnosis]:
1. Diagnosis of unresectable cutaneous, subcutaneous, or nodal lesions that are recurrent after initial surgery; and

    a. Not indicated in members with visceral metastases; and
2. Member is not immunocompromised or pregnant.

Keytruda® (Pembrolizumab) 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.

Keytruda® (Pembrolizumab) 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) 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 Stage III-IV 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
        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) 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) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

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

Keytruda® (Pembrolizumab) 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) 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) 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.

Keytruda® (Pembrolizumab) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Used in first-line or recurrent setting; and
2. Squamous cell histology; and
3. If used in the recurrent setting, member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) 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) 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; 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) 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)].

Keytruda® (Pembrolizumab) 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) 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) 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.

Keytruda® (Pembrolizumab) 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) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of high-risk, NMIBC; and
2. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
3. Member must be ineligible for or has elected not to undergo cystectomy.

Keytruda® (Pembrolizumab) Approval Criteria [Primary Mediastinal Large B-cell Lymphoma (PMBCL) Diagnosis]:

1. Diagnosis of PMBCL; and
2. Member must have refractory disease or relapsed after 2 or more prior lines of therapy; and
3. Authorizations will not be granted for members who require urgent cytoreduction; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) 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) 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) 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.

Keytruda® (Pembrolizumab) 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)].

Kimmtrak® (Tebentafusp-tebn) Approval Criteria [Uveal Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic uveal melanoma; and
2. Positive expression of HLA-A*02:01 genotype.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic BCC; and
2. Member has previously been treated with a hedgehog pathway inhibitor (HHI); or
3. Treatment with a HHI is not appropriate for the member.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cervical, Vaginal, or Vulvar Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical, vaginal, or vulvar cancer; and
2. Used as second-line or subsequent therapy; and
3. Used as a single agent; and
4. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab), Yervoy® (ipilimumab)].

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of metastatic or locally advanced cSCC; and
2. Member is ineligible for curative surgery or radiation; and
3. 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.

Mekinist® (Trametinib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
2. *BRAF* V600E mutation; and
3. No satisfactory locoregional treatment options.

Mekinist® (Trametinib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and
4. Used in combination with dabrafenib.

Mekinist® (Trametinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
    a. Used as first-line therapy in combination with dabrafenib; or
    b. Used as second-line or subsequent therapy with dabrafenib; or
    c. Used as second-line therapy or subsequent therapy as a single agent if:
        i. Member was intolerant to prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib); and
        ii. No evidence of disease progression on prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib).

Mekinist® (Trametinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and

    a. Trametinib is not indicated for wild-type *BRAF* NSCLC; and
3. 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. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
    b. Progression on primary, maintenance, or recurrence therapy; or
    c. Stable or persistent disease (if not on maintenance therapy); or
    d. Complete remission and relapse after completing chemotherapy.

Mekinist® (Trametinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with dabrafenib.

Mektovi® (Binimetinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
3. Used in combination with encorafenib.

Mektovi® (Binimetinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. *BRAF* V600E mutation; and
3. Used in combination with encorafenib.

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.

Opdivo® (Nivolumab) 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; 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. 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) 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).

Opdivo® (Nivolumab) 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
2. Diagnosis of esophageal or GEJ cancer; and
    a. Member has received preoperative chemoradiation; and
    b. Member underwent R0 (complete) resection and has residual disease; and
    c. As a single agent; 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
        ii. Used in the second-line or greater setting; and
            1. As a single agent; and
            2. Squamous cell pathology.

Opdivo® (Nivolumab) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic disease; and
2. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Opdivo® (Nivolumab) 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. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Must meet 1 of the following:
    a. If used as first-line therapy, must be used as single agent; and
        i. Ineligible for tyrosine kinase inhibitors or anti-angiogenic agents; or
    b. 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.

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

1. Diagnosis of relapsed or refractory classical 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
    c. In combination with brentuximab vedotin 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) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with ipilimumab.

Opdivo® (Nivolumab) 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. Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. 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.

Opdivo® (Nivolumab) 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. 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) 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)].

Opdivo® (Nivolumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member is 12 years of age or older; and
3. Used as a single agent or in combination with ipilimumab:
   a. As first-line therapy for untreated melanoma; or
   b. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
      i. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. 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) 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.

Opdualag® (Nivolumab/Relatlimab-rmbw) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member must be 12 years of age or older; and
3. As first-line therapy; and
4. Member has not previously failed programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab)].

Tafinlar® (Dabrafenib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
3. *BRAF* V600E mutation; and
4. No satisfactory locoregional treatment options.

Tafinlar® (Dabrafenib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and
4. Used in combination with trametinib.

Tafinlar® (Dabrafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Dabrafenib is not indicated for wild-type *BRAF* melanoma; and
3. Used as a single agent or in combination with trametinib; and
4. Must meet 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line or subsequent therapy.

Tafinlar® (Dabrafenib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
    a. Not indicated for wild-type BRAF NSCLC; and
3. Used as a single agent or 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 be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with trametinib.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Melanoma Diagnosis]:

1. Unresectable or metastatic disease; and
2. BRAF V600 mutation-positive; and
3. In combination with cobimetinib and vemurafenib; and
4. Member must be 18 years of age or older.

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 [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); and

3. Used in combination with nivolumab.

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.

Yervoy® (Ipilimumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Used as second-line or greater therapy; and
4. Used in combination with nivolumab; and
5. Must not have failed other checkpoint inhibitors.

Yervoy® (Ipilimumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with nivolumab.

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:
        i. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
        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 [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; and
2. Used in combination with nivolumab; and
3. Member has not failed previous programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows: 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.

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 [Erdheim-Chester Disease (ECD) Diagnosis]:

1. Diagnosis of ECD; and
2. *BRAF* V600E or V600K mutation; and
3. Used as a single agent.

Zelboraf® (Vemurafenib) Approval Criteria [Hairy-Cell Leukemia Diagnosis]:

1. Diagnosis of hairy-cell leukemia; and
    a. Used as a single agent; and
        i. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine); or
    b. Used in combination with rituximab or obinutuzumab for patients who are not candidates for purine analogs.

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.

Zelboraf® (Vemurafenib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
    a. Vemurafenib is not indicated for wild-type *BRAF* NSCLC; and
3. Used as a single agent.

Zynyz® (Retifanlimab-dlwr) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic or recurrent locally advanced MCC; and
2. Member must be 18 years of age or older; and
3. A maximum treatment duration of 24 months will apply.

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and
    a. Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6 months if there is no evidence of disease progression or adverse drug reactions; and
2. The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:
    a. Any request for an oncology medication which does not meet approval criteria; or
    b. Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or
    c. Any level-1 appeal request for an oncology medication; or
    d. Any peer-to-peer request for an oncology medication.

Utilization of Skin Cancer Medications: Fiscal Year 2025

The following utilization data includes medications indicated for skin cancer; however, the data does not differentiate between skin cancer 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	49	326	$3,468,711.61	$10,640.22	$345.21	25,652	10,048
Aetna	5	12	$93,817.85	$7,818.15	$260.61	645	360
Humana	4	8	$108,202.13	$13,525.27	$458.48	401	236
OCH	7	29	$282,203.35	$9,731.15	$311.14	2,484	907
2024 Total	**53**	**375**	**$3,952,934.94**	**$10,541.16**	**$342.22**	**29,182**	**11,551**
Fiscal Year 2025							
FFS	17	127	$1,542,758.10	$12,147.70	$399.89	10,659	3,858
Aetna	6	40	$355,300.82	$8,882.52	$310.31	2,669	1,145
Humana	8	43	$583,214.77	$13,563.13	$459.95	1,913	1,268
OCH	12	124	$1,339,674.48	$10,803.83	$345.99	19,180	3,872
2025 Total	**41**	**334**	**$3,820,948.17**	**$11,439.96**	**$376.71**	**34,421**	**10,143**
% Change	**-22.60%**	**-10.90%**	**-3.30%**	**8.50%**	**10.10%**	**18.00%**	**-12.20%**
Change	**-12**	**-41**	**-$131,986.77**	**$898.80**	**$34.49**	**5,239**	**-1,408**

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.

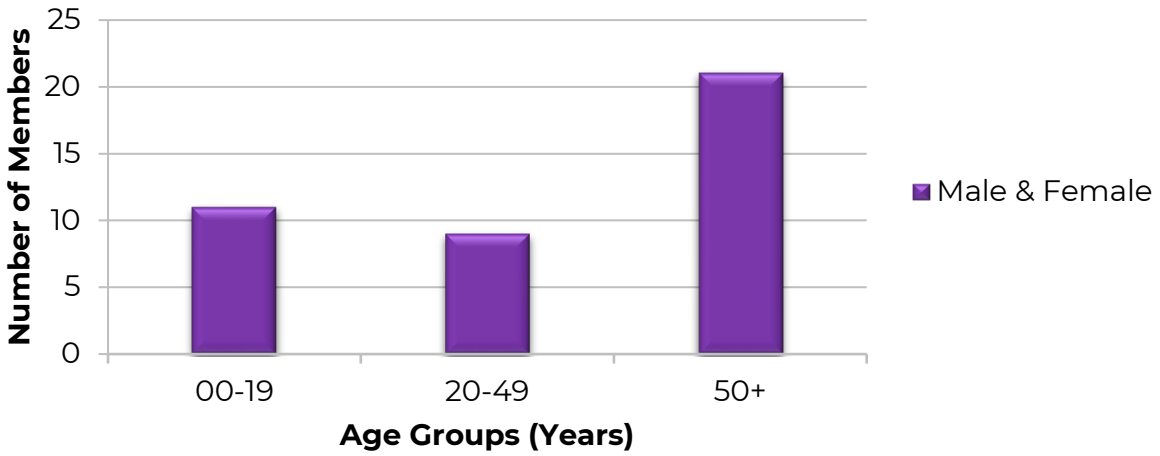
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	379	2,229	$25,841,917.21	$11,593.50	5.88
Aetna	7	13	$126,152.20	$9,704.02	1.86
Humana	6	7	$113,007.20	$16,143.89	1.17
OCH	22	36	$388,384.20	$10,788.45	1.64
2024 Total	**385**	**2,285**	**$26,469,460.81**	**$11,584.01**	**5.94**
Fiscal Year 2025					
FFS	230	1,180	$14,805,463.92	$12,547.00	5.13
Aetna	65	249	$2,699,885.15	$10,842.91	3.83
Humana	61	215	$2,360,776.29	$10,980.35	3.52
OCH	76	319	$3,456,318.17	$10,834.85	4.2
2025 Total	**381**	**1,963**	**$23,322,443.53**	**$11,881.02**	**5.15**
% Change	**-1.04%**	**-14.09%**	**-11.89%**	**2.56%**	**-13.30%**
Change	**-4**	**-322**	**-$3,147,017.28**	**$297.01**	**-0.79**

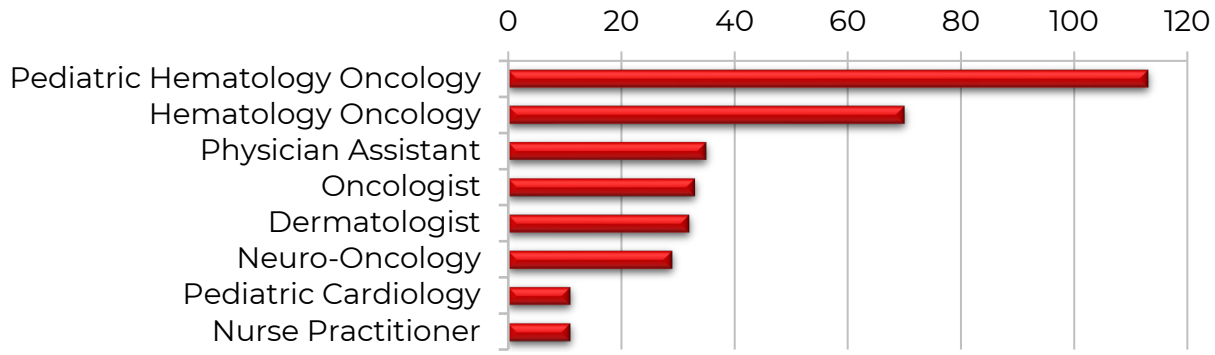
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2025 for skin cancer medications totaled $10,888,792.84.[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 Skin Cancer Medications: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Skin Cancer Medications by Number of Claims: Pharmacy Claims (All Plans)

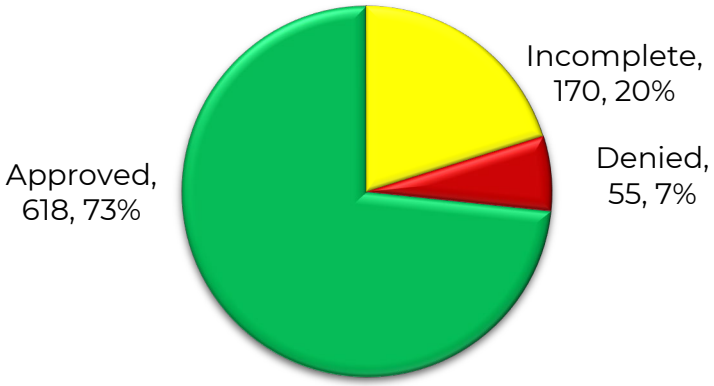


Prior Authorization of Skin Cancer Medications

There were 843 prior authorization requests submitted for skin cancer medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

[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.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	456	71%	159	25%	25	4%	**640**
Aetna	27	79%	1	3%	6	18%	**34**
Humana	62	86%	0	0%	10	14%	**72**
OCH	73	75%	10	10%	14	14%	**97**
Total	**618**	**73%**	**170**	**20%**	**55**	**7%**	**843**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27]

Anticipated Patent Expiration(s):

- Erivedge® (vismodegib): December 2028
- Zelboraf® (vemurafenib): June 2032
- Braftovi® (encorafenib): August 2033
- Mektovi® (binimetinib): October 2033
- Mekinist® (trametinib dimethyl sulfoxide): February 2034
- Odomzo® (sonidegib phosphate): March 2036
- Cotellic® (cobimetinib fumarate): December 2036
- Tafinlar® (dabrafenib mesylate): December 2038

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 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 gastroesophageal junction (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 cutaneous squamous cell carcinoma (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[28]

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[29]

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, gastroesophageal junction 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: 600mg nivolumab/10,000 units hyaluronidase per 5mL (120mg/2,000 units per mL) 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 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 $7,943.08 per SDV. 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 $15,886.16 per month or $206,520.08 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
4. *BRAF* V600E mutation; and
~~5. No satisfactory locoregional treatment options.~~
6. Used following progression following prior treatment options and no satisfactory alternative treatment options; and
7. 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.

Utilization Details of Skin Cancer Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DABRAFENIB PRODUCTS						
TAFINLAR CAP 75MG	64	13	$762,631.56	$11,916.12	4.92	19.96%
TAFINLAR CAP 50MG	40	8	$342,267.45	$8,556.69	5	8.96%
TAFINLAR TAB 10MG	12	2	$135,759.97	$11,313.33	6	3.55%
SUBTOTAL	**116**	**23**	**$1,240,658.98**	**$10,695.34**	**5.04**	**32.47%**
TRAMETINIB PRODUCTS						
MEKINIST TAB 0.5MG	41	6	$532,778.99	$12,994.61	6.83	13.94%
MEKINIST TAB 2MG	27	6	$445,015.34	$16,482.05	4.5	11.65%
MEKINIST SOL 0.05MG/ML	24	2	$113,986.37	$4,749.43	12	2.98%
SUBTOTAL	**92**	**14**	**$1,091,780.70**	**$11,867.18**	**6.57**	**28.57%**
VISMODEGIB PRODUCTS						
ERIVEDGE CAP 150MG	50	12	$615,204.09	$12,304.08	4.17	16.10%
SUBTOTAL	**50**	**12**	**$615,204.09**	**$12,304.08**	**4.17**	**16.10%**
SONIDEGIB PRODUCTS						
ODOMZO CAP 200MG	30	6	$360,810.77	$12,027.03	5	9.44%
SUBTOTAL	**30**	**6**	**$360,810.77**	**$12,027.03**	**5**	**9.44%**
COBIMETINIB PRODUCTS						
COTELLIC TAB 20MG	15	2	$120,306.65	$8,020.44	7.5	3.15%
SUBTOTAL	**15**	**2**	**$120,306.65**	**$8,020.44**	**7.5**	**3.15%**
VEMURAFENIB PRODUCTS						
ZELBORAF TAB 240MG	13	1	$121,322.37	$9,332.49	13	3.18%
SUBTOTAL	**13**	**1**	**$121,322.37**	**$9,332.49**	**13**	**3.18%**
ENCORAFENIB PRODUCTS						
BRAFTOVI CAP 75MG	12	5	$194,828.48	$16,235.71	2.4	5.10%
SUBTOTAL	**12**	**5**	**$194,828.48**	**$16,235.71**	**2.4**	**5.10%**
BINIMETINIB PRODUCTS						
MEKTOVI TAB 15MG	6	3	$76,036.13	$12,672.69	2	1.99%
SUBTOTAL	**6**	**3**	**$76,036.13**	**$12,672.69**	**2**	**1.99%**
TOTAL	**334**	**41***	**$3,820,948.17**	**$11,439.96**	**8.15**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution; 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
J9271 PEMBROLIZUMAB INJ	1,376	297	$17,213,671.90	$12,509.94	4.63
J9299 NIVOLUMAB INJ	458	76	$4,234,339.97	$9,245.28	6.03
J9228 IPILIMUMAB INJ	68	19	$981,433.15	$14,432.84	3.58
J9119 CEMIPLIMAB-RWLC INJ	47	10	$461,860.00	$9,826.81	4.7
J9298 NIVOL/RELATLIMAB-RMBW INJ	14	2	$431,138.51	$30,795.61	7
TOTAL	**1,963**	**381**	**$23,322,443.53**	**$11,881.02**	**5.15**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; NIVOL = nivolumab
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix O

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

Oklahoma Health Care Authority
December 2025

Current Prior Authorization Criteria

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®, a patient-specific, clinically significant reason why the member cannot use Soliris® 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 have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. 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
6. Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
8. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. For use of Bkemv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® 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
10. Use of Bkemv™, Epysqli®, or Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and
11. 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
12. 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®, a patient-specific, clinically significant reason why the member cannot use Soliris® 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.

Empaveli® (Pegcetacoplan) 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. Empaveli® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®; and
8. Member must not be receiving Empaveli® in combination with another complement inhibitor used to treat PNH; 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.

Enspryng® (Satralizumab-mwge) 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; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and
5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and
13. Member must not be receiving Enspryng® in combination with other immunomodulators to treat NMOSD; and
14. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
15. 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.

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; 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.

Fabhalta® (Iptacopan) 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. Fabhalta® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
5. For members switching from Soliris® (eculizumab) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 1 week after the last dose of Soliris®; and
6. For members switching from Ultomiris® (ravulizumab-cwvz) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 6 weeks after the last dose of Ultomiris®; and
7. Member must not be receiving Fabhalta® in combination with another complement 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.

Piasky® (Crovalimab-akkz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and

2. Member must be 13 years of age or older and must weigh ≥40kg; and
3. Piasky® 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 Piasky® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from another C5 inhibitor (i.e., Soliris® or Ultomiris®), the prescriber must verify the first intravenous (IV) loading dose of Piasky® will be administered no sooner than the time of the next scheduled C5 inhibitor dose and member will be monitored for Type III hypersensitivity reactions; and
7. Member must not be receiving Piasky® in combination with another complement inhibitor used to treat PNH; and
8. A quantity limit override for the loading dose will be approved upon meeting Piasky® approval criteria. A quantity limit of 6mL per 28 days will apply for the maintenance dose; 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.

Rystiggo® (Rozanolixizumab-noli) 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 IVa; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥3 (with at least 3 points from non-ocular symptoms); 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. Rystiggo® 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 Rystiggo® in combination with a complement inhibitor or with another neonatal Fc receptor blocker used to treat gMG; and
9. 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.

Soliris® (Eculizumab) 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 a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Soliris® 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 member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Soliris® in combination with other immunomodulators to treat NMOSD; 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.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Member must be:
    a. 1 month of age or older for the intravenous (IV) formulation; or
    b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
4. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS; and
5. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
6. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and

7. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
8. Member must not be receiving Ultomiris® in combination with another complement inhibitor used to treat aHUS; 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.

Ultomiris® (Ravulizumab-cwvz) 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 (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 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. Ultomiris® 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 Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. The subcutaneous (sub-Q) formulation of Ultomiris® will not be approved for a diagnosis of gMG; and
11. Member must not be receiving Ultomiris® in combination with a neonatal Fc receptor blocker or another complement inhibitor used to treat gMG; and
12. 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.

Ultomiris® (Ravulizumab-cwvz) 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 a history of at least 1 relapse in the last 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Ultomiris® 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 member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Ultomiris® in combination with other immunomodulators to treat NMOSD; 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.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be:
    a. 1 month of age or older for the intravenous (IV) formulation; or
    b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Ultomiris® 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 Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
7. Member must not be receiving Ultomiris® 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.

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 member has not received any vaccinations within 4 weeks prior to initiation of therapy; 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.

Veopoz® (Pozelimab-bbfg) Approval Criteria [CD55-Deficient Protein-Losing Enteropathy (PLE) Diagnosis]:

1. An FDA approved diagnosis of CD55-deficient PLE confirmed by all of the following:
   a. Genetic testing identifying biallelic pathogenic mutations in the *CD55* gene (results of genetic testing must be submitted); and
   b. A history of PLE; and
2. Member has active disease defined by hypoalbuminemia (serum albumin concentration ≤3.2g/dL) with 1 or more of the following signs or symptoms within the last 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema; and
3. Member must be 1 year of age or older; and
4. Prescriber must verify the member has received the meningococcal vaccine 2 weeks prior to treatment unless urgent treatment is needed; and
5. Veopoz® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or other specialist with expertise in the treatment of CD55-deficient PLE; and
6. The prescriber must verify that Veopoz® will be administered by a health care professional; 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. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a normalization of serum albumin or documentation of a positive clinical response to therapy. Subsequent approvals will be for 1 year.

Voydeya™ (Danicopan) 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. Voydeya™ must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Member must have been treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab-cwvz) for at least the previous 6 months; and
5. Prescriber must verify member is experiencing clinically significant extravascular hemolysis (EVH) while on Soliris® or Ultomiris®; and

6. Member must remain on treatment with Soliris® or Ultomiris® while on Voydeya™; and
7. Member must not be receiving Voydeya® in combination with another complement protein C3 inhibitor or complement factor B inhibitor used to treat PNH; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Voydeya™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment through therapy; and
10. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

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 intravenous immunoglobulin (IVIG) must be provided; and
5. 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. 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.

Zilbrysq® (Zilucoplan) 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 ≥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. Zilbrysq® 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 and pharmacy must be enrolled in the Zilbrysq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Member must not be receiving Zilbrysq® in combination with a neonatal Fc receptor blocker or another complement inhibitor used to treat gMG; and
11. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Zilbrysq®; and
12. 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.

Utilization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: 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	8	42	$2,014,985.01	$47,975.83	$1,239.23	4,760	1,626
Aetna	2	4	$162,049.63	$40,512.41	$1,884.30	507	86
Humana	1	3	$123,934.23	$41,311.41	$1,475.41	68	84
OCH	2	3	$145,593.74	$48,531.25	$1,692.95	353	86
2024 Total	**10**	**52**	**$2,446,562.61**	**$47,049.28**	**$1,299.98**	**5,688**	**1,882**
Fiscal Year 2025							
FFS	4	13	$744,599.80	$57,276.91	$1,060.68	1,200	702
Aetna	3	20	$1,183,170.27	$59,158.51	$1,955.65	2,575	605
Humana	1	2	$82,622.82	$41,311.41	$1,475.41	45	56
OCH	4	22	$937,084.38	$42,594.74	$1,419.82	3,229	660
2025 Total	**10**	**57**	**$2,947,477.27**	**$51,710.13**	**$1,456.98**	**7,050**	**2,023**
% Change	**0.00%**	**9.60%**	**20.50%**	**9.90%**	**12.10%**	**23.90%**	**7.50%**
Change	**0**	**5**	**$500,914.66**	**$4,660.85**	**$157.00**	**1,362**	**141**

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)

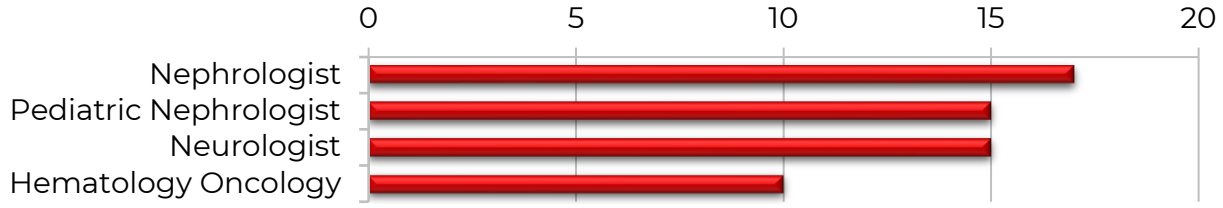
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	18	159	$3,653,783.50	$22,979.77	8.83
Aetna	1	1	$16,920.90	$16,920.90	1
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**18**	**160**	**$3,670,704.40**	**$22,941.90**	**8.89**
Fiscal Year 2025					
FFS	15	50	$2,075,054.82	$41,501.10	3.33
Aetna	4	8	$503,611.80	$62,951.48	2
Humana	1	3	$218,588.70	$72,862.90	3
OCH	3	22	$738,298.90	$33,559.04	7.33
2025 Total	**19**	**83**	**$3,535,554.22**	**$42,597.04**	**4.37**
% Change	**5.56%**	**-48.13%**	**-3.68%**	**85.67%**	**-50.86%**
Change	**1.00**	**-77.00**	**-$135,150.18**	**$19,655.14**	**-4.52**

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.

Demographics of Members Utilizing Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing complement inhibitors and miscellaneous immunomodulatory agents during fiscal year 2025, detailed demographic information could not be provided.

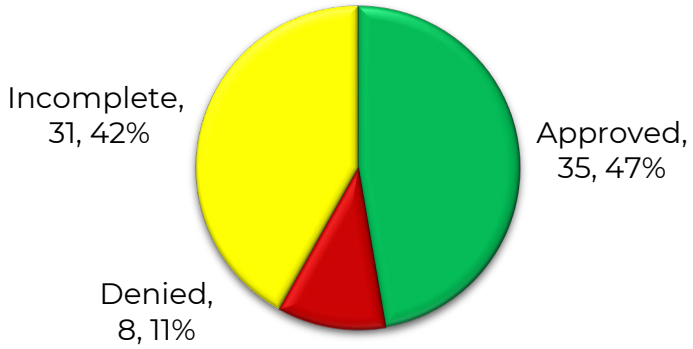
Top Prescriber Specialties of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Pharmacy Claims (All Plans)



Prior Authorization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents

There were 74 prior authorization requests submitted for the complement inhibitors and miscellaneous immunomodulatory agents 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	24	39%	30	49%	7	11%	**61**
Aetna	3	60%	1	20%	1	20%	**5**
Humana	4	100%	0	0%	0	0%	**4**
OCH	4	100%	0	0%	0	0%	**4**
Total	**35**	**47%**	**31**	**42%**	**8**	**11%**	**74**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16]

Anticipated Patent Expiration(s):

- Zilbrysq® (zilucoplan): June 2035
- Voydeya™ (danicopan): August 2038
- Empaveli® (pegcetacoplan): December 2038
- Fabhalta® (iptacopan): July 2041

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.

Guidelines:

- **Kidney Disease Improving Global Outcomes (KDIGO) Guideline Update:** KDIGO released a clinical practice update for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV) in October 2025, which replaced the guidelines from October 2021. Some of the key updates for IgAN included:
  - A diagnosis of IgAN can only be confirmed by a kidney biopsy and should be considered in all adults with proteinuria ≥0.5g/day (or equivalent) with a suspicion of IgAN. Once IgAN Is confirmed, the patient should be assessed for secondary causes of IgAN.
  - The definition of a patient at risk of progressive loss of kidney function was changed from the prior definition of proteinuria >0.75-1g/day despite ≥90 days of optimized supportive care. The update now defines at risk patients as having proteinuria ≥0.5g/day (or equivalent), while on or off treatment for IgAN, and recommends treatment/additional treatment should be started in all cases.
  - The treatment goal is to reduce the rate of loss of kidney function <1mL/min per year for the rest of a patient's life. Urine protein excretion is the only validated biomarker to help guide clinical decision making and should be maintained <0.5g/day (or equivalent), and ideally at <0.3g/day (or equivalent), and multiple treatment strategies may be needed to achieve this goal.

- The focus of management for most patients should be simultaneous to prevent or reduce IgA immune complex formation and immune complex-mediated glomerular injury [i.e. treatment with Tarpeyo® (budesonide delayed-release capsule)] as well as to manage the consequences of existing IgAN induced nephron loss [i.e., treatment with lifestyle modifications, renin-angiotensin system inhibitors (RASi), and sodium-glucose cotransporter-2 (SGLT-2) inhibitors].

Pipeline:

- **Gefurulimab:** Gefurulimab is a self-administered, sub-Q C5 inhibitor being studied for anti-AChR antibody positive gMG. The results of the Phase 3 PREVAIL trial showed patients treated with gefurulimab had a least squares mean change from baseline after 26 weeks in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score of -4.2 points versus -2.6 points for the placebo group, for a treatment difference of -1.6 ($P<0.0001$). Gefurulimab is designed to be smaller than other monoclonal antibodies on the market with hopes that it would allow better tissue penetration and potentially lead to greater efficacy; however, the results showed similar efficacy to other complement inhibitors. Long-term studies are still underway.
- **Uplizna® (Inebilizumab-cdon):** The safety and efficacy of Uplizna® were studied in the Phase 3 MINT trial in adults with anti-AChR antibody positive gMG. The results were announced in March 2025 and showed that more patients treated with Uplizna® had an improvement in the MG-ADL score than the placebo group with 72.3% of patients in the Uplizna® group showing a ≥3 point improvement in the score, compared to 45.2% in the placebo treated group. If approved, this would provide a twice-yearly treatment option, after initial loading doses, for patients with gMG. A Prescription Drug User Fee Act (PDUFA) date of December 14, 2025 has been set.
- **Vyvgart® (Efgartigimod Alfa-fcab):** Argenx, the manufacturer of Vyvgart®, is planning to submit a Supplemental Biologics License Application (sBLA) to the FDA by the end of 2025 to expand the indication for Vyvgart® to include adult anti-AChR antibody seronegative gMG patients across all 3 subtypes [MuSK+, low-density lipoprotein receptor-related protein 4 (LRP4+), and triple seronegative]. The submission will be based on the results of the ADAPT SERON trial which showed that anti-AChR antibody seronegative gMG patients treated with Vyvgart® achieved a statistically significant improvement in MG-ADL total score compared to placebo. This would be the first FDA approved treatment for patients with anti-LRP4+ gMG or for triple seronegative gMG.

Imaavy™ (Nipocalimab-aahu) Product Summary[17]

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**	**$324,480.00α**
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	$459,486.72Δ
Vyvgart® (efgartigimod alfa-fcab) 400mg/20mL	$315.71	$353,595.20¥
Rystiggo® (rozanolixizumab-noli) 560mg/4mL	$3,101.10	$372,132.00λ

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
αCost 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).
ΔCost 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).
λCost 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	$776.03	$558,741.60α
Empaveli® (pegcetacoplan) 1,080mg/20mL	$242.95	$505,336.00β

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Unit = capsule or mL
αCost based on the FDA approved dose of 200mg twice daily.
βCost 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 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; 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. 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
8. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. Member must not be receiving Fabhalta® in combination with another complement protein C3 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.

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.

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 intravenous immunoglobulin (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 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 must be confirmed by a kidney 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. 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
8. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. 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
10. Member must not be receiving Empaveli® in combination with another complement inhibitor used to treat C3G; and
11. 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 neuromyelitis optica spectrum disorder (NMOSD) criteria for Uplizna® (inebilizumab-cdon) to be consistent with clinical practice (changes shown in red):

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.

Utilization Details of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SOLIRIS INJ 10MG/ML	18	2	$839,304.28	$46,628.02	9	28.48%
ULTOMIRIS INJ 300MG/3ML	12	3	$732,242.53	$61,020.21	4	24.84%
EMPAVELI INJ 54MG/ML	10	1	$382,264.50	$38,226.45	10	12.97%
VYVGART INJ 400MG/20ML	6	1	$290,992.32	$48,498.72	6	9.87%
ULTOMIRIS INJ 1,100MG/11ML	6	3	$426,955.07	$71,159.18	2	14.49%
VYVGART HYT 180MG-2,000UNIT/ML	3	1	$193,095.75	$64,365.25	3	6.55%
ZILBRYSQ INJ 32.4MG/0.81ML	2	1	$82,622.82	$41,311.41	2	2.80%
TOTAL	**57**	**10***	**$2,947,477.27**	**$51,710.13**	**5.7**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; HYT = Hytrulo
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
ULTOMIRIS INJ 300MG/30ML (J1303)	59	11	$3,026,973.60	$51,304.64	5.36
SOLIRIS INJ 10MG/ML (J1300)	14	4	$253,813.50	$18,129.54	3.5
VYVGART HYT 180MG-2,000UNIT/ML (J9334)	5	2	$83,751.12	$16,750.22	2.5
VYVGART INJ 400MG/20ML (J9332)	4	1	$25,696.00	$6,424.00	4
UPLIZNA 100MG/10ML (J1823)	1	1	$145,320.00	$145,320.00	1
TOTAL	**83**	**19**	**$3,535,554.22**	**$42,597.04**	**4.37**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; HYT = Hytrulo
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix P

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)

Oklahoma Health Care Authority
December 2025

Introduction[1,2,3]

Immune globulin (IG) products intended for intravenous (IV) or subcutaneous (SC) use are immunoglobulins pooled from healthy donors and supplied as concentrated injectable formulations. IGIV and IGSC products provide the recipient with passive immunity against a broad spectrum of antigens, which can be beneficial in the treatment of a plethora of conditions, including immunodeficiencies, auto-immune, and inflammatory disorders.

There are numerous IGIV and IGSC products currently marketed in the United States, that vary regarding inactive ingredients, concentration, osmolality, and other characteristics. While all currently available IGIV and IGSC products in the United States are FDA approved for primary humoral immunodeficiency (PI), the breadth of FDA approved indications for each product and concentration differs, and the products are not considered equivalent. However, IGIV and IGSC products are often used off label with the support of clinical literature and clinical practice guidelines recommending product selection based on the preferred route of administration, patient tolerability, excipients, and costs.

Cost Comparison: IGIV Products

Product	Cost Per Gram	Cost Per Dose*	Cost Per Year⁺
Asceniv™ (IGIV, human-slra) 10%	**$946.47**	**$37,858.80**	**$681,458.40**
Alyglo™ (IGIV, human-stwk) 10%	**$312.90**	**$12,516.00**	**$225,288.00**
Gammagard S/D® (IGIV, human) 10g vial	**$157.59**	**$6,303.60**	**$113,464.80**
Panzyga® (IGIV, human-ifas) 10%	**$145.99**	**$5,839.60**	**$105,112.80**
Gammaplex® (IGIV, human) 10%	**$127.37**	**$5,094.80**	**$91,706.40**
Privigen® (IGIV, human) 10%	**$101.47**	**$4,058.80**	**$73,058.40**
Gammagard Liquid® (IG inf, human) 10%	**$90.63**	**$3,625.12**	**$65,252.16**
Bivigam® (IGIV, human) 10%	$150.53	$6,021.20	$108,381.60
Gammaked™ (IG inj, human) 10g/100mL	$97.93	$3,917.20	$70,509.60
Gamunex®-C (IG inj, human) 1g/10mL	$97.93	$3,917.20	$70,509.60
Octagam® (IGIV, human) 5%	$95.05	$3,802.00	$68,436.00

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⁺
Cuvitru® (IGSC, human) 20%	**$168.42**	**$1,684.20**	**$87,578.40**
Hizentra® (IGSC, human) 20%	**$168.42**	**$1,684.20**	**$87,578.40**
Xembify® (IGSC, human) 20%	**$168.42**	**$1,684.20**	**$87,578.40**
Gammagard Liquid® (IG inf, human) 10%	**$90.63**	**$906.30**	**$47,127.60**
Cutaquig® (IGSC, human) 16.5%	$127.20	$1,272.00	$66,144.00
Gammaked™ (IG inj, human) 10g/100mL	$97.93	$979.30	$50,923.60
Gamunex®-C (IG inj, human) 1g/10mL	$97.93	$979.30	$50,923.60

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 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), Cuvitru® (IGSC, human), Gammagard Liquid® (IG infusion, human), Gammgard S/D® (IGIV, human),

Gammaplex® (IGIV, human), Hizentra® (IGSC, human), Panzyga® (IGIV, human-ifas), Privigen® (IGIV, human), Xembify® (IGSC, human-klhw) with the following criteria (shown in red):

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) Approval Criteria:

1. Continuation of therapy will be approved for members stabilized on the requested product upon submission of supporting documentation; 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. As a medical benefit, approval of Gammagard Liquid®, Gammgard S/D®, Hizentra®, and Privigen® will require a patient-specific, clinically significant reason why the member cannot use all of the following as appropriate for the requested route of administration:
    a. For IV administration:
        i. Bivigam®(IGIV, human), and
        ii. Gammaplex®; and
        iii. Octagam® (IGIV, human); and
        iv. Panzyga®; or
    b. For SC administration:
        i. Cutaquig® (IGSC, human); and
        ii. Cuvitru®; and
        iii. Gammaked™ (IG injection, human); and
        iv. Gamunex®-C (IG injection, human); and
        v. Xembify®; or
4. As a pharmacy benefit, approval of Cuvitru®, Gammaplex®, Panzyga®, and Xembify® will require a patient-specific, clinically significant reason why the member cannot use all of the following as appropriate for the requested route of administration:
    a. For IV administration:
        i. Bivigam®; and
        ii. Gammgard Liquid®; and
        iii. Gammagard S/D®; and
        iv. Octagam®; and
        v. Privigen®; or
    b. For SC administration:
        i. Cutaquig®; and
        ii. Gammagard Liquid®; and
        iii. Gammaked™; and

iv. Gamunex®-C; and
v. Hizentra®; and

5. 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 the intended dosing frequency must be provided on the prior authorization request in order to authorize the appropriate amount of product; and
6. 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.

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[1] Arumugham VB, Rayi A. Intravenous Immunoglobulin (IVIG). *StatPearls*. Available online at: https://www.ncbi.nlm.nih.gov/books/NBK554446/. Last revised 07/03/2023. Last accessed 11/25/2025.
[2] U.S. Food and Drug Administration (FDA). Immune Globulins. Available online at: https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/immune-globulins. Last revised 03/08/2023. Last accessed 11/25/2025.
[3] American Academy of Allergy, Asthma, & Immunology (AAAAI). Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency. Available online at: https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/IVIG-guiding-principles.pdf. Issued 12/2011. Last accessed 11/25/2025.

Appendix Q

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

Oklahoma Health Care Authority
December 2025

Current Prior Authorization Criteria

Adzynma (ADAMTS13, Recombinant-krhn) Approval Criteria:

1. An FDA approved diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by:
   a. Molecular genetic testing confirming biallelic pathogenic variants in the ADAMTS13 gene (results of genetic testing must be submitted); and
   b. ADAMTS13 activity testing showing <10% of normal ADAMTS13 activity (results of activity testing must be submitted); and
2. Member's recent weight (within the last 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
3. For prophylactic therapy, member has a history of ≥1 documented TTP event or is currently receiving prophylactic therapy; and
4. Must be prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the treatment of cTTP; and
5. For prophylactic enzyme replacement therapy (ERT):
   a. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the durations of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to treatment (e.g., improvement in acute and subacute TTP events, TTP manifestations, other clinical symptoms associated with TTP); and
6. For on-demand ERT:
   a. Approvals will be for 1 month; and
   b. If additional days are needed, requests should specify that the acute event has not resolved.

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.

Alvaiz® (Eltrombopag) Approval Criteria [Chronic Hepatitis C-Associated Thrombocytopenia Diagnosis]:

1. Member must have diagnosis of chronic hepatitis C-associated thrombocytopenia; and
2. Member must have a platelet count of $<75 \times 10^9/L$; and
3. Member must be 18 years of age or older; and
4. Member must not have a recent diagnosis of myelodysplastic syndromes; and
5. Member must be initiating interferon-based therapy (regimen must be provided); and
6. 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
7. Prescriber must verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
8. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz® and concomitant hepatitis C therapy; and

9. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of hepatitis C-associated thrombocytopenia; and
10. Continuation requests will not be approved once antiviral therapy has been discontinued; and
11. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 72mg per day, as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 120 tablets per 30 days; or
    c. 36mg strength: 60 tablets per 30 days; or
    d. 54mg strength: 30 tablets per 30 days.

Alvaiz® (Eltrombopag) Approval Criteria [Refractory Severe Aplastic Anemia Diagnosis]:

1. Member must have diagnosis of refractory severe aplastic anemia; and
2. Member must have a platelet count of ≤30 x 10^9/L; and
3. Member must not have a diagnosis of Fanconi anemia; and
4. Member must be 18 years of age or older; and
5. Member must not have a recent diagnosis of myelodysplastic syndromes; and
6. Member must have a documented trial of immunosuppressive therapy; 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 verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
9. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz®; and
10. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of aplastic anemia; and
11. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 108mg per day as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 120 tablets per 30 days; or
    c. 36mg and 54mg strengths: 60 tablets per 30 days.

Cablivi® (Caplacizumab-yhdp) Approval Criteria:

1. An FDA approved indication for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy; and
2. Member must be undergoing plasma exchange therapy; and
    a. Dates of initiation of plasma exchange therapy must be listed on the prior authorization request; and

   b. Authorizations will be for the duration of plasma exchange and for 30 days after discontinuation of plasma exchange; and
3. Member must be utilizing immunosuppressant therapy; and
4. Cablivi® must be prescribed by, or in consultation with, a hematologist; and
5. A quantity limit of 11mg per day will apply. Initial approvals will be for the duration of plasma exchange plus 30 days. Reauthorization, after completing 30 days post-plasma exchange, may be considered if the prescriber documents sign(s) of persistent underlying disease remain. Reauthorization will be for a maximum of 28 days.

Doptelet® (Avatrombopag) Approval Criteria [Chronic Immune Thrombocytopenia (ITP) Diagnosis]:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic ITP who have had an insufficient response to a previous treatment; and
2. Member must be 18 years 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 weekly until a stable platelet count >50 x 10^9/L has been achieved, and then obtained monthly thereafter; 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 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. A quantity limit of 60 tablets 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.

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.

Tavalisse® (Fostamatinib) Approval Criteria:

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment; and
2. Member must be 18 years of age or older (Tavalisse® is not recommended for use in patients younger than 18 years of age because adverse effects on actively growing bones were observed in nonclinical studies); and
3. Member must have a clinical diagnosis of persistent/chronic ITP for at least 3 months; and
4. Previous insufficient response with at least 2 of the following treatments:
    a. Corticosteroids; or

   b. Immunoglobulins; or
   c. Splenectomy; or
   d. Thrombopoietin (TPO) receptor agonists; and
5. Prescriber must verify degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
6. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
7. Prescriber must verify the member's complete blood count (CBC), including platelet counts, will be monitored monthly until a stable platelet count (at least 50 x 10^9/L) is achieved and will be monitored regularly thereafter; and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored monthly; and
9. Prescriber must verify member's blood pressure will be monitored every 2 weeks until establishment of a stable dose, then monthly thereafter; and
10. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 1 month after therapy completion; and
11. Prescriber must verify female member is not breastfeeding; and
12. Member must not be taking strong CYP3A4 inducers (e.g., rifampicin) concurrently with Tavalisse®; and
13. Initial approvals will be for the duration of 12 weeks; and
14. Discontinuation criteria:
    a. Platelet count does not increase to a level sufficient to avoid clinically important bleeding after 12 weeks of therapy; and
15. A quantity limit of 2 tablets per day will apply.

Utilization of Thrombocytopenia 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	39	180	$2,387,523.31	$13,264.02	$453.56	6,179	5,264
Aetna	5	11	$223,755.34	$20,341.39	$678.05	390	330
Humana	4	5	$89,415.01	$17,883.00	$715.32	160	125
OCH	7	13	$151,104.30	$11,623.41	$444.42	350	340
2024 Total	**44**	**209**	**$2,851,797.96**	**$13,644.97**	**$470.67**	**7,079**	**6,059**
Fiscal Year 2025							
FFS	30	116	$1,520,286.42	$13,105.92	$449.66	3,708	3,381
Aetna	12	39	$823,937.10	$21,126.59	$713.37	1,387	1,155
Humana	11	39	$699,521.30	$17,936.44	$597.88	1,200	1,170
OCH	17	71	$1,176,451.82	$16,569.74	$587.64	8,621	2,002
2025 Total	**63**	**265**	**$4,220,196.64**	**$15,925.27**	**$547.51**	**14,916**	**7,708**
% Change	**43.20%**	**26.80%**	**48.00%**	**16.70%**	**16.30%**	**110.70%**	**27.20%**
Change	**19**	**56**	**$1,368,398.68**	**$2,280.30**	**$76.84**	**7,837**	**1,649**

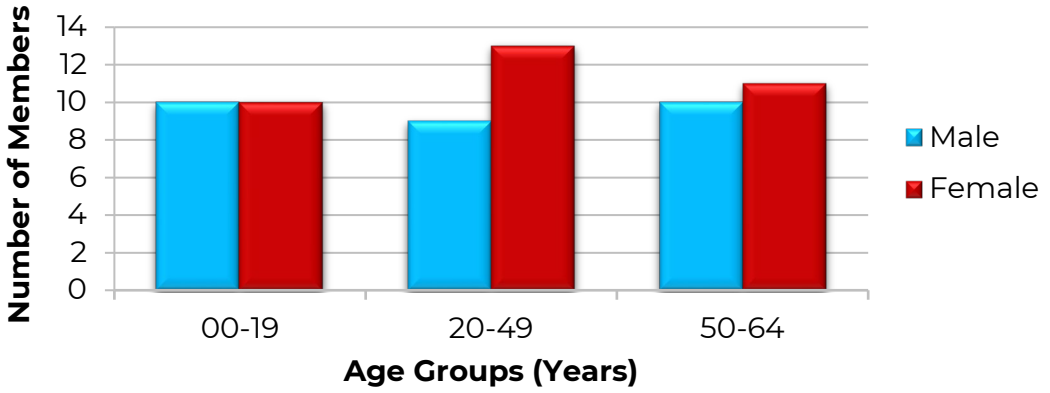
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Comparison of Fiscal Years: Medical Claims (All Plans)

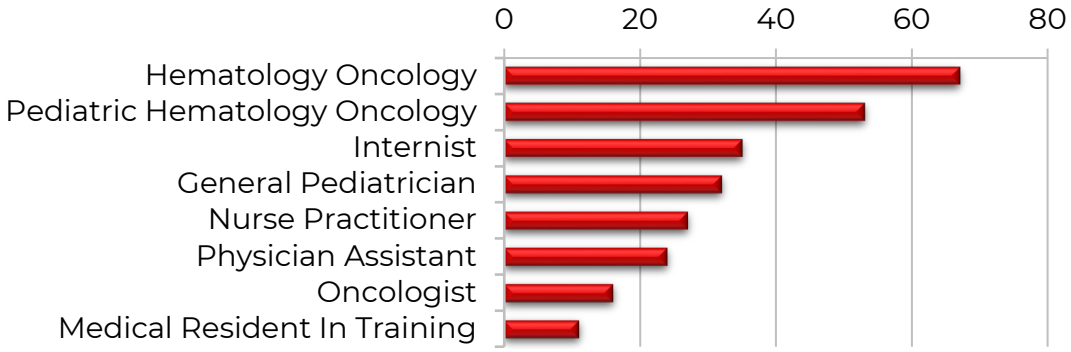
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	23	491	$1,396,708.46	$2,844.62	21.35
Aetna	0	0	$0.00	$0.00	0
Humana	2	11	$23,728.16	$2,157.11	5.50
OCH	1	7	$14,042.43	$2,006.06	7
2024 Total	**23**	**508**	**$1,434,585.80**	**$2,823.99**	**22.09**
Fiscal Year 2025					
FFS	6	180	$562,005.86	$3,122.25	30.00
Aetna	0	0	$0.00	$0.00	0
Humana	7	34	$71,029.46	$2,089.10	4.86
OCH	3	15	$55,494.46	$3,699.63	5.00
2025 Total	**14**	**229**	**$688,529.78**	**$3,006.68**	**16.36**
% Change	**-39.13%**	**-54.92%**	**-52.00%**	**6.47%**	**-25.95%**
Change	**-9**	**-279**	**-$746,056.02**	**$182.69**	**-5.73**

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.

Demographics of Members Utilizing Thrombocytopenia Medications: Pharmacy Claims (All Plans)



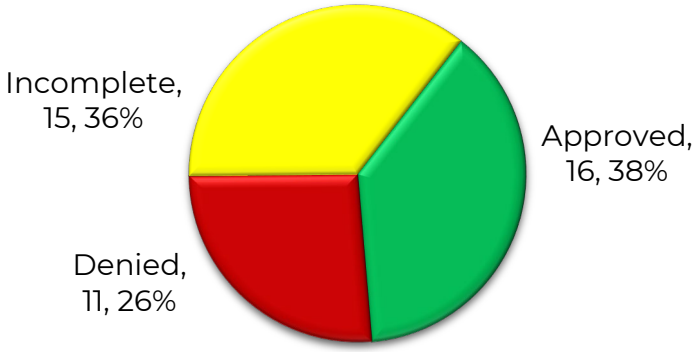
Top Prescriber Specialties of Thrombocytopenia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Thrombocytopenia Medications

There were 42 prior authorization requests submitted for thrombocytopenia 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	9	36%	12	48%	4	16%	**25**
Aetna	3	60%	1	20%	1	20%	**5**
Humana	0	0%	0	0%	2	100%	**2**
OCH	4	40%	2	20%	4	40%	**10**
Total	**16**	**38%**	**15**	**36%**	**11**	**26%**	**42**

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):

- Promacta® (eltrombopag oral suspension): January 2026
- Promacta® (eltrombopag tablets): February 2028
- Doptelet® (avatrombopag): July 2027
- Doptelet® Sprinkle (avatrombopag): July 2027
- Mulpleta® (lusutrombopag): September 2031
- Tavalisse® (fostamatinib): July 2032
- Alvaiz® (eltrombopag): November 2038
- Wayrilz™ (rilzabrutinib): February 2041

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.

Pipeline:

- **Ianalumab:** Ianalumab is an investigational fully human monoclonal antibody being studied in combination with eltrombopag in patients with ITP previously treated with corticosteroids (CS). Results from the VAYHIT2 Phase 3 trial showed that ianalumab plus eltrombopag significantly prolonged the time to treatment failure when compared to placebo plus eltrombopag. Full data from the trial is expected to be presented at upcoming meetings and included in future regulatory submissions in 2027. Ianalumab has been granted Orphan Drug designation by the FDA for ITP.

Wayrilz™ (Rilzabrutinib) Product Summary

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 $\geq 50x10^9$/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 $\geq 50x10^9$/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	$5,506.02	$44,048.16ᵝ	$572,626.08
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	$421.90	$25,314.00¥	$303,768.00
Tavalisse® (fostamatinib) 150mg tab	$255.83	$15,349.80€	$184,197.60

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).
tab = tablet; Unit = tablet or vial
*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 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.

Utilization Details of Thrombocytopenia Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	COST/ MEMBER	% COST
ELTROMBOPAG PRODUCTS						
PROMACTA TAB 50MG	104	32	$1,551,269.93	$14,916.06	3.25	36.76%
PROMACTA TAB 25MG	45	10	$333,290.60	$7,406.46	4.5	7.90%
PROMACTA TAB 75MG	43	15	$1,195,709.33	$27,807.19	2.87	28.33%
PROMACTA TAB 12.5MG	28	3	$217,992.53	$7,785.45	9.33	5.17%
PROMACTA POW 25MG	9	4	$68,932.04	$7,659.12	2.25	1.63%
PROMACTA POW 12.5MG	4	2	$30,771.39	$7,692.85	2	0.73%
ELTROMBOPAG TAB 50MG	3	3	$55,859.58	$18,619.86	1	1.32%
ELTROMBOPAG TAB 25MG	3	3	$18,543.09	$6,181.03	1	0.44%
ELTROMBOPAG TAB 75MG	1	1	$16,759.03	$16,759.03	1	0.40%
SUBTOTAL	**240**	**73**	**$3,489,127.52**	**$14,538.03**	**3.29**	**82.68%**
AVATROMBOPAG PRODUCTS						
DOPTELET TAB 20MG	18	7	$159,241.13	$8,846.73	2.57	3.77%
SUBTOTAL	**18**	**7**	**$159,241.13**	**$8,846.73**	**2.57**	**3.77%**
CAPLACIZUMAB-YHDP PRODUCTS						
CABLIVI KIT 11MG	2	2	$504,433.22	$252,216.61	1	11.95%
SUBTOTAL	**2**	**2**	**$504,433.22**	**$252,216.61**	**1**	**11.95%**
FOSTAMATINIB PRODUCTS						
TAVALISSE TAB 150MG	2	1	$29,255.82	$14,627.91	2	0.69%
SUBTOTAL	**2**	**1**	**$29,255.82**	**$14,627.91**	**2**	**0.69%**
LUSUTROMBOPAG PRODUCTS						
MULPLETA TAB 3MG	2	2	$17,022.82	$8,511.41	1	0.40%
SUBTOTAL	**2**	**2**	**$17,022.82**	**$8,511.41**	**1**	**0.40%**
ADAMTS13, RECOMBINANT-KRHN PRODUCTS						
ADZYNMA KIT 1,500IU	1	1	$21,116.13	$21,116.13	1	0.50%
SUBTOTAL	**1**	**1**	**$21,116.13**	**$21,116.13**	**1**	**0.50%**
TOTAL	**265**	**63***	**$4,220,196.64**	**$15,925.27**	**4.21**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
IU = international unit; POW = powder; 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
ROMIPLOSTIM INJ (J2796)	214	12	$653,605.48	$3,054.23	17.83
ADAMTS13, RECOMB-KRHN INJ (J7171)	15	3	$34,924.30	$2,328.29	5
TOTAL	**229**	**14**	**$688,529.78**	**$3,006.68**	**16.36**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; RECOMB = recombinant
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[10] Kuter D, Ghanima W, Cooper N, et al. Safety and Efficacy of Rilzabrutinib vs Placebo in Adults with Immune Thrombocytopenia: The Phase 3 LUNA3 Study. *Blood* 2025; 145 (24): 2914-2926. doi: 10.1182/blod.2024027336.

Appendix R

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)

Oklahoma Health Care Authority
December 2025

Current Prior Authorization Criteria

Muscle Relaxant Medications		
Tier-1	**Tier-2**	**Special PA***
baclofen 10mg, 20mg (Lioresal®)	metaxalone (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®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		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.

Muscle Relaxant Medications Tier-2 Approval Criteria:

1. Member must have failure with at least 2 Tier-1 medications within the past 90 days defined as no beneficial response after at least 2 weeks of use during which time the drug has been titrated to the recommended dose; and
2. Approvals will be for the duration of 3 months, except for members with chronic diseases such as multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or other chronic musculoskeletal diagnosis confirmed with diagnostic results, in which case authorizations will be for the duration of 1 year; and
3. For repeat authorizations, there must be documentation of a failed withdrawal attempt within the past 3 months defined as increase in pain and debilitating symptoms when medication was discontinued.

Amrix® [Cyclobenzaprine Extended-Release (ER) Capsule] and Fexmid® (Cyclobenzaprine 7.5mg Tablet) Approval Criteria:

1. Authorization requires clinical documentation of inability to take other generically available forms of cyclobenzaprine tablets; and
2. The following quantity limits apply:
    a. Amrix® 15mg and 30mg ER capsules: 30 capsules per 30 days; or
    b. Fexmid® 7.5mg tablets: 90 tablets per 30 days.

Baclofen 5mg Tablet and Baclofen 15mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including splitting a baclofen 10mg tablet to achieve a 5mg or 15mg dose, must be provided.

Chlorzoxazone 250mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot split a 500mg chlorzoxazone tablet to achieve the 250mg dose 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.

Lorzone® (Chlorzoxazone) Approval Criteria:

1. Generic chlorzoxazone 500mg tablets must be tried prior to consideration of Lorzone®; and
2. A patient-specific, clinically significant reason why the member cannot use generic chlorzoxazone 500mg tablets must be provided; and
3. The following quantity limits apply:
    a. Lorzone® 375mg tablets: 120 tablets per 30 days; or
    b. Lorzone® 750mg tablets: 120 tablets per 30 days.

Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/ Aspirin/Caffeine) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all lower-tiered products 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 350mg) Approval Criteria:

1. Members may receive 3 months of carisoprodol 350mg per rolling 365 days without prior authorization; and
2. 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
3. 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
4. A quantity limit of 120 tablets per 30 days will apply.

Zanaflex® (Tizanidine Capsule) Approval Criteria:

1. Tizanidine tablets must be tried prior to consideration of tizanidine capsules; and
2. The capsule formulation may be considered for approval only if there is supporting information as to why the member cannot take the tablets.

Utilization of Muscle Relaxant Medications: Fiscal Year 2025

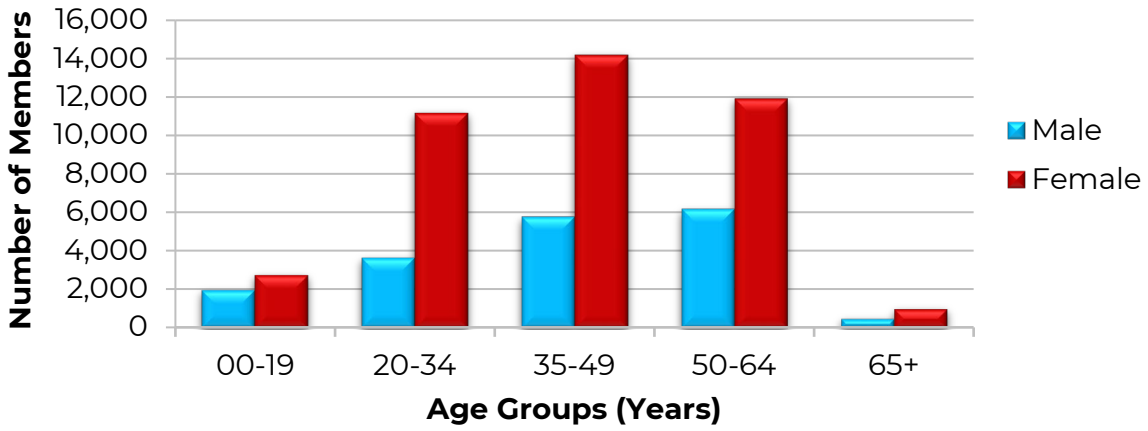
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	53,964	140,305	$1,749,761.61	$12.47	$0.51	9,032,792	3,440,331
Aetna	4,467	6,615	$90,146.08	$13.63	$0.62	373,657	145,369
Humana	5,614	9,040	$123,506.79	$13.66	$0.61	531,371	203,757
OCH	4,449	6,371	$89,864.36	$14.11	$0.64	362,964	139,562
2024 Total	**60,180**	**162,331**	**$2,053,278.84**	**$12.65**	**$0.52**	**10,300,783**	**3,929,019**
Fiscal Year 2025							
FFS	24,651	69,971	$884,252.97	$12.64	$0.49	4,901,134	1,787,143
Aetna	11,930	28,695	$381,272.10	$13.29	$0.60	1,615,627	639,081
Humana	14,330	38,365	$533,759.07	$13.91	$0.57	2,428,145	941,997
OCH	12,626	29,747	$403,159.27	$13.55	$0.62	1,638,398	647,420
2025 Total	**59,058**	**166,778**	**$2,202,443.41**	**$13.21**	**$0.55**	**10,583,303**	**4,015,641**
% Change	**-1.90%**	**2.70%**	**7.30%**	**4.40%**	**5.80%**	**2.70%**	**2.20%**
Change	**-1,122**	**4,447**	**$149,164.57**	**$0.56**	**$0.03**	**282,520**	**86,622**

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.

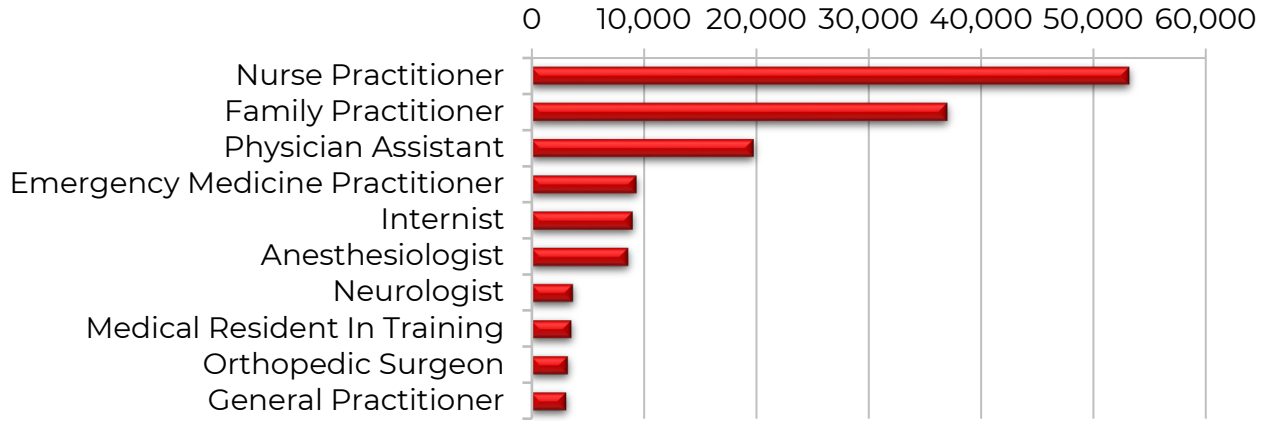
- Aggregate drug rebates collected during fiscal year 2025 for muscle relaxant medications totaled $34,741.49.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Muscle Relaxant 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.

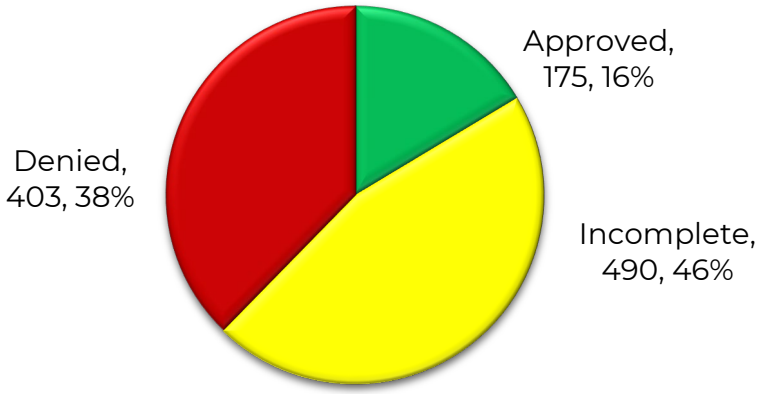
Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Muscle Relaxant Medications

There were 1,068 prior authorization requests submitted for muscle relaxant 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	124	22%	336	58%	116	20%	**576**
Aetna	8	3%	133	46%	146	51%	**287**
Humana	17	18%	0	0%	77	82%	**94**
OCH	26	23%	21	19%	64	58%	**111**
Total	**175**	**16%**	**490**	**46%**	**403**	**38%**	**1,068**

FFS = fee-for-service; OCH = OK Complete Health

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

Anticipated Patent Expiration(s):

- Fleqsuvy® (baclofen oral suspension): September 2037
- Metaxalone 640mg tablet: July 2039
- Lyvispah® (baclofen oral granules): September 2041
- Atmeksi® (methocarbamol oral suspension): October 2044

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[5,6,7]

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[8,9]

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[10,11,12]

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)	$2.81	$674.40	$8,092.80
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[13,14,15]

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)	$0.15	$27.00	$324.00
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

Carisoprodol Products Cost Comparison

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®)
		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.

Utilization Details of Muscle Relaxant Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 10MG	48,973	21,051	$575,407.69	$11.75	2.33	26.13%
CYCLOBENZAPRINE TAB 5MG	15,139	8,691	$176,602.77	$11.67	1.74	8.02%
SUBTOTAL	**64,112**	**29,742**	**$752,010.46**	**$11.73**	**2.16**	**34.14%**
TIZANIDINE PRODUCTS						
TIZANIDINE TAB 4MG	37,301	11,862	$493,034.50	$13.22	3.14	22.39%
TIZANIDINE TAB 2MG	7,412	3,305	$94,517.05	$12.75	2.24	4.29%
SUBTOTAL	**44,713**	**15,167**	**$587,551.55**	**$13.14**	**2.95**	**26.68%**
BACLOFEN PRODUCTS						
BACLOFEN TAB 10MG	17,345	5,072	$224,543.88	$12.95	3.42	10.20%
BACLOFEN TAB 20MG	6,316	1,308	$97,280.81	$15.40	4.83	4.42%
SUBTOTAL	**23,661**	**6,380**	**$321,824.69**	**$13.60**	**3.71**	**14.61%**
METHOCARBAMOL PRODUCTS						
METHOCARBAMOL TAB 500MG	14,432	8,519	$183,282.75	$12.70	1.69	8.32%
METHOCARBAMOL TAB 750MG	12,450	6,224	$169,604.29	$13.62	2	7.70%
SUBTOTAL	**26,882**	**14,743**	**$352,887.04**	**$13.13**	**1.82**	**16.02%**
ORPHENADRINE PRODUCTS						
ORPHENADRINE TAB 100MG ER	4,959	3,368	$109,684.42	$22.12	1.47	4.98%
SUBTOTAL	**4,959**	**3,368**	**$109,684.42**	**$22.12**	**1.47**	**4.98%**
CHLORZOXAZONE PRODUCTS						
CHLORZOXAZONE TAB 500MG	677	213	$17,637.41	$26.05	3.18	0.80%
SUBTOTAL	**677**	**213**	**$17,637.41**	**$26.05**	**3.18**	**0.80%**
TIER-1 SUBTOTAL	**165,004**	**69,613**	**$2,141,595.57**	**$12.98**	**2.37**	**97.24%**
TIER-2 UTILIZATION						
METAXALONE PRODUCTS						
METAXALONE TAB 800MG	165	64	$7,213.86	$43.72	2.58	0.33%
METAXALONE TAB 400MG	33	9	$7,510.05	$227.58	3.67	0.34%
TIER-2 SUBTOTAL	**198**	**73**	**$14,723.91**	**$74.36**	**2.71**	**0.67%**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
CARISOPRODOL PRODUCTS						
CARISOPRODOL TAB 350MG	871	316	$12,268.09	$14.09	2.76	0.56%
CARISOPRODOL TAB 250MG	15	9	$572.65	$38.18	1.67	0.03%
SUBTOTAL	**886**	**325**	**$12,840.74**	**$14.49**	**2.73**	**0.58%**
BACLOFEN PRODUCTS						
BACLOFEN TAB 5MG	290	111	$5,395.69	$18.61	2.61	0.24%
BACLOFEN SOL 10MG/5ML	19	5	$6,317.55	$332.50	3.8	0.29%
BACLOFEN TAB 15MG	9	5	$1,151.47	$127.94	1.8	0.05%
BACLOFEN SUS 25MG/5ML	9	5	$3,406.65	$378.52	1.8	0.15%
BACLOFEN SOL 5MG/5ML	4	3	$941.83	$235.46	1.33	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**331**	**129**	**$17,213.19**	**$52.00**	**2.57**	**0.78%**
TIZANIDINE PRODUCTS						
TIZANIDINE CAP 4MG	158	123	$3,036.85	$19.22	1.28	0.14%
TIZANIDINE CAP 6MG	92	39	$2,386.86	$25.94	2.36	0.11%
TIZANIDINE CAP 2MG	66	49	$1,008.60	$15.28	1.35	0.05%
SUBTOTAL	**316**	**211**	**$6,432.31**	**$20.36**	**1.5**	**0.29%**
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 7.5MG	34	22	$869.72	$25.58	1.55	0.04%
CYCLOBENZAPRINE CAP 30MG ER	2	1	$119.38	$59.69	2	0.01%
CYCLOBENZAPRINE CAP 15MG ER	1	1	$27.49	$27.49	1	0.00%
SUBTOTAL	**37**	**24**	**$1,016.59**	**$27.48**	**1.54**	**0.05%**
METHOCARBAMOL PRODUCTS						
TANLOR TAB 1,000MG	3	3	$7,730.43	$2,576.81	1	0.35%
SUBTOTAL	**3**	**3**	**$7,730.43**	**$2,576.81**	**1**	**0.35%**
CHLORZOXAZONE PRODUCTS						
CHLORZOXAZONE TAB 750MG	1	1	$42.76	$42.76	1	0.00%
CHLORZOXAZONE TAB 375MG	1	1	$39.10	$39.10	1	0.00%
CHLORZOXAZONE TAB 250MG	1	1	$808.81	$808.81	1	0.04%
SUBTOTAL	**3**	**3**	**$890.67**	**$296.89**	**1**	**0.04%**
SPECIAL PA SUBTOTAL	**1,576**	**695**	**$46,123.93**	**$29.27**	**2.27**	**2.09%**
TOTAL	**166,778**	**59,058***	**$2,202,443.41**	**$13.21**	**2.82**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; SOL = solution; SUS = suspension; TAB = tablet
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 11/2025. Last accessed 11/18/2025.
[2] Atmeksi® (Methocarbamol) – New Drug Approval. OptumRx®. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval-atmeksi-080125.pdf. Issued 07/30/2025. Last accessed 11/18/2025.
[3] U.S. FDA. National Drug Code Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm. Last accessed 11/18/2025.
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Appendix S

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

Oklahoma Health Care Authority
December 2025

Current Prior Authorization Criteria

Berinert® (C1 Esterase Inhibitor), Firazyr® (Icatibant), Kalbitor® (Ecallantide), Ruconest® (C1 Esterase Inhibitor), and Sajazir™ (Icatibant) Approval Criteria:

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. For authorization consideration of Firazyr® (icatibant) or Kalbitor® (ecallantide), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) must be provided; or
4. For authorization consideration of Ruconest® (C1 esterase inhibitor) or Sajazir™ (icatibant), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor), Firazyr® (icatibant), or Kalbitor® (ecallantide) must be provided.

Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:

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. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and

7. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and
8. Cinryze® Dosing:
    a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
    b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
    c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); and
        i. For requests exceeding the quantity limit, clinical documentation supporting the need for the dose increase (i.e., up to a maximum of 16,000 units per month) must be provided for a quantity limit override; or
9. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
    b. 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
    c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or
10. Orladeyo® Dosing:
    a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and
    b. A quantity limit of 28 capsules per 28 days will apply; or
11. Takhzyro® Dosing:
    a. For members 12 years of age of older: The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    b. For members 6-11 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    c. For members 2 to 5 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 4 weeks; and
    d. Prescriber must verify member or caregiver has been trained by a health professional on proper storage and sub-Q administration of Takhzyro®; and
    e. A quantity limit of (2) vials per 28 days will apply.

Market News and Updates[1,2,3]

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

- **June 2025:** The FDA approved Andembry® (garadacimab-gxxii) 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	$680,815.20
Cinryze® (C1 esterase inhibitor) 500 IU/5mL vial	$665,223.52
Haegarda® (C1 esterase inhibitor) 2,000 and 3,000 IU vials	$629,323.76
Orladeyo® (berotralstat) 150mg capsule	$571,941.39

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	$17,119.73
Ruconest® (C1 esterase inhibitor) 2,100 IU vial	$15,441.72
Berinert® (C1 esterase inhibitor) 500 IU vial	$11,378.85
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 $227,458.60 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 $13,360.22 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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Appendix T

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

Oklahoma Health Care Authority
December 2025

Current Prior Authorization Criteria

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 10mg/10mL soln (UDC)
fluvoxamine (Luvox®)			fluoxetine 20mg/5mL soln (UDC)
paroxetine (Paxil®)			fluoxetine tabs
sertraline tabs & soln (Zoloft®)			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®)			venlafaxine besylate ER 112.5mg tablets

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
venlafaxine IR tabs (Effexor®)			venlafaxine ER 225mg tabs (Effexor XR®)
venlafaxine 37.5mg. 75mg & 150mg ER 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; UDC = unit dose cups

Antidepressants Tier-2 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial of 2 Tier-1 medications at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response. Tier-1 selection must include at least 1 medication from the SSRI category; or
2. Prior stabilization on the Tier-2 medication documented within the last 100 days. A past history of success on the Tier-2 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by Tier-1 medications or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Tier-3 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier 1 selection must include at least 1 medication from the SSRI category) and a trial of a Tier-2 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or

2. Prior stabilization on the Tier-3 medication documented within the last 100 days. A past history of success on the Tier-3 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by a lowered tiered medication or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Auvelity® (Dextromethorphan/Bupropion) 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. Prescriber must agree that member's blood pressure will be assessed prior to treatment initiation and monitored periodically during treatment; and
4. Prescriber must agree to screen members for history of bipolar disorder, mania, or hypomania; and
5. Member must not be taking any other medications containing bupropion or dextromethorphan; and
6. Member must not have any contraindications to therapy (i.e., seizure disorder; current or prior diagnosis of bulimia or anorexia nervosa; abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs; concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; known hypersensitivity to bupropion, dextromethorphan, or other components of Auvelity®); and
7. Member must not have severe hepatic or renal impairment; and
8. The maximum approvable dose is 1 tablet once daily if the member has moderate renal impairment, is taking a strong CYP2D6 inhibitor (e.g., paroxetine, fluoxetine, quinidine), or is a known poor CYP2D6 metabolizer; and
9. Prescriber must verify that female members are not currently pregnant and will use effective contraception while receiving treatment with Auvelity®; and
10. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier 1 selection must include bupropion as 1 of the 2 trials), 1 Tier-2 medication, and 1 Tier-3 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or
11. Prior stabilization on the requested medication documented within the last 100 days. A history of success on the requested medication will also be considered with adequate documentation; and
12. A quantity limit of 60 tablets per 30 days will apply.

Citalopram Capsule Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD) in adults; and
2. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without prior authorization, in place of the capsule formulation must be provided; and
4. Citalopram capsules will not be approved for members 60 years of age or older; and
5. A quantity limit of 30 capsules per 30 days will apply.

Citalopram 20mg/10mL, Escitalopram 10mg/10mL, and Fluoxetine 20mg/5mL Unit Dose Cups Approval Criteria:

1. An FDA approved indication; and
2. A patient-specific, clinically significant reason why the member cannot use the bulk medication must be provided.

Desyrel® (Trazodone 300mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products including 2 trazodone 150mg tablets or 3 trazodone 100mg tablets to achieve a 300mg dose must be provided.

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. 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. A quantity limit of 30 capsules per 30 days will apply.

Exxua™ (Gepirone) 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. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier-1 selection must include at least 1 medication from the SSRI category), 1 Tier-2 medication, and 1 Tier-3 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; and
4. Member must not have any contraindications to Exxua™, including:
    a. Prolonged QTc interval >450msec; and
    b. Congenital long QT syndrome; and

    c. Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin); and
    d. Severe hepatic impairment; and
    e. Concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; and
5. A quantity limit of 30 tablets per 30 days will apply.

Fluoxetine Tablet Approval Criteria:

1. Fluoxetine capsules are available without prior authorization. The tablet formulation will require prior authorization and a patient-specific, clinically significant reason why the tablet formulation is required in place of the capsule formulation.

Forfivo XL® [Bupropion Extended-Release (ER)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products, including using 3 bupropion 150mg XL tablets to achieve the 450mg dose, must be provided.

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

Luvox CR® (Fluvoxamine CR) and Paxil CR® (Paroxetine CR) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Tier-1 immediate-release products that are available without prior authorization must be provided.

Marplan® (Isocarboxazid) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use any of the Tier-3 monoamine oxidase inhibitors (MAOIs) or other cost-effective, lower tiered alternatives in place of Marplan® must be provided.

Prozac® Weekly [Fluoxetine Delayed-Release (DR)] Approval Criteria:

1. Clients currently stabilized on Prozac® Weekly should be continued; and
2. New start clients must meet all of the following criteria:
    a. Client must have been stabilized on 20mg daily of fluoxetine for at least 12 weeks.
    b. Start date should be 7 days after the last daily dose.

c. Client must have a compelling clinical reason for use of this convenience only medication. This medication should not be approved for patients in nursing homes or assisted living centers compliance/convenience should not be an issue).

3. Prior authorization can be given for a 12-week supply per petition.
4. The quantity limit for Prozac® Weekly is 3 packs of 4 tablets each (12-week supply).

Sertraline Capsule Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD) in adults or obsessive-compulsive disorder (OCD) in adults and pediatric members 6 years of age and older; and
2. Member must have initiated treatment with sertraline tablets for dose titration up to the 150mg or 200mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use sertraline tablets, which are available without prior authorization, in place of the capsule formulation must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Depressive Symptoms in Adults with Major Depressive Disorder (MDD) with Acute Suicidal Ideation or Behavior Diagnosis]:

1. An FDA approved indication of depressive symptoms in adults with MDD with acute suicidal ideation or behavior; 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. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
5. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with package labeling; and
6. Member must not have any contraindications to therapy [i.e., 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
7. Member must not have severe hepatic impairment (Child Pugh C); and
8. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
9. Prescriber must verify female member is not breastfeeding; and
10. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
11. Member must be enrolled in the Spravato® REMS program; and

12. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
13. For initial approval, the number of doses the member received while hospitalized, if applicable, and the dates of these doses must be provided to allow authorization of the appropriate quantity for the initial 4 weeks of treatment; and
14. For continued authorization, prescriber must verify member demonstrated an adequate response during the initial 4 weeks of treatment, verify member is using Spravato® in combination with an oral antidepressant, and provide patient-specific, clinically significant information to support continued use of Spravato®; and
15. A quantity limit of 8 kits per 28 days will apply.

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.

Venlafaxine Besylate Extended-Release (ER) Tablets Approval Criteria:

1. An FDA approved indication for the treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD); and
2. Member must be 18 years of age or older; and
3. Member must have received at least 75mg of venlafaxine ER capsules for at least 4 days; and
4. A patient-specific, clinically significant reason why the member cannot use venlafaxine ER capsules must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Venlafaxine Extended-Release (ER) 225mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products, including using 3 venlafaxine ER 75mg capsules or tablets to achieve the 225mg dose, must be provided.

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.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment of Major Depressive Disorder (MDD):*

1. For Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), or Vraylar® (cariprazine), a diagnosis of MDD requires current use of an antidepressant and requires previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting antidepressant) and a trial of aripiprazole tablets that did not yield adequate response; and
2. Tier structure rules still apply.

*Utilization data for Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), and Vraylar® (cariprazine) and approval criteria for indications other than MDD can be found in the June 2025 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the atypical antipsychotic medications.

Utilization of Antidepressants: 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	128,325	557,722	$12,443,961.41	$22.31	$0.53	27,249,730	23,646,493
Aetna	13,820	26,974	$745,865.96	$27.65	$0.64	1,332,270	1,164,850
Humana	16,320	34,854	$969,879.57	$27.83	$0.70	1,628,555	1,395,255
OCH	15,656	31,014	$649,629.44	$20.95	$0.53	1,379,970	1,217,702
2024 Total	**137,268**	**650,564**	**$14,809,336.38**	**$22.76**	**$0.54**	**31,590,524**	**27,424,300**
Fiscal Year 2025							
FFS	58,697	251,198	$6,448,233.67	$25.67	$0.63	12,023,183	10,312,198
Aetna	27,097	111,381	$4,059,230.61	$36.44	$0.80	5,755,709	5,066,394
Humana	30,598	142,988	$5,660,013.98	$39.58	$0.91	7,120,967	6,191,206
OCH	30,726	134,064	$3,777,248.22	$28.17	$0.64	6,725,167	5,942,804
2025 Total	**129,163**	**639,631**	**$19,944,726.48**	**$31.18**	**$0.72**	**31,625,026**	**27,512,602**
% Change	**-5.90%**	**-1.70%**	**34.70%**	**37.00%**	**33.30%**	**0.10%**	**0.30%**
Change	**-8,105**	**-10,933**	**$5,135,390.10**	**$8.42**	**$0.18**	**34,502**	**88,302**

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.

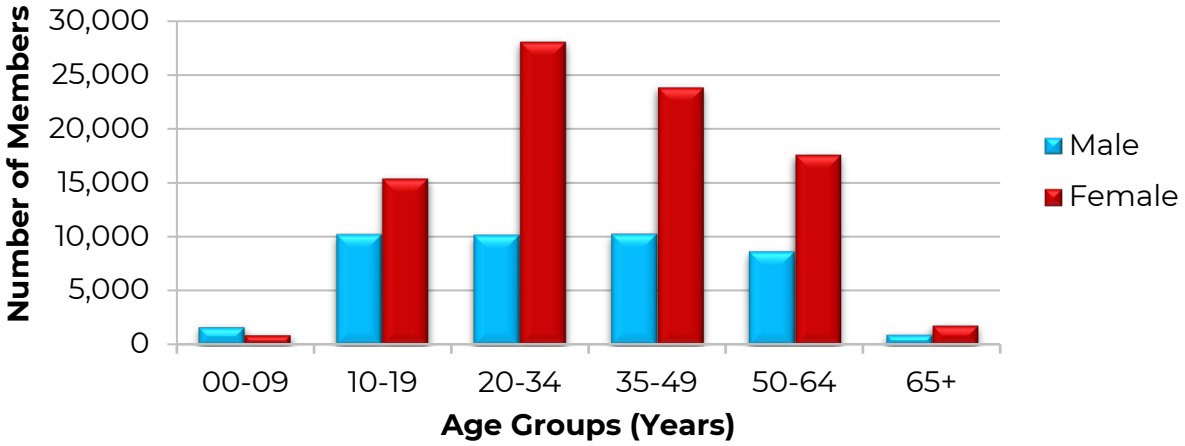
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	2	35	$34,371.05	$982.03	17.5
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**2**	**35**	**$34,371.05**	**$982.03**	**17.5**
Fiscal Year 2025					
FFS	0	0	$0.00	$0.00	0
Humana	1	2	$2,026.02	$1,013.01	2
Aetna	3	21	$18,234.18	$868.29	7
OCH	0	0	$0.00	$0.00	0
2025 Total	**4**	**23**	**$20,260.20**	**$880.88**	**5.75**
% Change	**100.00%**	**-34.29%**	**-41.05%**	**-10.30%**	**-67.14%**
Change	**2**	**-12**	**-$14,110.85**	**-$101.15**	**-11.75**

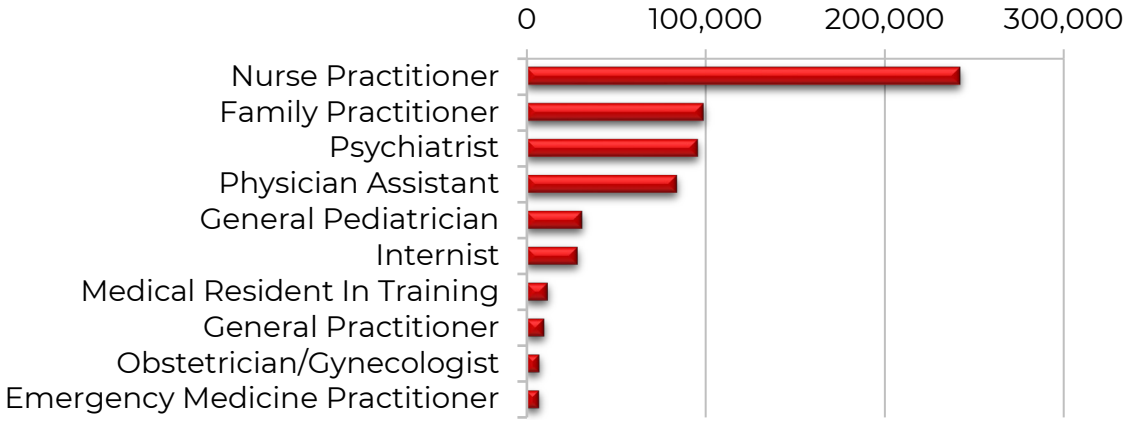
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for antidepressants totaled $4,227,590.56.[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 Antidepressants: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Antidepressants by Number of Claims: Pharmacy Claims (All Plans)

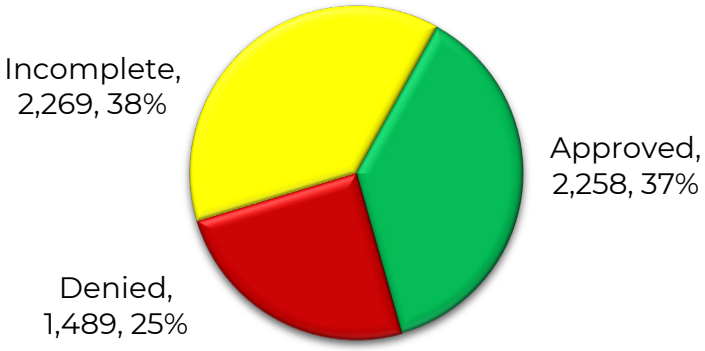


Prior Authorization of Antidepressants

There were 6,016 prior authorization requests submitted for antidepressants during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

[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.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	1,014	34%	1,569	52%	414	14%	**2,997**
Aetna	290	24%	429	36%	488	40%	**1,207**
Humana	149	50%	0	0%	152	50%	**301**
OCH	805	53%	271	18%	435	29%	**1,511**
Total	**2,258**	**37%**	**2,269**	**38%**	**1,489**	**25%**	**6,016**

FFS = fee-for-service; OCH = OK Complete Health

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

Anticipated Patent Expiration(s):

- Forfivo XL® (bupropion ER tablets): August 2028
- Raldesy™ (trazodone oral solution): March 2029
- Exxua™ (gepirone ER tablets): September 2030
- Trintellix® (vortioxetine tablets): September 2032
- Fetzima® (levomilnacipran ER capsules): May 2032
- Drizalma Sprinkle™ [duloxetine delayed-release (DR) capsules]: April 2037
- Zurzuvae® (zuranolone capsules): August 2037
- Spravato® (esketamine nasal spray): February 2040
- Auvelity® (dextromethorphan/bupropion ER tablets): April 2043

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.

Pipeline:

- **BPL-003:** BPL-003 is an investigational intranasal formulation of mebufotenin benzoate being studied for the treatment of TRD and alcohol use disorder. BPL-003 was granted Breakthrough Therapy designation for TRD by the FDA based on results from a Phase 2b trial that showed a single administration of 8mg or 12mg of BPL-003 led to clinically meaningful and statistically significant reductions in depressive symptoms within 24 hours, with effects sustained through the eight-week trial period. Phase 3 trials are anticipated to be initiated in the second quarter of 2026.
- **NRX-100 [Intravenous (IV) Ketamine]:** NRX-100 is an investigational IV preservative-free ketamine being studied for acute treatment of suicidal depression. NRX-100 differs from ketamine used for anesthesia in that it contains no potentially toxic preservatives and utilizes diversion-resistant packaging to enhance the traceability of a medicine known to have abuse potential. An NDA has been submitted to the FDA based on results of well-controlled clinical trials conducted under the auspices of the U.S. National Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx Pharmaceuticals was awarded Fast Track designation for development of NRX-100 by the FDA as part of a protocol to treat patients with acute suicidality in 2017. An anticipated Prescription Drug User Fee Act (PDUFA) date for the NDA is prior to December 31, 2025.

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)	$0.55	$16.50	$198.00
trazodone 100mg tablet (generic)	$0.05	$4.50	$54.00
trazodone 150mg tablet (generic)	$0.01	$0.60	$7.20

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).
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.

Utilization Details of Antidepressants: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	50,596	16,945	$561,192.01	$11.09	2.99	2.81%
TRAZODONE TAB 100MG	37,109	10,136	$453,665.30	$12.23	3.66	2.27%
TRAZODONE TAB 150MG	18,897	4,620	$271,386.34	$14.36	4.09	1.36%
SUBTOTAL	**106,602**	**31,701**	**$1,286,243.65**	**$12.07**	**3.36**	**6.45%**
SERTRALINE PRODUCTS						
SERTRALINE TAB 50MG	41,895	15,944	$554,467.05	$13.23	2.63	2.78%
SERTRALINE TAB 100MG	40,840	11,569	$580,933.36	$14.22	3.53	2.91%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SERTRALINE TAB 25MG	22,389	9,430	$274,606.87	$12.27	2.37	1.38%
SERTRALINE CON 20MG/ML	817	206	$40,104.69	$49.09	3.97	0.20%
ZOLOFT TAB 50MG	11	1	$5,610.30	$510.03	11	0.03%
SUBTOTAL	**105,952**	**37,150**	**$1,455,722.27**	**$13.74**	**2.85**	**7.30%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	40,768	14,363	$489,831.87	$12.02	2.84	2.46%
FLUOXETINE CAP 40MG	24,316	7,319	$335,722.29	$13.81	3.32	1.68%
FLUOXETINE CAP 10MG	20,662	8,101	$260,069.90	$12.59	2.55	1.30%
FLUOXETINE SOL 20MG/5ML	1,868	388	$71,638.58	$38.35	4.81	0.36%
PROZAC CAP 20MG	8	4	$15,208.11	$1,901.01	2	0.08%
PROZAC CAP 40MG	6	2	$10,282.39	$1,713.73	3	0.05%
SUBTOTAL	**87,628**	**30,177**	**$1,182,753.14**	**$13.50**	**2.9**	**5.93%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	36,788	14,535	$491,713.25	$13.37	2.53	2.47%
ESCITALOPRAM TAB 20MG	32,151	9,406	$469,700.18	$14.61	3.42	2.36%
ESCITALOPRAM TAB 5MG	9,781	4,348	$126,671.92	$12.95	2.25	0.64%
ESCITALOPRAM SOL 5MG/5ML	397	89	$22,807.13	$57.45	4.46	0.11%
LEXAPRO TAB 20MG	12	3	$14,763.82	$1,230.32	4	0.07%
LEXAPRO TAB 10MG	11	6	$11,880.69	$1,080.06	1.83	0.06%
LEXAPRO TAB 5MG	2	2	$833.11	$416.56	1	0.00%
SUBTOTAL	**79,142**	**28,389**	**$1,138,370.10**	**$14.38**	**2.79**	**5.71%**
BUPROPION PRODUCTS						
BUPROPION XL TAB 150MG	30,223	11,868	$482,491.50	$15.96	2.55	2.42%
BUPROPION XL TAB 300MG	22,174	6,726	$403,724.12	$18.21	3.3	2.02%
BUPROPION SR TAB 150MG	7,725	3,075	$127,379.75	$16.49	2.51	0.64%
BUPROPION SR TAB 100MG	3,730	1,529	$55,820.47	$14.97	2.44	0.28%
BUPROPION TAB 75MG	2,772	1,057	$40,907.58	$14.76	2.62	0.21%
BUPROPION SR TAB 200MG	2,031	651	$37,670.55	$18.55	3.12	0.19%
BUPROPION TAB 100MG	1,872	629	$30,384.13	$16.23	2.98	0.15%
WELLBUTRIN XL TAB 150MG	17	7	$88,572.01	$5,210.12	2.43	0.44%
APLENZIN TAB 348MG	7	2	$19,722.14	$2,817.45	3.5	0.10%
WELLBUTRIN SR TAB 150MG	6	2	$2,780.26	$463.38	3	0.01%
WELLBUTRIN XL TAB 300MG	1	1	$7,599.44	$7,599.44	1	0.04%
APLENZIN TAB 174MG	1	1	$2,140.22	$2,140.22	1	0.01%
SUBTOTAL	**70,559**	**25,548**	**$1,299,192.17**	**$18.41**	**2.76**	**6.51%**
DULOXETINE PRODUCTS						
DULOXETINE DR CAP 60MG	28,275	8,071	$494,493.70	$17.49	3.5	2.48%
DULOXETINE DR CAP 30MG	20,596	7,999	$321,945.18	$15.63	2.57	1.61%
DULOXETINE DR CAP 20MG	6,262	2,634	$102,498.01	$16.37	2.38	0.51%
CYMBALTA CAP 20MG	3	2	$2,193.95	$731.32	1.5	0.01%
CYMBALTA CAP 60MG	2	2	$1,362.92	$681.46	1	0.01%
SUBTOTAL	**55,138**	**18,708**	**$922,493.76**	**$16.73**	**2.95**	**4.63%**
VENLAFAXINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VENLAFAXINE ER CAP 75MG	12,158	4,069	$190,239.33	$15.65	2.99	0.95%
VENLAFAXINE ER CAP 150MG	11,954	3,340	$215,508.20	$18.03	3.58	1.08%
VENLAFAXINE ER CAP 37.5MG	6,219	2,957	$95,511.93	$15.36	2.1	0.48%
VENLAFAXINE TAB 75MG	1,947	557	$27,050.12	$13.89	3.5	0.14%
VENLAFAXINE TAB 37.5MG	1,146	474	$14,595.19	$12.74	2.42	0.07%
VENLAFAXINE TAB 100MG	697	154	$10,276.63	$14.74	4.53	0.05%
VENLAFAXINE ER TAB 150MG	526	135	$9,412.68	$17.89	3.9	0.05%
VENLAFAXINE TAB 50MG	377	111	$5,478.67	$14.53	3.4	0.03%
VENLAFAXINE ER TAB 75MG	321	113	$7,998.33	$24.92	2.84	0.04%
VENLAFAXINE TAB 25MG	227	98	$3,108.07	$13.69	2.32	0.02%
VENLAFAXINE ER TAB 37.5MG	224	88	$5,146.66	$22.98	2.55	0.03%
EFFEXOR XR CAP 150MG	29	4	$31,949.50	$1,101.71	7.25	0.16%
EFFEXOR XR CAP 75MG	11	3	$6,336.29	$576.03	3.67	0.03%
EFFEXOR XR CAP 37.5MG	1	1	$517.75	$517.75	1	0.00%
SUBTOTAL	**35,837**	**12,104**	**$623,129.35**	**$17.39**	**2.96**	**3.12%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	16,222	5,374	$214,589.90	$13.23	3.02	1.08%
MIRTAZAPINE TAB 30MG	8,863	2,868	$119,789.25	$13.52	3.09	0.60%
MIRTAZAPINE TAB 7.5MG	4,237	1,528	$103,386.38	$24.40	2.77	0.52%
MIRTAZAPINE TAB 45MG	3,222	831	$47,258.78	$14.67	3.88	0.24%
MIRTAZAPINE ODT 15MG	498	159	$10,737.68	$21.56	3.13	0.05%
MIRTAZAPINE ODT 30MG	161	46	$3,919.91	$24.35	3.5	0.02%
MIRTAZAPINE ODT 45MG	160	46	$4,390.85	$27.44	3.48	0.02%
SUBTOTAL	**33,363**	**10,852**	**$504,072.75**	**$15.11**	**3.07**	**2.53%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	11,950	4,394	$135,967.72	$11.38	2.72	0.68%
CITALOPRAM TAB 40MG	7,898	2,452	$91,424.72	$11.58	3.22	0.46%
CITALOPRAM TAB 10MG	6,477	2,585	$74,500.80	$11.50	2.51	0.37%
CITALOPRAM SOL 10MG/5ML	128	22	$5,934.24	$46.36	5.82	0.03%
CELEXA TAB 40MG	6	3	$2,913.97	$485.66	2	0.01%
SUBTOTAL	**26,459**	**9,456**	**$310,741.45**	**$11.74**	**2.8**	**1.56%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	5,211	1,986	$68,065.88	$13.06	2.62	0.34%
PAROXETINE TAB 40MG	3,814	1,074	$59,340.51	$15.56	3.55	0.30%
PAROXETINE TAB 10MG	3,202	1,417	$44,441.83	$13.88	2.26	0.22%
PAROXETINE TAB 30MG	2,182	695	$30,244.57	$13.86	3.14	0.15%
PAROXETINE SUS 10MG/5ML	144	25	$46,379.32	$322.08	5.76	0.23%
SUBTOTAL	**14,553**	**5,197**	**$248,472.11**	**$17.07**	**2.8**	**1.25%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	2,469	447	$55,153.79	$22.34	5.52	0.28%
FLUVOXAMINE TAB 50MG	2,222	529	$41,436.87	$18.65	4.2	0.21%
FLUVOXAMINE TAB 25MG	582	215	$10,136.77	$17.42	2.71	0.05%
SUBTOTAL	**5,273**	**1,191**	**$106,727.43**	**$20.24**	**4.43**	**0.54%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 SUBTOTAL	**620,506**	**210,473**	**$9,077,918.18**	**$14.63**	**2.95**	**45.52%**
TIER-2 UTILIZATION						
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 50MG	3,366	1,093	$95,497.77	$28.37	3.08	0.48%
DESVENLAFAXINE ER TAB 100MG	3,123	736	$97,009.87	$31.06	4.24	0.49%
DESVENLAFAXINE ER TAB 25MG	968	440	$27,641.78	$28.56	2.2	0.14%
PRISTIQ TAB 50MG	5	2	$2,990.88	$598.18	2.5	0.01%
PRISTIQ TAB 100MG	1	1	$430.66	$430.66	1	0.00%
TIER-2 SUBTOTAL	**7,463**	**2,272**	**$223,570.96**	**$29.96**	**3.28**	**1.12%**
TIER-3 UTILIZATION						
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	2,301	365	$1,096,869.39	$476.69	6.3	5.50%
TRINTELLIX TAB 10MG	1,662	390	$783,586.83	$471.47	4.26	3.93%
TRINTELLIX TAB 5MG	458	158	$220,119.86	$480.61	2.9	1.10%
SUBTOTAL	**4,421**	**913**	**$2,100,576.08**	**$475.14**	**4.84**	**10.53%**
VILAZODONE PRODUCTS						
VILAZODONE TAB 40MG	1,219	197	$51,532.76	$42.27	6.19	0.26%
VILAZODONE TAB 20MG	568	161	$22,483.66	$39.58	3.53	0.11%
VILAZODONE TAB 10MG	208	92	$8,613.94	$41.41	2.26	0.04%
VIIBRYD TAB 20MG	30	5	$18,676.41	$622.55	6	0.09%
VIIBRYD TAB 40MG	25	9	$8,694.01	$347.76	2.78	0.04%
VIIBRYD TAB 10MG	1	1	$360.55	$360.55	1	0.00%
SUBTOTAL	**2,051**	**465**	**$110,361.33**	**$53.81**	**4.41**	**0.55%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 40MG	48	15	$24,107.39	$502.24	3.2	0.12%
FETZIMA CAP 80MG	44	10	$21,720.65	$493.65	4.4	0.11%
FETZIMA CAP 20MG	41	15	$19,658.13	$479.47	2.73	0.10%
FETZIMA CAP 120MG	20	5	$9,258.94	$462.95	4	0.05%
SUBTOTAL	**153**	**45**	**$74,745.11**	**$488.53**	**3.4**	**0.37%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 100MG	68	23	$9,786.17	$143.91	2.96	0.05%
DESVENLAFAXINE ER TAB 50MG	37	19	$4,986.04	$134.76	1.95	0.02%
SUBTOTAL	**105**	**42**	**$14,772.21**	**$140.69**	**2.5**	**0.07%**
TRANYLCYPROMINE PRODUCTS						
TRANYLCYPROMINE TAB 10MG	15	2	$1,566.30	$104.42	7.5	0.01%
SUBTOTAL	**15**	**2**	**$1,566.30**	**$104.42**	**7.5**	**0.01%**
PHENELZINE PRODUCTS						
PHENELZINE TAB 15MG	14	2	$775.22	$55.37	7	0.00%
SUBTOTAL	**14**	**2**	**$775.22**	**$55.37**	**7**	**0.00%**
SELEGILINE PRODUCTS						
EMSAM PATCH 9MG/24HR	9	3	$19,056.70	$2,117.41	3	0.10%
EMSAM PATCH 6MG/24HR	3	2	$6,299.31	$2,099.77	1.5	0.03%
SUBTOTAL	**12**	**5**	**$25,356.01**	**$2,113.00**	**2.4**	**0.13%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NEFAZODONE PRODUCTS						
NEFAZODONE TAB 200MG	7	1	$652.30	$93.19	7	0.00%
NEFAZODONE TAB 150MG	2	1	$183.58	$91.79	2	0.00%
NEFAZODONE TAB 50MG	1	1	$29.59	$29.59	1	0.00%
SUBTOTAL	**10**	**3**	**$865.47**	**$86.55**	**3.33**	**0.00%**
TIER-3 SUBTOTAL	**6,781**	**1,477**	**$2,329,017.73**	**$343.46**	**4.59**	**11.68%**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
ESKETAMINE PRODUCTS						
SPRAVATO SOL 84MG DOSE	1,806	258	$6,114,548.36	$3,385.69	7	30.66%
SPRAVATO SOL 56MG DOSE	219	178	$320,169.38	$1,461.96	1.23	1.61%
SUBTOTAL	**2,025**	**436**	**$6,434,717.74**	**$3,177.64**	**4.64**	**32.26%**
FLUOXETINE PRODUCTS						
FLUOXETINE TAB 10MG	528	214	$6,710.89	$12.71	2.47	0.03%
FLUOXETINE TAB 20MG	287	148	$4,420.50	$15.40	1.94	0.02%
FLUOXETINE TAB 60MG	192	90	$4,381.93	$22.82	2.13	0.02%
FLUOXETINE DR CAP 90MG	25	3	$2,801.96	$112.08	8.33	0.01%
SUBTOTAL	**1,032**	**455**	**$18,315.28**	**$17.75**	**2.27**	**0.09%**
DEXTROMETHORPHAN/BUPROPION PRODUCTS						
AUVELITY TAB 45-105MG	415	103	$427,421.93	$1,029.93	4.03	2.14%
SUBTOTAL	**415**	**103**	**$427,421.93**	**$1,029.93**	**4.03**	**2.14%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER TAB 225MG	356	86	$10,812.96	$30.37	4.14	0.05%
VENLAFAXINE ER TAB 112.5MG	5	1	$1,999.55	$399.91	5	0.01%
SUBTOTAL	**361**	**87**	**$12,812.51**	**$35.49**	**4.15**	**0.06%**
PAROXETINE PRODUCTS						
PAROXETINE ER TAB 25MG	170	33	$4,522.31	$26.60	5.15	0.02%
PAROXETINE ER TAB 37.5MG	105	18	$2,680.68	$25.53	5.83	0.01%
PAROXETINE ER TAB 12.5MG	44	14	$1,098.79	$24.97	3.14	0.01%
SUBTOTAL	**319**	**65**	**$8,301.78**	**$26.02**	**4.91**	**0.04%**
DULOXETINE PRODUCTS						
DULOXETINE DR CAP 40MG	231	98	$14,426.36	$62.45	2.36	0.07%
SUBTOTAL	**231**	**98**	**$14,426.36**	**$62.45**	**2.36**	**0.07%**
SERTRALINE PRODUCTS						
SERTRALINE CAP 150MG	65	40	$11,137.69	$171.35	1.63	0.06%
SERTRALINE CAP 200MG	56	29	$9,558.43	$170.69	1.93	0.05%
SUBTOTAL	**121**	**69**	**$20,696.12**	**$171.04**	**1.75**	**0.10%**
BUPROPION PRODUCTS						
BUPROPION XL TAB 450MG	117	42	$31,967.33	$273.23	2.79	0.16%
SUBTOTAL	**117**	**42**	**$31,967.33**	**$273.23**	**2.79**	**0.16%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 300MG	98	48	$4,326.35	$44.15	2.04	0.02%
RALDESY SOL 10MG/ML	1	1	$254.41	$254.41	1	0.00%
SUBTOTAL	**99**	**49**	**$4,580.76**	**$46.27**	**2.02**	**0.02%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ZURANOLONE PRODUCTS						
ZURZUVAE CAP 25MG	82	82	$1,324,939.22	$16,157.80	1	6.64%
SUBTOTAL	**82**	**82**	**$1,324,939.22**	**$16,157.80**	**1**	**6.64%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE ER CAP 150MG	58	11	$12,632.67	$217.80	5.27	0.06%
FLUVOXAMINE ER CAP 100MG	19	5	$3,069.48	$161.55	3.8	0.02%
SUBTOTAL	**77**	**16**	**$15,702.15**	**$203.92**	**4.81**	**0.08%**
CITALOPRAM PRODUCTS						
CITALOPRAM CAP 30MG	2	2	$338.43	$169.22	1	0.00%
SUBTOTAL	**2**	**2**	**$338.43**	**$169.22**	**1**	**0.00%**
SPECIAL PA SUBTOTAL	**4,881**	**1,504**	**$8,314,219.61**	**$1,703.38**	**3.25**	**41.69%**
TOTAL	**639,631**	**129,163***	**$19,944,726.48**	**$31.18**	**4.95**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CON = concentrate; DR = delayed-release; ER = extended-release; ODT = orally disintegrating tablet; SOL = solution; SR = sustained-release; SUS = suspension; TAB = tablet; XL = extended-release
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
ESKETAMINE >56MG (G2083)	23	4	$20,260.20	$880.88	5.75
TOTAL	**23**	**4**	**$20,260.20**	**$880.88**	**5.75**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix U

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: November 24, 2025

FDA Approves Gene Therapy for Treatment of Spinal Muscular Atrophy

The FDA approved Itvisma® (onasemnogene abeparvovec-brve) for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in the survival motor neuron 1 (*SMN1*) gene. Itvisma® is an adeno-associated virus (AAV) vector-based gene therapy.

SMA is an autosomal-recessive neurodegenerative disorder caused by mutations in the *SMN*1 gene, characterized by irreversible and progressive motor neuron loss, leading to progressive muscle atrophy and weakness, and subsequent paralysis and death in the most severe cases. SMA has an incidence of approximately 4-10 per 10,000 live births. Prior to the availability of effective treatment, SMA was considered one of the leading causes of infant mortality due to genetic disease in the U.S.

Itvisma® demonstrated substantial evidence of effectiveness for the treatment of SMA in pediatric patients 2 years of age and older with a confirmed mutation in the *SMN1* gene based on primary evidence of effectiveness from the adequate and well controlled Phase 3 study, and the confirmatory evidence of effectiveness from data characterizing the mechanism of the product's action, as well as efficacy findings from Zolgensma® (onasemnogene abeparvovec-xioi) which contains the same active ingredient in an intravenous formulation. The applicant provided adequate justification to support expanding the indication beyond the pivotal study population to include adult patients with SMA; however, warnings and precautions are warranted due to the potentially increased risks of adverse events of special interest (e.g., hepatotoxicity and cardiotoxicity) in adult patients with preexisting chronic medical conditions.

The active ingredient in Itvisma® is identical to Zolgensma® but formulated at a different concentration. Zolgensma® is administered intravenously based on patient weight to pediatric patients less than 2 years of age with SMA due to bi-allelic mutations in the *SMN1* gene. Itvisma® is a concentrated formulation in a smaller delivery volume, administered directly to the central nervous system via a single intrathecal injection independent of patient weight, which expands treatment options available to patients with SMA older than 2 years of age.

The direct administration of Itvisma® into the cerebrospinal fluid surrounding the spinal cord allows for delivery to motor neurons with a lower

dose of vector, without the need to adjust for the patient's body weight. This provides a treatment with rapid onset and direct targeting of the genetic root cause of SMA. By addressing the root cause of SMA, Itvisma® restores SMN protein production and halts further disease progression.

The FDA review team worked collaboratively to leverage Zolgensma® safety data and most of the side effects of Itvisma® are consistent with identified risks associated with Zolgensma®. Information from the hepatotoxicity boxed warning in the Zolgensma® label is retained in the Itvisma® label with appropriate modifications. This approach is supported by clinical data showing hepatotoxicity in Itvisma® clinical studies.

The FDA granted this application Fast Track, Breakthrough Therapy, and Priority Review designations. Itvisma® also received Orphan Drug designation, which provides incentives to encourage the development of drugs for rare diseases. Itvisma® is manufactured by Novartis Gene Therapies, Inc.

FDA NEWS RELEASE

For Immediate Release: November 14, 2025

FDA Approves New Safety Warning and Revised Indication that Limits Use for Elevidys Following Reports of Fatal Liver Injury

The FDA announced it is taking action to approve new labeling submitted by Sarepta Therapeutics that includes the addition of a *Boxed Warning* to Elevidys (delandistrogene moxeparvovec-rokl), and that the indication section of the labeling limits the therapy's indication to ambulatory patients 4 years of age and older with Duchenne muscular dystrophy (DMD). These actions follow reports of fatal acute liver failure in non-ambulatory patients treated with the product.

Elevidys is an AAVrh74 adeno-associated virus (AAV) vector-based gene therapy approved for the treatment of DMD in certain patients. In June 2025, the FDA issued a Center for Biologics Evaluation and Research (CBER) Safety Communication following 2 reports of fatal acute liver failure in non-ambulatory pediatric males with DMD after receiving Elevidys. In response, the manufacturer voluntarily paused distribution of Elevidys for use in non-ambulatory patients.

In both fatal cases, patients developed markedly elevated liver enzymes and required hospitalization within 2 months of Elevidys infusion. An additional serious, non-fatal case of acute liver injury has involved complications such as mesenteric vein thrombosis, bowel ischemia and necrosis, and portal hypertension.

After a comprehensive evaluation of the available safety data, the FDA has now approved substantial labeling revisions for Elevidys, including:

- Addition of a *Boxed Warning* describing the risk of serious liver injury and acute liver failure, including fatal outcomes;

- Limiting the indication to ambulatory patients with DMD who are 4 years of age and older with a confirmed mutation in the *DMD* gene;
- Removal of the indication for non-ambulatory patients with DMD;
- Addition of a Limitations of Use statement to guide clinical decision-making;
- Updates to the *Warnings and Precautions*, *Dosage and Administration*, *Adverse Reactions*, *Use in Specific Populations*, *Clinical Studies*, and *Patient Counseling Information* sections; and
- Inclusion of a new *Medication Guide* for patients and caregivers.

Additionally, the revised labeling includes specific safety information and monitoring recommendations:

- Liver monitoring: Weekly liver function tests are advised for at least 3 months after treatment. Patients should remain near an appropriate medical facility for at least 2 months post-infusion.
- Prompt medical attention: Patients should contact their health care provider immediately if they experience yellowing of the skin or eyes, if they miss or vomit corticosteroid doses, or if the patient experiences a change in mental status.
- Infection risk: Corticosteroid therapy may suppress immune function, increasing susceptibility to infections and serious complications including death.
- Cardiac monitoring: Weekly testing for cardiac injury (troponin-I) is advised for 1 month following treatment.
- Contraindications: Elevidys should not be used in patients with deletions involving *DMD* exons 8 and/or 9.
- Limitations of Use: Elevidys is not recommended in patients with preexisting liver impairment, recent vaccinations, or recent/active infections.

The FDA is requiring the manufacturer to conduct a postmarketing observational study to further assess the risk of serious liver injury. The study will enroll approximately 200 patients with DMD and follow them for at least 12 months after administration of Elevidys, with periodic liver function assessments.

Health care professionals and patients are encouraged to report adverse events, including cases of liver injury, to the FDA MedWatch program. Adverse events may also be reported to Sarepta Therapeutics, Inc. The FDA remains committed to the continued evaluation of the safety and effectiveness of gene therapies and will provide updates as new information becomes available.

FDA NEWS RELEASE

For Immediate Release: November 10, 2025

HHS Advances Women's Health, Removes Misleading FDA Warnings on Hormone Replacement Therapy

The U.S. Department of Health and Human Services (HHS) today announced historic action to restore gold-standard science to women's health. After more than 2 decades of fear and misinformation surrounding hormone replacement therapy (HRT), the FDA is initiating the removal of broad "black box" warnings from HRT products for menopause.

HHS Secretary Robert F. Kennedy Jr. and FDA Commissioner Marty Makary, M.D., M.P.H. made the announcement at a press conference at HHS with more than 200 people in attendance, including Second Lady of the United States Usha Vance and Secretary of Labor Lori Chavez-DeRemer.

Women have used HRT products for decades to relieve menopausal symptoms. However, their use plummeted in the early 2000s when the FDA applied boxed warnings following a Women's Health Initiative study that found a statistically non-significant increase in the risk of breast cancer diagnosis. The average age of women in the study was 63 years old — over a decade past the average age of a woman experiencing menopause — and study participants were given a hormone formulation no longer in common use.

The FDA is initiating removal of the boxed warnings following a comprehensive review of the scientific literature, an expert panel in July, and a public comment period. The agency is working with companies to update language in product labeling to remove references to risks of cardiovascular disease, breast cancer, and probable dementia. The FDA is not seeking to remove the boxed warning for endometrial cancer for systemic estrogen-alone products.

As women go through menopause, the ovaries produce less estrogen and progesterone. FDA-approved HRT containing estrogen and progesterone (or estrogen alone as indicated for postmenopausal women without a uterus) can restore these declining hormones, and relieve symptoms such as hot flashes, night sweats, sleep disturbances, and bone loss.

Randomized studies show that women who initiate HRT within 10 years of the onset of menopause (generally before age 60) have a reduction in all-cause mortality and fractures. Women may also reduce their risk of cardiovascular diseases by as much as 50%, Alzheimer's disease by 35%, and bone fractures by 50 to 60%. Though the starting time of HRT and duration of use are decisions made between the prescriber and the individual patient, the FDA's labeled recommendation will be to start HRT within 10 years of menopause onset or before 60 years of age for systemic HRT.

In addition to the removal of boxed warnings, the FDA is also approving 2 new drugs to expand treatment options for menopausal symptoms. The first is the approval of a generic version of Premarin® (conjugated estrogens),

the first such approval in more than 30 years for this widely used hormone replacement therapy. The new generic product is expected to improve affordability and access while maintaining the same quality, safety, and effectiveness as the brand-name drug.

The second approval is for a non-hormonal treatment for moderate to severe vasomotor symptoms, such as hot flashes, associated with menopause. This option provides relief for women who cannot or choose not to use hormone therapy.

FDA NEWS RELEASE

For Immediate Release: November 6, 2025

FDA Awards Second Batch of National Priority Vouchers

The FDA announced 6 additional awardees under the Commissioner's National Priority Voucher (CNPV) pilot program. This second cohort brings the total number of voucher recipients to 15, underscoring the FDA's commitment to accelerating the review of products with the potential to address key national priorities.

Upon submission of a complete application, national priority voucher holders will receive a decision within months, a drastic reduction of the typical review timeline. The faster timeframe is contingent upon additional requirements from the company, and FDA staff reserve the right to extend the review as needed.

The cornerstone of the accelerated timeline is a one-day "tumor board style" meeting which convenes a multidisciplinary group of physicians and scientists for a team-based review. Under the Federal Food, Drug, and Cosmetic Act; the 21st Century Cures Act; and the Food and Drug Administration Safety and Innovation Act, the FDA is authorized to test innovative regulatory approaches to accelerate review, foster public health preparedness, and improve access to safe, effective, and affordable therapies. The following products were selected following external applications and internal nominations from FDA review divisions:

- Zongertinib for HER2 lung cancer
- Bedaquiline for drug-resistant tuberculosis in young children
- Dostarlimab for rectal cancer
- Casgevy® for sickle cell disease
- Orforglipron for obesity and related health conditions
- Wegovy® for obesity and related health conditions

Current Drug Shortages Index (as of November 24, 2025):

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***
Methamphetamine Hydrochloride Tablet	***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***
Nitroglycerin Injection	***Currently in Shortage***
Parathyroid Hormone Injection	***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***