OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Thursday,
November 12, 2026
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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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 – November 12, 2026

DATE: November 4, 2026

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

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

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Enclosed are the following items related to the November 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

Action Item – Approval of 2027 DUR Board Meeting Dates – Appendix B

Update on the Medication Coverage Authorization Unit – Appendix C

Journavx (Suzetrigine) Utilization Update – Appendix D

Action Item – Vote to Prior Authorize Cetirizine Oral Solution Unit Dose Cups (UDCs) and Update the Approval Criteria for the Antihistamine Medications (Systemic) – Appendix E

Action Item – Vote to Update the Approval Criteria for the Constipation and Diarrhea Medications – Appendix F

Action Item – Vote to Update the Approval Criteria for the Anticoagulants and Platelet Aggregation Inhibitors – Appendix G

Action Item – Vote to Prior Authorize Epioxa HD/Epioxa (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa (Veligrotug-vvze) and Update the Approval Criteria for the Various Ophthalmic Medications – Appendix H

Action Item – Vote to Prior Authorize Beizray (Docetaxel), Beizray Kit (Docetaxel/ Albumin), Docivyx (Docetaxel), Inluriyo (Imlunestrant), and Veppanu (Vepdegestrant) and Update the Approval Criteria for the Breast Cancer Medications – Appendix I

Action Item – Vote to Prior Authorize Decnupaz (Pivekimab Sunirine-pvzy), Jakafi XR [Ruxolitinib Extended-Release (ER)], and Mimrylo (Rusfertide) and Update the Approval Criteria for the Myeloproliferative Neoplasm (MPN) Medications – Appendix J

Action Item – Vote to Prior Authorize Icotyde (Icotrokinra), Immgolis (Golimumab-sldi), Immgolis Intri (Golimumab-sldi), Lisraya (Brepocitinib), and Zimrixby (Rituximab-cdxx) and Update the Approval Criteria for the Targeted Immunomodulator Agents – Appendix K

Action Item – Vote to Prior Authorize Tonmya [Cyclobenzaprine Sublingual (SL) Tablet] and Update the Approval Criteria for the Fibromyalgia Medications – Appendix L

Action Item – Vote to Prior Authorize Aqvesme (Mitapivat) and Update the Approval Criteria for the Anemia Medications – Appendix M

Action Item – Annual Review of Rhapsido (Remibrutinib) – Appendix N

Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Sarclisa Escena (Isatuximab-irfc) and Zenbexus (Iberdomide) – Appendix O

Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Adquey (Difamilast 1% Ointment) – Appendix P

Annual Review of Bone Density Regulators and 30-Day Notice to Prior Authorize Aukelso (Denosumab-kyqq), Bosaya (Denosumab-kyqq),

Enoby (Denosumab-qbde), Jubereq (Denosumab-desu), Osvyrti (Denosumab-desu), and Xtrenbo (Denosumab-qbde) – Appendix Q

Annual Review of Ophthalmic Anti-Inflammatory Products and 30-Day Notice to Prior Authorize Byqlovi (Clobetasol 0.05% Suspension) – Appendix R

Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Beclomethasone Dipropionate HFA, Exdensur (Depemokimab-ulaa), and Trimbow (Beclomethasone/Formoterol/Glycopyrrolate) – Appendix S

Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications (Non-Oncology) and 30-Day Notice to Prior Authorize Vobrig (Leuprolide) – Appendix T

Annual Review of Brinsupri (Brensocatib) – Appendix U

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – November 12, 2026 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Cassidy Blaiss –	participating in person
Ms. Jennifer Boyett –	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

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Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 910 6408 1365
Passcode: 44589980

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.
- In lieu of speaking at the DUR Board meeting, written correspondence by members or providers may be submitted to DURPublicComment@okhca.org. Other written correspondence is not permitted.

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. September 9, 2026 DUR Board Meeting Minutes
   B. September 9, 2026 DUR Board Recommendations Memorandum
   C. October 14, 2026 DUR Board Meeting Minutes
   D. October 14. 2026 DUR Board Recommendations Memorandum

Items to be presented by Dr. Haymore, Chairman:

4. **Action Item – Approval of 2027 DUR Board Meeting Dates – See Appendix B**

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

5. **Update on Medication Coverage Authorization Unit – See Appendix C**
   A. Pharmacy Help Desk Activity for October 2026
   B. Medication Coverage Activity for October 2026

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

6. **Journavx (Suzetrigine) Utilization Update – See Appendix D**
   A. Introduction

B. Utilization of Journavx
C. Utilization Trends of Journavx in the SoonerCare Population
D. Conclusions
E. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Cetirizine Oral Solution Unit Dose Cups (UDCs) and Update the Approval Criteria for the Antihistamine Medications (Systemic) – See Appendix E**

A. Cost Comparison: Cetirizine Products
B. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Update the Approval Criteria for the Constipation and Diarrhea Medications – See Appendix F**

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

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

9. **Action Item – Vote to Update the Approval Criteria for the Anticoagulants and Platelet Aggregation Inhibitors – See Appendix G**

A. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Epioxa HD/Epioxa (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa (Veligrotug-vvze) and Update the Approval Criteria for the Various Ophthalmic Medications – See Appendix H**

A. Market News and Updates
B. Lumvoa (Veligrotug-vvze) Product Summary
C. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), Docivyx (Docetaxel), Inluriyo (Imlunestrant), and Veppanu (Vepdegestrant) and Update the Approval Criteria for the Breast Cancer Medications – See Appendix I**

A. Market News and Updates
B. Product Summaries
C. Cost Comparison: Trastuzumab Products
D. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Prior Authorize Decnupaz (Pivekimab Sunirine-pvzy), Jakafi XR [Ruxolitinib Extended-Release (ER)], and Mimrylo (Rusfertide)**

and Update the Approval Criteria for the Myeloproliferative Neoplasm (MPN) Medications – See Appendix J

A. Market News and Updates
B. Product Summaries
C. College of Pharmacy Recommendations

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

13. **Action Item – Vote to Prior Authorize Icotyde (Icotrokinra), Immgolis (Golimumab-sldi), Immgolis Intri (Golimumab-sldi), Lisraya (Brepocitinib), and Zimrixby (Rituximab-cdxx) and Update the Approval Criteria for the Targeted Immunomodulator Agents – See Appendix K**

A. Market News and Updates
B. Product Summaries
C. Cost Comparison: Rituximab Products
D. College of Pharmacy Recommendations

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

14. **Action Item – Vote to Prior Authorize Tonmya [Cyclobenzaprine Sublingual (SL) Tablet] and Update the Approval Criteria for the Fibromyalgia Medications – See Appendix L**

A. Market News and Updates
B. Tonmya (Cyclobenzaprine SL Tablet) Product Summary
C. College of Pharmacy Recommendations

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

15. **Action Item – Vote to Prior Authorize Aqvesme (Mitapivat) and Update the Approval Criteria for the Anemia Medications – See Appendix M**

A. Market News and Updates
B. Aqvesme (Mitapivat) Product Summary
C. College of Pharmacy Recommendations

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

16. **Action Item – Annual Review of Rhapsido (Remibrutinib) – See Appendix N**

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

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

17. **Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Sarclisa Escena (Isatuximab-irfc) and Zenbexus (Iberdomide) – See Appendix O**

A. Current Prior Authorization Criteria

B. Utilization of Multiple Myeloma Medications
C. Prior Authorization of Multiple Myeloma Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Multiple Myeloma Medications

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

18. Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Adquey (Difamilast 1% Ointment) – See Appendix P

A. Current Prior Authorization Criteria
B. Utilization of AD Medications
C. Prior Authorization of AD Medications
D. Market News and Updates
E. Adquey (Difamilast 1% Ointment) Product Summary
F. Cost Comparison: Topical Products
G. College of Pharmacy Recommendations
H. Utilization Details of AD Medications

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

19. Annual Review of Bone Density Regulators and 30-Day Notice to Prior Authorize Aukelso (Denosumab-kyqq), Bosaya (Denosumab-kyqq), Enoby (Denosumab-qbde), Jubereq (Denosumab-desu), Osvyrti (Denosumab-desu), and Xtrenbo (Denosumab-qbde) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Bone Density Regulators
C. Prior Authorization of Bone Density Regulators
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Bone Density Regulators

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

20. Annual Review of Ophthalmic Anti-Inflammatory Products and 30-Day Notice to Prior Authorize Byqlovi (Clobetasol 0.05% Suspension) – See Appendix R

A. Current Prior Authorization Criteria
B. Utilization of Ophthalmic Anti-Inflammatory Products
C. Prior Authorization of Ophthalmic Anti-Inflammatory Products
D. Market News and Updates
E. Byqlovi (Clobetasol 0.05% Suspension) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Ophthalmic Anti-Inflammatory Products

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

21. **Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Beclomethasone Dipropionate HFA, Exdensur (Depemokimab-ulaa), and Trimbow (Beclomethasone/Formoterol/Glycopyrrolate) – See Appendix S**
    A. Current Prior Authorization Criteria
    B. Utilization of Asthma and COPD Maintenance Medications
    C. Prior Authorization of Asthma and COPD Maintenance Medications
    D. Market News and Updates
    E. Exdensur (Depemokimab-ulaa) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of Asthma and COPD Maintenance Medications

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

22. **Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications (Non-Oncology) and 30-Day Notice to Prior Authorize Vobrig (Leuprolide) – See Appendix T**
    A. Current Prior Authorization Criteria
    B. Utilization of GnRH Medications
    C. Prior Authorization of GnRH Medications
    D. Market News and Updates
    E. Vobrig (Leuprolide) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of GnRH Medications

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

23. **Annual Review of Brinsupri (Brensocatib) – See Appendix U**
    A. Current Prior Authorization Criteria
    B. Utilization of Brinsupri (Brensocatib)
    C. Prior Authorization of Brinsupri (Brensocatib)
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Brinsupri (Brensocatib)

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

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

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

25. **Future Business* (Upcoming Product and Class Reviews)**
    A. Antidepressants
    B. Antifungal Medications (Systemic)
    C. Antihyperlipidemics
    D. Complement Inhibitors and Miscellaneous Immunomodulatory Agents
    E. Glycogen and Lysosomal Storage Disease Medications

F. Skin Cancer Medications

*Future product and class reviews subject to change.

26. 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.



Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING SEPTEMBER 9, 2026

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP		X
Jennifer Boyett, 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	
Darius Dorsey, Pharm.D.; Pharmacy Resident	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Lezlie Grimes, Pharm.D.; Clinical Pharmacist	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Whitney Bueno, Pharm.D., BCOP		X
Christine Hughes, Pharm.D., MBA, BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.		X
Mark Wendelboe		X
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Josh Anderson, Chief of Staff		X
Mark Brandenburg, M.D., MSC; Medical Director	X	
Terry Cothran, D.Ph.; Pharmacy Director	X	
Bradford Eckhart, J.D.; Deput General Counsel		X

Elan Gada, M.D.; Chief Medical Officer		X
Sidney Jones; J.D.; Deputy General Counsel	X	
Melissa Miller, State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Jai Persico, Neurocrine	JJ Roth, Mirum
Eardie Curry, Genentech	Scott Burns, Johnson & Johnson
Taha Khan, Vertex	Kristen Winters, Centene
Kellie Vazzana, Alkermes	Bob Atkins, Biogen
Katie Lambert, Exeltis	Roberto Pedraza, Vertex
Brandon Ross, Merck	Ashlee Waring, Organon
Deidra Williams, Humana	Julie Rhodes, AbbVie
Andy Gorzynski, Cytokinetics	Miranda Ryzenman, Artia Solutions
Irene Chung, Aetna	Gary Parenteau, Dexcom
Alice Chan, Mannkind	Sergio Mayorga, Concis Labs
Phillip Lohec, Viatris	Jami Toole, Takeda
Mike Sullivan, Amgen	David Mendoza, Otsuka
Molly Carson, Creative Capitol Strategies	Laura Cordell, Sanofi
Leia Roeges, Neurocrine Biosciences	Melissa Abbott, Compass Pathways
Payal Tejani, Biogen	

PRESENT FOR PUBLIC COMMENT:	
Taha Khan, Vertex	

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.17 TAHA KHAN

ACTION: NONE REQUIRED

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

3A: JULY 8, 2026 DUR MINUTES

Materials included in agenda packet; presented by Dr. Haymore
Dr. Ground moved to approve; seconded by Dr. Holderread

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT**

4A: PHARMACY HELPDESK ACTIVITY FOR AUGUST 2026

4B: MEDICATION COVERAGE ACTIVITY FOR AUGUST 2026

Non-presentation item; materials included in agenda packet by Dr. Grimes

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITOR UTILIZATION UPDATE**

5A: INTRODUCTION
5B: MAILING SUMMARY
5C: MAILING RESULTS
5D: DPP-4 INHIBITOR UTILIZATION IN THE SOONERCARE POPULATION
5E: CONCLUSIONS
5F: RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE ENBUMYST (BUMETANIDE NASAL SPRAY), LASIX ONYU (FUROSEMIDE ON-BODY INFUSOR), AND MYQORZO (AFICAMTEN) AND UPDATE THE APPROVAL CRITERIA FOR THE HEART FAILURE (HF) MEDICATIONS**

6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE LEQEMBI IQLIK (LECANEMAB-IRMB)**

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

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

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE AWIQLI (INSULIN ICODEC-ABAE), GLIPIZIDE 15MG TABLET, KIRSTY (INSULIN ASPART-XJHZ), AND LANGLARA (INSULIN GLARGINE-ALDY) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-DIABETIC MEDICATIONS AND KERENDIA (FINERENONE)**

8A: MARKET NEWS AND UPDATES
8B: AWIQLI (INSULIN ICODEC-ABAE)
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE JOVENE (BEVACIZUMAB-NWGD)**

9A: MARKET NEWS AND UPDATES
9B: COST COMPARISON: BEVACIZUMAB PRODUCTS
9C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE MODEYSO (DORDAVIPRONE) AND VISTOGARD (URIDINE TRIACETATE) AND UPDATE THE APPROVAL CRITERIA FOR THE MISCELLANEOUS CANCER MEDICATIONS**

10A: MARKET NEWS AND UPDATES

10B: PRODUCT SUMMARIES
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Ground moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE IRON PRODUCTS
11A: MARKET NEWS AND UPDATES
11B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Holderread moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE IRON CHELATING AGENTS
12A: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Grimes
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> VOTE TO PRIOR AUTHORIZE AMCINONIDE 0.1% OINTMENT AND UPDATE THE APPROVAL CRITERIA FOR THE TOPICAL CORTICOSTEROIDS
13A: MARKET NEWS AND UPDATES
13B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 14:</u> VOTE TO PRIOR AUTHORIZE CONTEMPO (FOSFOMYCIN FOR INJECTION), DOXYCYCLINE HYCLATE 75MG CAPSULE, AND ORLYNVAH (SULOPENEM ETZADROXIL/PROBENECID) AND UPDATE THE APPROVAL CRITERIA FOR THE VARIOUS SYSTEMIC ANTIBIOTICS
14A: MARKET NEWS AND UPDATES
14B: ORLYNVAH (SULOPENEM ETZADROXIL/PROBENECID) PRODUCT SUMMARY
14C: COST COMPARISONS
14D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 15:</u> VOTE TO PRIOR AUTHORIZE ZYCUBO (COPPER HISTIDINATE)
15A: MARKET NEWS AND UPDATES
15B: ZYCUBO (COPPER HISTIDINATE) PRODUCT SUMMARY
15C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Dorsey
Dr. Muñoz moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 16:</u> VOTE TO PRIOR AUTHORIZE MORPHINE ORAL SOLUTION SYRINGES AND TAPENTADOL TABLET, EXTENDED-RELEASE (ER) TABLET, AND ORAL SOLUTION AND UPDATE THE APPROVAL CRITERIA FOR THE

OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
16A: MARKET NEWS AND UPDATES
16B: COST COMPARISONS
16C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 17: ANNUAL REVIEW OF CYSTIC FIBROSIS (CF) MEDICATIONS
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF CF MEDICATIONS
17C: PRIOR AUTHORIZATION OF CF MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: COLLEGE OF PHARMACY RECOMMENDATIONS
17F: UTILIZATION DETAILS OF CF MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 18: ANNUAL REVIEW OF AMYLOIDOSIS MEDICATIONS
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF AMYLOIDOSIS MEDICATIONS
18C: PRIOR AUTHORIZATION OF AMYLOIDOSIS MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF AMYLOIDOSIS MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Ground moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 19: ANNUAL REVIEW OF BLADDER CONTROL MEDICATIONS
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF BLADDER CONTROL MEDICATIONS
19C: PRIOR AUTHORIZATION OF BLADDER CONTROL MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: COLLEGE OF PHARMACY RECOMMENDATIONS
19F: UTILIZATION DETAILS OF BLADDER CONTROL MEDICATIONS
Materials included in agenda packet; presented by Dr. Grimes
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 20: ANNUAL REVIEW OF BREAST CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BEIZRAY (DOCETAXEL), BEIZRAY KIT (DOCETAXEL/ALBUMIN), DOCIVYX (DOCETAXEL), INLURIYO (IMLUNESTRANT), AND VEPPANU (VEPDEGESTRANT)
20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF BREAST CANCER MEDICATIONS
20C: PRIOR AUTHORIZATION OF BREAST CANCER MEDICATIONS
20D: MARKET NEWS AND UPDATES
20E: PRODUCT SUMMARIES

20F: COST COMPARISON: TRASTUZUMAB PRODUCTS
20G: COLLEGE OF PHARMACY RECOMMENDATIONS
20H: UTILIZATION DETAILS OF BREAST CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER

<u>AGENDA ITEM NO. 21:</u> ANNUAL REVIEW OF VARIOUS OPHTHALMIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EPIOXA HD/EPIOXA (RIBOFLAVIN 5'-PHOSPHATE OPHTHALMIC SOLUTION) AND LUMVOA (VELIGROTUG-VVZE)
21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: UTILIZATION OF VARIOUS OPHTHALMIC MEDICATIONS
21C: PRIOR AUTHORIZATION OF VARIOUS OPHTHALMIC MEDICATIONS
21D: MARKET NEWS AND UPDATES
21E: LUMVOA (VELIGROTUG-VVZE) PRODUCT SUMMARY
21F: COLLEGE OF PHARMACY RECOMMENDATIONS
21G: UTILIZATION DETAILS OF VARIOUS OPHTHALMIC MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER

<u>AGENDA ITEM NO. 22:</u> ANNUAL REVIEW OF ANTIHISTAMINE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CETIRIZINE ORAL SOLUTION UNIT DOSE CUPS (UDC)
22A: CURRENT PRIOR AUTHORIZATION CRITERIA
22B: UTILIZATION OF SYSTEMIC ANTIHISTAMINE MEDICATIONS
22C: PRIOR AUTHROIZATION OF SYSTEMIC ANTIHISTAMINE MEDICATIONS
22D: MARKET NEWS AND UPDATES
22E: COST COMPARISON: CETIRIZINE PRODUCTS
22F: COLLEGE OF PHARMACY RECOMMENDATIONS
22G: UTILIZATION DETAILS OF SYSTEMIC ANTIHISTAMINE MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER

<u>AGENDA ITEM NO. 23:</u> ANNUAL REVIEW OF BENIGN PROSTATIC HYPERPLASIA (BPH) MEDICATIONS
23A: CURRENT PRIOR AUTHORIZATION CRITERIA
23B: UTILIZATION OF BPH MEDICATIONS
23C: PRIOR AUTHORIZATION OF BPH MEDICATIONS
23D: COLLEGE OF PHARMACY RECOMMENDATIONS
23E: UTILIZATION DETAILS OF BPH MEDICATIONS
Non-presentation item; materials included in agenda packet by Dr. Dorsey
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 24:</u> U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. Grimes
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 25:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
25A: ANEMIA MEDICATIONS
25B: ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
25C: CONSTIPATION AND DIARRHEA MEDICATIONS
25D: FIBROMYALGIA MEDICATIONS

25E: MYELOPROLIFERATIVE NEOPLASM (MPN) MEDICATIONS
25F: TARGETED IMMUNOMODULATOR AGENTS
*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 26: ADJOURNMENT
The meeting was adjourned at 5:18pm.

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

Memorandum

Date: September 11, 2026

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

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

Subject: DUR Board Recommendations from Meeting on September 9, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Utilization Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten) and Update the Approval Criteria for the Heart Failure (HF) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Enbumyst™ (bumetanide nasal spray), Lasix® ONYU (furosemide on-body infusor), and Myqorzo™ (aficamten) with the following criteria (shown in red):

Enbumyst™ (Bumetanide Nasal Spray) Approval Criteria:

1. An FDA approved indication of the treatment of edema associated with congestive heart failure, hepatic disease, or renal disease, including nephrotic syndrome; and
2. Member must be 18 years of age or older; and
3. Member is currently showing signs of edema; and
4. Member must not currently have significant nasal mucosal or structural abnormalities, such as acute episodes of rhinitis or congestion due to any cause; and
5. Enbumyst™ must be prescribed by, or in consultation with, a specialist in the area of the patient's diagnosis (e.g., cardiologist, nephrologist, hepatologist, gastroenterologist); and
6. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and
7. Prescriber must verify the member will discontinue oral diuretics during the treatment with Enbumyst™ and will transition back to oral diuretic maintenance therapy when practical; and
8. Prescriber must verify the member or caregiver will be counseled on the proper administration of Enbumyst™; and
9. Approvals will be issued per incident of edema; and
    a. A quantity limit of 36 nasal spray devices per 36 days will apply; or
    b. For requests exceeding the quantity limit, clinical documentation supporting the need for additional supply must be provided for a quantity limit override; and
10. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema.

Lasix® ONYU (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of edema in members with chronic heart failure; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of edema; and
5. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and

6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Lasix® ONYU and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member or caregiver will be trained on the proper use of Lasix® ONYU and is able to detect and respond to the device alarms; and
8. Member must not have any contraindications for use of Lasix® ONYU; and
9. Member must not have conditions that require immediate hospitalization; and
10. The following quantity limits will apply:
    a. Approval quantities for the kit (i.e., co-packaged prefilled-cartridge and disposable unit) will be issued per incident of edema; and
    b. 1 Reusable Unit (drug delivery device) per year; or
        i. For requests exceeding this limit, approval of an additional Reusable Unit will be granted upon verification that the previously dispensed Reusable Unit has reached its lifespan of 48 uses, as indicated in package labeling; and
        ii. Only 1 Reusable Unit will be approved at a time; and
11. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema.

Myqorzo™ (Aficamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55% to initiate therapy; and
    a. Prescriber must agree to assess the member's clinical status and LVEF during treatment and adjust or interrupt the Myqorzo™ dose accordingly; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or non-dihydropyridine calcium channel blockers; and
7. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments or increased monitoring according to package labeling, prior to and during treatment with Myqorzo™; and
8. Prescriber, pharmacy, and member must be enrolled in the Myqorzo™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and

9. A quantity limit of 30 tablets per 30 days will apply; and
10. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the duration of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to treatment.

The College of Pharmacy also recommends updating the approval criteria for Camzyos® (mavacamten), Furoscix® (furosemide on-body infusor), and Verquvo® (vericiguat) based on recent FDA approvals (changes shown in red):

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
    a. Prescriber must agree to assess the member's clinical status and LVEF during treatment and adjust or interrupt the Camzyos® dose accordingly; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or non-dihydropyridine calcium channel blockers; and
7. ~~Member must not be taking concurrent strong CYP2C19 inhibitors (e.g., fluvoxamine, fluconazole), moderate to strong CYP2C19 inducers (e.g., rifampin), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and~~
8. ~~If the member is taking moderate to strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or weak to moderate CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole), the prescriber must verify that the Camzyos® dose will be adjusted according to the package labeling; and~~
9. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments, according to package labeling, prior to and during treatment with Camzyos®; and
10. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos®; and
11. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 4 months after the final dose of Camzyos®; and

12. Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
13. A quantity limit of 30 capsules per 30 days will apply; and
14. Initial approvals will be for the duration of 6 months. Subsequent ~~Further~~ approvals, for the duration of 1 year, may be granted if the prescriber attests ~~documents~~ that the member is tolerating and responding well to treatment.~~; and~~
~~15. Subsequent approvals will be for the duration of 1 year.~~

Furoscix® (Furosemide On-Body Injection) Approval Criteria:

1. An FDA approved indication for the treatment of edema in members with chronic heart failure or chronic kidney disease (CKD), including nephrotic syndrome; and
~~2. Member must be 18 years of age or older; and~~
3. Member must weigh ≥43kg; and
4. Furoscix® must be prescribed by, or in consultation with, a cardiologist, nephrologist, or a provider trained in managing acute decompensated heart failure (ADHF) or CKD; and
5. Member is currently showing signs of edema; and
6. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and
7. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
~~8. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:~~
    ~~a. Oxygen saturation ≥90% on exertion; and~~
    ~~b. Respiratory rate <24 breaths per minute; and~~
    ~~c. Resting heart rate <100 beats per minute; and~~
    ~~d. Systolic blood pressure >100mmHg; and~~
~~9. Member must have an adequate environment for at-home administration, have been trained on the proper use of Furoscix®, and be able to detect and respond to the device alarms; and~~
10. Prescriber must verify the member or caregiver will be trained on the proper use of Furoscix® and is able to detect and respond to the device alarms; and
11. Member must not have any contraindications for use of Furoscix® ~~including anuria or hepatic cirrhosis;~~ and
12. Member must not have conditions that require immediate hospitalization; and
13. Approvals will be issued per incident of edema ~~fluid overload~~; and

14. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema ~~fluid overload~~.

Verquvo® (Vericiguat) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
   a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
   b. Reduced left ventricular ejection fraction (LVEF) <45%; and
   c. Already receiving guideline-directed medical therapy for HF, as documented in member's pharmacy claims history; and
2. Member has evidence of worsening HF (decompensation) demonstrated by at least 1 of the following:
   a. Hospitalization for HF within the past 6 months; or
   b. Received outpatient intravenous (IV) diuretics within the past 3 months; and
3. Member must be 18 years of age or older; and
4. Member must not be taking concomitant soluble guanylate cyclase (sGC) stimulators (e.g., riociguat); and
5. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during treatment and for 1 month after the final dose of Verquvo®; and
6. Prescriber must attest that the member will be assessed for symptomatic hypotension before initiation and during treatment per package labeling; and
7. Prescriber must verify that the dose will be adjusted per package labeling for members at increased risk for symptomatic hypotension; and
8. Prescriber must agree to titrate to the target maintenance dose according to package labeling, as tolerated by the member; and
9. Initial approvals will be for the duration of 6 months. Compliance will be checked for continued approval every 6 months; and
10. A quantity limit of 30 tablets per 30 days will apply.

Recommendation 4: Vote to Prior Authorize Leqembi Iqlik® (Lecanemab-irmb)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Leqembi Iqlik® (lecanemab-irmb) with criteria similar to Leqembi® (lecanemab-irmb), including updates to the magnetic resonance imaging (MRI) monitoring criteria based on the Drug Safety Communication and corresponding label updates (changes shown in red):

Leqembi® and Leqembi Iqlik® (Lecanemab-irmb) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
   a. Mini-Mental State Exam (MMSE) score between 22 and 30; or
   b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
   c. Montreal Cognitive Assessment (MoCA) score ≥19; or
   d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Lecanemab-irmb ~~Leqembi®~~ 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. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing intracerebral hemorrhage with the concomitant use have been discussed and are acceptable to the member prior to initiating lecanemab-irmb ~~Leqembi®~~; and
8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or
    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with lecanemab-irmb, ~~Leqembi® and~~ after 1 month, 2

months, 3 months, and 6 months of treatment, and as clinically indicated ~~the 5th, 7th, and 14th infusions~~; and

12. Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with lecanemab-irmb ~~Leqembi®~~; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Verification that lecanemab-irmb will be shipped via cold chain supply to the administering location (i.e., member's home, clinic) and storage and handling requirements will be followed as per the package labeling; and
15. Requests for Leqembi® IV will require the following:
    a. Leqembi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and
        ~~i. Leqembi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and~~
    b. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. Requests for Leqembi Iqlik® subcutaneous (sub-Q) formulation will require the following:
    ~~a. Member has received treatment with the IV formulation at a dose of 10mg/kg every 2 weeks for 18 months; and~~
    b. Leqembi Iqlik® must be initiated under the guidance and supervision of a health care professional; and
    c. For self or caregiver administration, the prescriber must attest to the following:
        i. Direct guidance for at least 2 consecutive sub-Q doses has been provided by a health care professional; and
        ii. Member or caregiver will be trained by a health care professional on the sub-Q administration, ability to recognize and manage symptoms of hypersensitivity, and proper storage of Leqembi Iqlik®; and
17. For maintenance dosing, the prescriber must verify the member has completed 18 months of an FDA-approved starting dosage regimen; and
18. Initial approvals will be for 6 months. Confirmation that MRIs have been completed per package labeling and were acceptable to the provider ~~prior to the 5th and 7th infusions~~ is required for continuation; and

19. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
20. Approval quantities will be dependent on the member's weight and/or dosing based on package labeling; and
21. The maximum dose approvable is 10mg/kg per 14 days for the IV formulation and 10mL per 28 days for the sub-Q formulation; and
22. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Recommendation 5: Vote to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone)

MOTION CARRIED by unanimous approval.

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

1. Prior authorization of glipizide 15mg tablet and placement into the Special Prior Authorization (PA) Tier with the following additional criteria; and
2. Designating Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin) as brand preferred and moving generic sitagliptin, generic sitagliptin/metformin, and Janumet XR® (sitagliptin/metformin ER) to the Special PA Tier with the following additional criteria based on net costs; and
3. Moving Onglyza® (saxagliptin) from the Special PA Tier to Tier-3 based on net costs; and
4. Moving Nesina® (alogliptin) and Oseni® (alogliptin/pioglitazone) from Tier-3 to the Special PA Tier based on net costs; and
5. Moving Zituvio® (sitagliptin), Zituvimet® (sitagliptin/metformin), and Zituvimet® XR (sitagliptin/metformin ER) from Special PA to Tier-2 based on net costs and generic availability; and
6. Removing the brand preferred status from Farxiga® (dapagliflozin) and moving generic dapagliflozin from the Special PA Tier to Tier-1 based on net costs; and
7. Updating the GLP-1 Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)/GLP-1 Agonists Special PA Approval Criteria based on clinical practice and for clarity.

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)*
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/glipizide (Metaglip®)			metformin 625mg & 750mg tab
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	~~**alogliptin (Nesina®)**~~	**alogliptin (Nesina®)**
	linagliptin/metformin (Jentadueto®) **– Brand Preferred**	alogliptin/metformin (Kazano®)	**alogliptin/ pioglitazone (Oseni®)**
	linagliptin/metformin ER (Jentadueto® XR)	~~**alogliptin/ pioglitazone (Oseni®)**~~	linagliptin/metformin (generic)*
	sitagliptin (Januvia®) **– Brand Preferred**	**saxagliptin (Onglyza®)**	~~**saxagliptin (Onglyza®)**~~
	sitagliptin (Zituvio®)		saxagliptin/metformin (Kombiglyze®, Kombiglyze XR®)
	sitagliptin/metformin (Janumet®) **– Brand Preferred**		**sitagliptin (generic Januvia®)***
	~~**sitagliptin/ metformin ER (Janumet XR®)**~~		~~**sitagliptin (Zituvio®)***~~
	sitagliptin/ metformin (Zituvimet®)		**sitagliptin/metformin (generic Janumet®)***
	sitagliptin/ metformin ER (Zituvimet® XR)		**sitagliptin/metformin ER (Janumet XR®)***
			~~**sitagliptin/metformin (Zituvimet®)***~~
			~~**sitagliptin/metformin ER (Zituvimet® XR)***~~
			sitagliptin oral solution (Brynovin®)*

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
DPP-4 Inhibitors/SGLT-2 Inhibitors			
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	semaglutide (Ozempic®)	exenatide (Byetta®)*
	liraglutide (Victoza®) – **Brand Preferred**	semaglutide (Rybelsus®)	liraglutide (generic)*
			tirzepatide (Mounjaro®)*
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)*	
		insulin glargine/ lixisenatide (Soliqua® 100/33)*	
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®) ~~– **Brand Preferred**~~	dapagliflozin/ metformin ER (Xigduo® XR) – **Brand Preferred**	canagliflozin (Invokana®)	~~**dapagliflozin (generic)***~~
empagliflozin (Jardiance®)		canagliflozin/ metformin (Invokamet®)	dapagliflozin/ metformin ER (generic)*
empagliflozin/ metformin (Synjardy®)		canagliflozin/ metformin ER (Invokamet® XR)	ertugliflozin (Steglatro®)
empagliflozin/ metformin ER (Synjardy® XR)			ertugliflozin/metformin (Segluromet®)
			sotagliflozin (Inpefa®)*
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Sulfonylureas			
glimepiride (Amaryl®)			glimepiride 3mg tablet*
glipizide (Glucotrol®)			glipizide 2.5mg immediate-release tablet*
glipizide SR (Glucotrol XL®)			**glipizide 15mg immediate-release tablet***
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

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.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GIP = gastric inhibitory polypeptide; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release; susp = suspension

Anti-Diabetic Medications Special PA Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
3. Use of Brynovin® (sitagliptin oral solution) will require a patient-specific, clinically significant reason why a special formulation is needed and why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors); and
4. Use of generic ~~dapagliflozin or~~ dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why the member cannot use brand name ~~Farxiga® (dapagliflozin) or~~ Xigduo® XR (dapagliflozin/ metformin ER) and all available lower-tiered sodium-glucose cotransporter-2 (SGLT-2) inhibitors; and
5. Use of glimepiride 3mg tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using the lower strengths of glimepiride to achieve the 3mg dose; and

6. Use of glipizide 2.5mg immediate-release tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a glipizide 5mg tablet to achieve a 2.5mg dose; and
7. Use of glipizide 15mg tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using the lower strengths of glipizide to achieve the 15mg dose; and
8. Use of generic linagliptin/metformin will require a patient-specific, clinically significant reason why the member cannot use brand name Jentadueto® (linagliptin/metformin); and
9. Use of generic sitagliptin (generic Januvia®) or sitagliptin/metformin (generic Janumet®) will require a patient-specific, clinically significant reason why the member cannot use brand name Januvia® (sitagliptin) or Janumet® (sitagliptin/metformin) and all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors); and
10. Use of Janumet XR® (sitagliptin/metformin ER) ~~Zituvio® (sitagliptin), and Zituvimet® (sitagliptin/metformin), and Zituvimet® XR (sitagliptin/metformin)~~ will require a patient-specific, clinically significant reason why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors).

Glucagon-Like Peptide-1 (GLP-1) Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)/GLP-1 Agonists Special PA Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. ~~Member must be currently stabilized on the requested product (documentation must be provided) or a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered GLP-1 or GIP/GLP-1 agonists must be provided; and~~
3. Documentation of member's current A1c and goal A1c must be submitted with all requests; and
4. Member must meet 1 of the following:
    a. Member must be currently stabilized on the requested product [documentation must be provided (e.g., pharmacy records and clinical documentation of glycemic control and/or reduction in A1c while on therapy)]; or
    b. Member must have failed to achieve glycemic control and/or goal A1c reduction despite a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with all available lower-tiered GLP-1 or GIP/GLP-1 agonists and have a documented clinical reason why the member cannot continue treatment with the lower tier medications; and

i. Clinical documentation of follow-up glycemic status after trials (e.g., A1c levels, blood glucose levels) must be provided; and
ii. For members who did not complete a 3-month trial with a lower-tiered GLP-1 or GIP/GLP-1 agonist (i.e., due to intolerable adverse effects), detailed information regarding adverse effects occurring with the lower-tiered medication(s) that are not expected to occur with the requested medication must be provided; and

5. Use of generic liraglutide will require a patient-specific, clinically significant reason why the member cannot use brand name Victoza® (liraglutide); and
6. A clinical exception will apply for medications with a unique FDA approved indication or guideline supported efficacy not covered by all Tier-2 and Tier-3 GLP-1 or GIP/GLP-1 agonists. Tier structure rules for unique FDA approved indications and guideline supported efficacy will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Awiqli® (insulin icodec-abae) with the following criteria, Kirsty™ (insulin aspart-xjhz) with criteria similar to Merilog™ (insulin aspart-szjj), and Langlara™ (insulin glargine-aldy) with criteria similar to Rezvoglar™ (insulin glargine-aglr) (changes shown in red):

Awiqli® (Insulin Icodec-abae) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use a daily basal insulin must be provided.

Kirsty™ (Insulin Aspart-xjhz) and Merilog™ (Insulin Aspart-szjj) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Novolog® (insulin aspart) or Fiasp® (insulin aspart) 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.

Langlara™ (Insulin Glargine-aldy) and Rezvoglar™ (Insulin Glargine-aglr) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) 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.

Next, the College of Pharmacy recommends removing the prior authorization from Humalog® KwikPen® U-200 (insulin lispro 200 units/mL), Lyumjev® U-100 (insulin lispro-aabc 100 units/mL), and brand name Tresiba® (insulin degludec) based on net costs and updating the Xultophy® 100/3.6 (insulin degludec/liraglutide) approval criteria based on the removal of the prior authorization from Tresiba® (changes shown in red):

Admelog® (Insulin Lispro) ~~and Lyumjev® U-100 (Insulin Lispro-aabc 100 Units/mL)~~ Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use insulin lispro U-100 (unbranded Humalog® U-100) or Lyumjev® U-100 (insulin lispro-aabc 100 units/mL).

~~Humalog® KwikPen® U-200 (Insulin Lispro 200 Units/mL) and~~ Lyumjev® KwikPen® U-200 (Insulin Lispro-aabc 200 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. Authorization of the 200 units/mL strength requires a patient-specific, clinically significant reason why the member cannot use the 100 units/mL strength; and
3. A patient-specific, clinically significant reason why the member cannot use Humalog® KwikPen® U-200 (insulin lispro 200 units/mL).

~~Tresiba® (Insulin Degludec) Approval Criteria:~~

~~1. An FDA approved diagnosis of diabetes mellitus; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) must be provided.~~

Xultophy® 100/3.6 (Insulin Degludec/Liraglutide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine), ~~or~~ Semglee® (insulin glargine-yfgn), or brand name Tresiba® (insulin degludec) with Victoza® (liraglutide) must be provided; and
3. Current Tier-3 criteria will apply.

Next, the College of Pharmacy recommends updating the Afrezza® (insulin human inhalation powder) approval criteria based on the FDA approved age expansion (changes shown in red):

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus (DM); and
2. Member must be 6 ~~18~~ years of age or older; and

3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate must be provided; and
4. For the diagnosis of type 1 DM, the member must use Afrezza® with a long-acting insulin; and
5. Member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Additionally, the College of Pharmacy recommends updating the Kerendia® (finerenone) approval criteria based on the new FDA approved indication and clinical practice (changes shown in red):

Kerendia® (Finerenone) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure (HF) in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
        i. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and
        ii. Member has albuminuria (urine albumin-to-creatinine ratio ≥30mg/g) despite maximum tolerated dosing of an ACE or ARB; or
    b. To reduce the risk of cardiovascular death, hospitalization for HF, and urgent HF visits in adult members with HF with left ventricular ejection fraction (LVEF) ≥40%; and
        i. Member is currently receiving guideline-directed management and therapy (GDMT) appropriate to their stage of HF or has a contraindication or documented intolerance to GDMT; and
2. Member is currently stabilized on a sodium-glucose cotransporter-2 (SGLT-2) inhibitor or a patient specific, clinically significant reason why the member cannot use an SGLT-2 inhibitor must be provided; and
3. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
4. Member must not have adrenal insufficiency; and
5. Member must not have severe hepatic impairment (Child Pugh C); and
6. Prescriber must measure serum potassium and eGFR and verify the member meets the following prior to initiation of Kerendia®; and
    a. Serum potassium ≤5mEq/L; and
    b. eGFR ≥25mL/min/1.73m^2; and
7. ~~Prescriber must verify serum potassium is not >5.0mEq/L prior to treatment initiation with Kerendia®; and~~

8. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
9. ~~Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and~~
10. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
    a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
    b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2; and
11. A maximum approvable dose will apply based on indication per the package labeling:
    a. CKD associated with T2DM: 20mg once daily; or
    b. HF with LVEF ≥40%: 40mg once daily; and
12. 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 and that serum potassium levels and eGFR are monitored periodically and the dose is adjusted accordingly per the package labeling. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends updating the Tzield® (teplizumab-mzwv) approval criteria based on the new FDA approvals and label updates (changes shown in red):

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
        i. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies (documentation must be submitted with results of autoantibody testing); and
        ii. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by 1 of the following (results of lab testing must be submitted):
            1. Fasting plasma glucose ≥100mg/dL and <126mg/dl; or
            2. 2-hour plasma glucose ≥140 mg/dL and <200mg/dl; or
            3. Hemoglobin A1c ≥5.7% and <6.5% or ≥10% increase in A1c; or
            4. 30-, 60-, or 90-minute value ≥200mg/dl on 2 separate occasions; ~~and~~ or
    b. Recently diagnosed Stage 3 Type 1 DM. Diagnosis must be confirmed by the following:
        i. Member was diagnosed within the last 8 weeks; and

ii. Laboratory testing confirming the presence of ≥1 pancreatic islet autoantibody (documentation must be submitted with results of autoantibody testing); and
iii. Peak C-peptide ≥0.2pmol/mL on a mixed-meal tolerance test (MMTT) or alternative if MMTT is not available (results of lab testing must be submitted); and

2. Member must be:
   a. ~~8 years~~ 1 year of age or older for Stage 2 Type 1 DM; or
   b. 8 to 17 years of age for Stage 3 Type 1 DM; and
3. ~~Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and~~
4. Prescriber must confirm that the member's diagnosis is of autoimmune origin and does not suggest insulin resistance due to obesity, type 2 diabetes mellitus (T2DM), or dysglycemia due to other forms of diabetes including but not limited to genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), or diabetes secondary to medications or surgery; and
5. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
6. ~~All of the following will be required for initiation of treatment:~~
   ~~a. Verification that female members of reproductive potential are not pregnant and are currently using reliable contraception; and~~
   ~~b. Verification that the member has no active infection(s); and~~
   ~~c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
   ~~d. Liver function tests and verification that levels are acceptable to the prescriber; and~~
   ~~e. Verification that all age-appropriate vaccinations have been administered prior to treatment; and~~
   ~~f. Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and~~
7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Tzield®; and
8. Prescriber must confirm that the member does not have any contraindications for use of Tzield®; and
9. Prescriber must verify that Tzield® treatment will be interrupted and/or discontinued when appropriate, as per the package labeling [e.g., prolonged severe lymphopenia, viral reactivation, liver enzymes >5 times the upper limit of normal (ULN), or bilirubin >3 times ULN, severe cytokine release syndrome, serious infections]; and

10. Tzield® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tzield® will be administered; and
    a. Tzield® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tzield® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Tzield®; and
11. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
12. ~~A quantity limit of 28mL per 14 days will apply; and~~
13. Approval quantities will be based on the recommended dosing per package labeling based on the member's diagnosis and recent BSA; and
14. Approvals will be for the following:
    a. Stage 2 T1DM: (1) 14-day cycle per member per lifetime; or
    b. Stage 3 T1DM: (2) 12-day cycles per member per lifetime.

Recommendation 6: Vote to Prior Authorize Jobevne™ (Bevacizumab-nwgd) and Update the Approval Criteria for the Colorectal Cancer (CRC) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Jobevne™ (bevacizumab-nwgd) with criteria similar to the other non-preferred bevacizumab products based on net costs and recommends making Vegzelma® (bevacizumab-adcd) a preferred product based on net cost (changes shown in red):

Alymsys® (Bevacizumab-maly), Avzivi® (Bevacizumab-tnjn), and Jobevne™ (Bevacizumab-nwgd), ~~and Vegzelma® (Bevacizumab-adcd)~~ Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab), Mvasi® (bevacizumab-awwb), Vegzelma® (bevacizumab-adcd), or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, 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.

Recommendation 7: Vote to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate) and Update the Approval Criteria for the Miscellaneous Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Modeyso™ (dordaviprone) and Vistogard® (uridine triacetate) with the following criteria (shown in red):

Modeyso™ (Dordaviprone) Approval Criteria [Glioma Diagnosis]:

1. Diagnosis of diffuse midline glioma; and
2. Member must be 1 year of age or older; and
3. Presence of H3 K27M mutation; and
4. Member has progressed on at least 1 prior therapy.

Vistogard® (Uridine Triacetate) Approval Criteria:

1. Member received fluorouracil or capecitabine within the previous 96 hours; and
2. Member meets 1 of the following:
    a. Following fluorouracil or capecitabine overdose regardless of the presence of symptoms; or
    b. Exhibits early-onset, severe or life-threatening toxicity affecting cardiac or central nervous system; or
    c. Exhibits early-onset, unusually severe adverse reactions; and
3. A quantity limit of 20 packets for 5 days will apply; and
    a. Doses administered in an emergency room (ER) or inpatient (IP) setting do not require prior authorization. The number of remaining doses (following any ER or IP doses) must be specified on the request. Only the number of remaining doses for outpatient use will be approved.

Next, the College of Pharmacy recommends updating the Omisirge® (omidubicel-onlv) and Tecelra® (afamitresgene autoleucel) approval criteria based on recent FDA approvals with the following updates (shown in red):

Omisirge® (Omidubicel-onlv) Approval Criteria [Severe Aplastic Anemia Diagnosis]:

1. Diagnosis of severe aplastic anemia; and
2. Member is 6 years of age or older; and
3. Allogeneic stem cell transplant using umbilical cord blood donor source is planned; and
    a. No compatible donor is available; and
    b. Documentation of the donor source must be provided; and
4. Reduced intensity conditioning regimen will be used; and
    a. Documentation of the member's conditioning regimen must be provided; and

5. Will be used to reduce time to neutrophil recovery and incidence of infection.

Tecelra® (Afamitresgene Autoleucel) Approval Criteria [Synovial Sarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic synovial sarcoma; and
2. Member must be ~~18~~ 12 years of age or older; and
3. Has received previous anthracycline or ifosfamide-containing chemotherapy; and
4. HLA-A*02:01P, -A*02:02P, A*02:03P, or -A*02:06P positive; and
5. Tumor expresses melanoma-associated antigen A4 (MAGE-A4) as detected by an FDA-approved test; and
6. Health care facilities must be able to administer cellular therapies and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
7. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating Voranigo® (vorasidenib) approval criteria to be consistent with the FDA approved age range with the following updates (shown in red):

Voranigo® (Vorasidenib) Approval Criteria [Astrocytoma or Oligodendroglioma Diagnosis]:

1. Diagnosis of grade 2 astrocytoma or oligodendroglioma; and
2. Member must be 12 years of age or older; and
3. Presence of susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.

Recommendation 8: Vote to Update the Approval Criteria for the Iron Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Accrufer® (ferric maltol) approval criteria based on the recent FDA approved age expansion with the following changes (shown in red):

Accrufer® (Ferric Maltol) Approval Criteria:

1. Diagnosis of iron deficiency anemia (IDA); and
2. Lab results verifying IDA must be submitted; and
3. Member must be ~~18~~ 10 years of age or older; and
4. For members 18 years of age or older, all of the following must be met:
    a. Member must have a documented diagnosis of chronic kidney disease (CKD) or inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis); and

b. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
c. A recent, failed trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
d. A patient-specific clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided; and

5. For members younger than 18 years of age, all of the following must be met:
   a. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
   b. A patient-specific clinically significant reason why the member cannot utilize IV iron must be provided; and
6. Initial approvals will be for the duration of 3 months of treatment. Subsequent approvals (for 3 months of treatment) will require updated recent laboratory results documenting continued IDA.

Recommendation 9: Vote to Update the Approval Criteria for the Iron Chelating Agents

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Jadenu® (deferasirox), Jadenu® Sprinkle (deferasirox), and Ferriprox® (deferiprone) approval criteria with regard to Exjade® (deferasirox) for clarity and to include additional criteria for Ferriprox® tablet (deferiprone twice daily formulation) based on net cost (changes shown in red):

Jadenu® (Deferasirox), Jadenu® Sprinkle (Deferasirox), and Ferriprox® (Deferiprone) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox), which is available without prior authorization, must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; and
4. For Ferriprox® 1,000mg tablet (deferiprone twice daily formulation), a patient-specific, clinically significant reason other than convenience why the member cannot use and Ferriprox® 1,000mg tablet (deferiprone 3 times daily formulation); and

5. 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.

Recommendation 10: Vote to Prior Authorize Amcinonide 0.1% Ointment and Update the Approval Criteria for the Topical Corticosteroids

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Topical Corticosteroids Product Based Prior Authorization (PBPA) Tier chart based on net costs (changes are shown in red in the following Tier chart):

1. Ultra-High to High Potency:
   a. Prior authorization of amcinonide 0.1% ointment and placement into Tier-3; and
   b. Move augmented betamethasone dipropionate 0.05% (Diprolene®) gel, clobetasol propionate/skin cleanser 0.05% (Clodan®) kit, desoximetasone 0.05% (Topicort®) gel, and halobetasol propionate 0.05% (Ultravate®) lotion from Tier-2 to Tier-3; and
   c. Move desoximetasone 0.25% (Topicort®) spray from Tier-3 to Tier-2; and
   d. Move clobetasol propionate 0.05% (Temovate® Emollient) emollient cream from Tier-1 to Tier-2; and
2. Medium-High to Medium Potency:
   a. Move hydrocortisone butyrate 0.1% solution from Tier-2 to Tier-3; and
   b. Move triamcinolone acetonide 0.1% lotion from Tier-1 to Tier-2; and
3. Low Potency:
   a. Move fluocinolone acetonide/skin cleanser 0.01% (Synalar® TS) kit from Tier-2 to Tier-3.

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,L,O	~~**augmented betamethasone dipropionate 0.05% (Diprolene®)**~~	~~**G**~~	amcinonide 0.1%	C**,O**
betamethasone dipropionate 0.05% (Diprosone®)	C,O	clobetasol propionate 0.05% (Clobex®, Clodan®)	L,Sh,Spr	**augmented betamethasone dipropionate 0.05% (Diprolene®)**	**G**
clobetasol propionate 0.05% (Olux®)	F	~~**clobetasol propionate/skin cleanser 0.05% kit (Clodan®)**~~	~~**Sh**~~	clobetasol propionate 0.025% (Impoyz®)	C

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	clobetasol propionate emollient 0.05% (Olux-E®, Tovet®)	F
~~**clobetasol propionate emollient 0.05% (Temovate® Emollient**~~	~~**C**~~	**clobetasol propionate emollient 0.05% (Temovate® Emollient**	**C**	**clobetasol propionate/skin cleanser 0.05% kit (Clodan®)**	**Sh**
desoximetasone 0.25% (Topicort®)	C,O	~~**desoximetasone 0.05% (Topicort®)**~~	~~**G**~~	~~**desoximetasone 0.25% (Topicort®)**~~	~~**Spr**~~
fluocinonide 0.05%	C,O,So	**desoximetasone 0.25% (Topicort®)**	**Spr**	**desoximetasone 0.05% (Topicort®)**	**G**
fluocinonide 0.1% (Vanos®)	C	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
halobetasol propionate 0.05% (Ultravate®)	C,O	~~**halobetasol propionate 0.05% (Ultravate®)**~~	~~**L**~~	halcinonide 0.1% (Halog®)	C,So
				halobetasol propionate 0.05%	F
				halobetasol propionate 0.05% (Ultravate®)	**L**
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone valerate 0.12% (Luxiq®)	F	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)	O,Sus
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.1% (Beta-Val®)	L	clocortolone pivalate 0.1% (Cloderm®)	C
fluticasone propionate 0.005% (Cutivate®)	O	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F	desoximetasone 0.05% (Topicort LP®)	C,O
fluticasone propionate 0.05% (Cutivate®)	C	fluocinolone acetonide 0.025% (Synalar®)	C,O	flurandrenolide 0.05%	L

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
hydrocortisone valerate 0.2% (Westcort®)	C	fluocinolone acetonide/emollient 0.025% kit (Synalar®)	C,O	fluticasone propionate 0.05% (Cutivate®)	L
mometasone furoate 0.1% (Elocon®)	C,L,O, So	fluocinonide emollient 0.05% (Lidex E®)	C	hydrocortisone butyrate 0.1%	C,L,**So**
triamcinolone acetonide 0.025%	O	hydrocortisone butyrate 0.1%	O,~~**So**~~	triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr
triamcinolone acetonide 0.1%	C,~~**L**~~,O	hydrocortisone probutate 0.1% (Pandel®)	C		
triamcinolone acetonide 0.5%	C,O	hydrocortisone valerate 0.2% (Westcort®)	O		
		triamcinolone acetonide 0.05% (Trianex®)	O		
		triamcinolone acetonide 0.1%	**L**		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,O	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	**fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)**	**C**
hydrocortisone acetate 1%	C,O	fluocinolone acetonide 0.01% (Synalar®)	C	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O	~~**fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)**~~	~~**C**~~		
triamcinolone acetonide 0.025%	C,L				

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).
C = cream; F = foam; G = gel; L = lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

Recommendation 11: Vote to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid) and Update the Approval Criteria for the Various Systemic Antibiotics

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Contepo™ (fosfomycin for injection) and Orlynvah™ (sulopenem etzadroxil/probenecid) with the following criteria (shown in red):

Contepo™ (Fosfomycin for Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including acute pyelonephritis, caused by Escherichia coli or Klebsiella pneumoniae (culture/sensitivity results must be submitted with the request); and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate cephalosporin (e.g., cefuroxime, ceftriaxone, cefepime), penicillin/beta lactamase inhibitor combination (e.g., piperacillin/ tazobactam), a fluoroquinolone (e.g., ciprofloxacin or levofloxacin), or other cost-effective therapeutic equivalent alternative(s); and
3. A quantity limit of 42 vials per 14 days will apply.

Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by designated susceptible microorganisms in members who have limited or no alternative oral treatment options (culture/sensitivity results must be submitted); and
    a. Must not be used for the treatment of complicated urinary tract infections (cUTI) or complicated intraabdominal infections (cIAI) or as step-down treatment after intravenous antibacterial treatment of cUTI or cIAI; and
2. Member must be a female 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
4. A quantity limit of 10 tablets per 5 days will apply.

The College of Pharmacy recommends updating the approval criteria for Blujepa (gepotidacin) based on the new FDA approved indication and for clarity (changes shown in red):

Blujepa (Gepotidacin) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Uncomplicated urinary tract infection (uUTI) caused by ~~the designated microorganisms~~ *Escherichia coli*, *Klebsiella*

pneumoniae, Citrobacter freundii complex, *Staphylococcus saprophyticus,* ~~and~~ or *Enterococcus faecalis* (culture/sensitivity results must be submitted); and
    i. Member must be a female 12 years of age or older and weigh ≥40kg; ~~and~~ or
b. Uncomplicated urogenital gonorrhea in members who have limited or no alternative treatment options; and
    i. Member must be 12 years of age or older and weigh ≥45kg; and
2. Member must have an estimated glomerular filtration rate (eGFR) >30mL/min/1.73m^2) and must not be on dialysis; and
3. Member must not have severe hepatic impairment (Child Pugh C); and
~~4. Prior to and during treatment, the potential for drug interactions should be evaluated, including:~~
    ~~a. Avoid concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole) or inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and~~
    ~~b. Avoid concomitant administration with CYP3A4 substrates with a narrow therapeutic index (e.g., quinidine, cyclosporine); and~~
    ~~c. Monitor digoxin serum concentrations as clinically indicated; and~~
    ~~d. Monitor for adverse effects with concomitant administration with acetylcholinesterase inhibitors, anticholinergic medications, or non-depolarizing neuromuscular blocking agents; and~~
5. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Blujepa and agree to address interactions with concomitant medications according to package labeling; and
6. Prescriber must verify that members with medical conditions that may be exacerbated by acetylcholinesterase inhibition will be monitored for adverse effects; and
7. If administration of Blujepa cannot be avoided in members with a history of QTc interval prolongation, taking antiarrhythmic medications, or taking other medications that may prolong the QTc interval, prescriber must verify that serum electrolyte abnormalities will be corrected and monitored and an ECG should be collected prior to administration and during treatment, as clinically indicated; and
~~8. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and~~
9. A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., ceftriaxone, nitrofurantoin, fosfomycin, sulfamethoxazole/trimethoprim) must be provided; and
~~10. A quantity limit of 20 tablets per 5 days will apply.~~
11. Approval quantity will be based on package labeling and FDA-approved dosing regimens.

The College of Pharmacy also recommends replacing the Oral Antibiotic Special Formulation approval criteria with individual criteria describing the preferred cost-effective therapeutic equivalent products for clarity and recommends the prior authorization of doxycycline hyclate 75mg capsule within the new approval criteria for the doxycycline special formulations (changes shown in red):

~~**Oral Antibiotic Special Formulation Approval Criteria:**~~

~~1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.~~
~~2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:~~
   - ~~Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)~~
   - ~~Cephalexin 250mg and 500mg tablets~~
   - ~~Cephalexin 750mg capsules~~
   - ~~Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)~~
   - ~~Doxycycline hyclate 50mg tablet (Targadox®)~~
   - ~~Doxycycline hyclate delayed-release (DR) tablets (Doryx®, Doryx® MPC)~~
   - ~~Doxycycline monohydrate 75mg capsules~~
   - ~~Doxycycline monohydrate 150mg capsules and tablets~~
   - ~~Doxycycline monohydrate DR 40mg capsules (Oracea®)~~
   - ~~Metronidazole 125mg tablets~~
   - ~~Metronidazole 375mg capsules~~
   - ~~Minocycline ER tablets (Minolira™)~~
   - ~~Minocycline ER tablets (Solodyn®)~~
   - ~~Nitrofurantoin 50mg/5mL suspension~~

Amoxicillin/Clavulanate Potassium Extended Release (ER) Tablets (Augmentin XR®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the generic immediate release (IR) tablet formulations, which are available without prior authorization, must be provided.

Cephalexin 750mg Capsule and Cephalexin 250mg and 500mg Tablets Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the 250mg or 500mg capsule formulations, which are available without prior authorization, must be provided.

Doxycycline Hyclate 75mg and 150mg Tablets (Acticlate®), Doxycycline Hyclate 75mg Capsule, Doxycycline Hyclate 50mg Tablet (Targadox®), Doxycycline Hyclate Delayed Release (DR) Tablets (Doryx®, Doryx® MPC), Doxycycline Monohydrate 75mg Capsule, Doxycycline Monohydrate 150mg Capsules and Tablets, and Doxycycline Monohydrate DR 40mg Capsules (Oracea®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic immediate release (IR) doxycycline hyclate 20mg tablet, 50mg capsule, or 100mg capsule or tablet or doxycycline monohydrate 50mg capsule or tablet, 75mg tablet, or 100mg capsule or tablet, which are available without prior authorization, must be provided; and
2. For doxycycline hyclate 75mg capsule, a patient specific, clinically significant reason why the member cannot use the doxycycline hyclate 75mg tablet formulation must be provided.

Metronidazole 125mg Tablet and 375 mg Capsule Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use a dosing regimen with the 250mg or 500mg generic metronidazole tablets, which are available without prior authorization, must be provided.

Minocycline (50mg, 75mg, and 100mg) Immediate-Release (IR) Tablet, Minocycline ER Tablet (Minolira™), and Minocycline ER Tablet (Solodyn®) Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member ~~requires the IR tablet formulation and~~ cannot use the IR capsule formulation and/or other cost effective therapeutic equivalent medication(s).

Nitrofurantoin 50mg/5mL Suspension Approval Criteria:

1. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral capsule formulations cannot be used; and
2. A patient-specific, clinically significant reason why the member cannot use the generic nitrofurantoin 25mg/5mL suspension, which is available without prior authorization for members 10 years of age or younger, must be provided.

The College of Pharmacy also recommends updating the approval criteria for Avycaz® (ceftazidime/avibactam), Baxdela® (delafloxacin), ciprofloxacin 250mg/mL and 500mg/mL oral suspension and levofloxacin 25mg/mL oral solution, Likmez® (metronidazole 500mg/5mL suspension), and Zerbaxa® (ceftolozane/avibactam) based on clinical practice and for clarity (changes shown in red):

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
    a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
    b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
    c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); ~~and~~ or
    d. Other diagnosis in which treatment with Avycaz® is supported by compendia or clinical literature (documentation must be submitted with the request); and
2. Member must be at least 31 weeks gestational age or older; and
3. For the diagnosis of cIAI, Avycaz® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use a ~~an appropriate~~ penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria ~~[Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]~~:

1. An FDA approved diagnosis of 1 of the following caused by designated susceptible bacteria (culture/sensitivities must be provided):
    a. Acute Bacterial Skin and Skin Structure Infection (ABSSSI) ~~caused by designated susceptible bacteria; and~~ or
    b. Community Acquired Bacteria Pneumonia (CABP); and
2. A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., other fluroquinolone, beta-lactam, doxycycline, linezolid, trimethoprim/sulfamethoxazole, vancomycin) must be provided; and
~~3. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and~~
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-

specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

~~**Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:**~~

~~1. An FDA approved diagnosis of CABP caused by designated susceptible bacteria; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use an appropriate beta lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, monotherapy with a respiratory fluoroquinolone (e.g., levofloxacin, moxifloxacin, gemifloxacin), or other cost-effective therapeutic equivalent alternative(s) must be provided; and~~
~~3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and~~

Ciprofloxacin 250mg/mL and 500mg/mL Oral Suspension and Levofloxacin 25mg/mL Oral Solution Approval Criteria:

~~1. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations cannot be used.~~
2. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations, which are available without prior authorization, cannot be used, including but not limited to:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Treatment course was initiated inpatient; and
3. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request.

Likmez® (Metronidazole 500mg/5mL Suspension) Approval Criteria:

1. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a ~~A~~ patient-specific clinically significant reason (beyond convenience) must be provided regarding why the member cannot use the 250mg and 500mg tablets, which are available without prior authorization, including but not limited to:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Treatment course was initiated inpatient; and

2. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request; and
3. A quantity limit of 200mL per 10 days will apply

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); ~~and~~ or
   d. Other diagnosis in which treatment with Zerbaxa® is supported by compendia or clinical literature (documentation must be submitted with the request); and
2. For the diagnosis of HABP/VABP, member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use a ~~an appropriate~~ penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Lastly, the College of Pharmacy recommends adding age restriction criteria for the nitrofurantoin 25mg/5mL suspension, which is available without prior authorization, for clarity (shown in red):

Nitrofurantoin 25mg/5mL Suspension Approval Criteria:

1. Nitrofurantoin 25mg/5mL 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 nitrofurantoin oral capsules must be provided.

Recommendation 12: Vote to Prior Authorize Zycubo® (Copper Histidinate)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization Zycubo® (copper histidinate) with the following criteria (shown in red):

Zycubo® (Copper Histidinate) Approval Criteria:

1. An FDA approved diagnosis of Menkes disease; and
2. Diagnosis must be confirmed by 1 of the following (results of the selected test must be submitted):
    a. Plasma catecholamine analysis indicating elevated ratios of dihydroxyphenylacetic acid to dihydroxyphenylglycol and dopamine to norepinephrine; or
    b. Genetic testing identifying pathogenic or likely pathogenic variants in the *ATP7A* gene; or
    c. If plasma catecholamine analysis or genetic testing is pending:
        i. Documentation of clinical signs and symptoms consistent with Menkes disease; and
3. Member must be younger than 18 years of age; and
4. Member must not have occipital horn syndrome; and
5. Zycubo® must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease (or an advanced care practitioner with a supervising physician who is a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease); and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Zycubo®; and
7. For member or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper preparation, administration, and storage of Zycubo®; and
8. Initial approval and subsequent approvals will be for the duration of 1 year. Subsequent approvals will be granted if the prescriber documents the member is responding well to therapy; or
    a. If the diagnosis of Menkes disease was based on clinical signs and symptoms, initial approvals will be for 3 months. Subsequent approvals for the duration of 1 year will require submitted documentation of a plasma catecholamine analysis or genetic testing confirming the diagnosis; and
9. A quantity limit of 1 vial (2.9mg) per day will apply; or
    a. For members younger than 1 year of age, a quantity limit override will be granted based on FDA approved dosing.

Recommendation 13: Vote to Prior Authorize Morphine Oral Solution Syringes and Tapentadol Tablet, Extended-Release (ER) Tablet, and Oral Solution and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Opioid Analgesics Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red in the following Tier chart and approval criteria):

1. Prior authorization of tapentadol tablet, tapentadol oral solution, and tapentadol ER tablet with placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of morphine oral solution syringes with placement into the Special PA Tier with the following additional criteria; and
3. Making buprenorphine ER buccal film (Belbuca®) brand preferred; and
4. Moving hydrocodone/ibuprofen (IBU) 5/200mg and 7.5/200mg tablets (Vicoprofen®, Ibudone®, Reprexain™) from Tier-1 to Tier-2.

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®) – **Brand Preferred**	methadone soln (Dolophine®)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tramadol ER tab (Ultram® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER) – **Brand Preferred**	**tapentadol ER tab**
	tramadol ER tab (Ryzolt®)	hydromorphone ER tab (Exalgo®)	tramadol ER cap (ConZip®)
		methadone tab (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
Short-Acting			
APAP/butalbital/ caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab ~~**10/200mg**~~ (Ibudone®, Reprexain™, **Vicoprofen®**)		APAP/butalbital/ caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)		APAP/codeine elixir & soln

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
codeine tab			hydrocodone/ APAP soln
codeine/APAP tab (Tylenol® with Codeine)			hydrocodone/ APAP tab (Xodol®)
hydrocodone/ APAP tab (Norco®)			levorphanol tab
~~**hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)**~~			**morphine oral soln syringes**
hydromorphone tab & soln (Dilaudid®)			oxycodone tab (RoxyBond™)
meperidine tab & soln (Demerol®)			oxycodone/APAP tab (Nalocet®)
morphine IR tab & soln (MSIR®)			oxycodone/APAP tab & soln (Prolate®)
oxycodone/APAP tab & soln (Percocet®)			**tapentadol tab & soln**
oxycodone IR cap (Oxy IR®)			tramadol 25mg, 75mg, & 100mg tab
oxycodone IR tab & soln (Roxicodone®)			tramadol soln (Qdolo™)
tramadol 50mg tab (Ultram®)			***Oncology Only:***
tramadol/APAP (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

*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).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Actiq® is approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
   a. Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use

of these products despite the medication being contraindicated for the member's age; or
   b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.
5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
   a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; or
   b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; and
   c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
6. Levorphanol Tablet Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
7. Methadone Oral Solution Approval Criteria:
   a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or
   b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.
8. Morphine Oral Solution Syringes (5mg/0.25mL Syringe, 10mg/0.5mL Syringe, and 20mg/mL Syringe) Approval Criteria:
   a. For morphine oral solution syringes, a patient-specific, clinically significant reason why the member cannot use morphine oral solution in bulk solution must be provided.
9. Oxycodone (RoxyBond™) Approval Criteria:

a. A patient specific, clinically significant reason why the member cannot use any other available short-acting opioid analgesic must be provided.

10. Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and
    b. For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.
11. Oxymorphone ER Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other available ER opioid analgesic must be provided.
12. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    c. A quantity limit of 2,400mL per 30 days will apply.
13. Tapentadol ER Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered ER opioid analgesic must be provided.
14. Tapentadol Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered short-acting opioid analgesic must be provided.
15. Tapentadol Oral Solution Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use lower-tiered opioid analgesic oral solutions must be provided; and
    b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation must be provided.
16. Tramadol 25mg, 75mg, and 100mg Tablet Approval Criteria:

a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose or split a tramadol 50mg tablet to achieve a 25mg or 75mg dose must be provided; and
b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

The College of Pharmacy also recommends the following changes to the MAT medications based on clinical practice (changes shown in red):

Suboxone® [Buprenorphine/Naloxone Sublingual (SL) Film] and Zubsolv® (Buprenorphine/ Naloxone SL Tablet) Approval Criteria:

1. Generic buprenorphine/naloxone SL tablet and buprenorphine SL tablet are the preferred products. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why the preferred SL tablets are not appropriate; and
2. Member must have an FDA approved diagnosis of opioid abuse/ dependence [i.e., opioid use disorder (OUD)]; and
3. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
4. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
5. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 60 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg: A quantity limit of 60 SL tablets per 30 days will apply.

Sublocade® [Buprenorphine Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder (OUD); and
2. Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
3. Concomitant treatment with opioids (including tramadol) will be denied; and
4. Medication should only be prepared and administered by a health care provider; and
5. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual (SL) tablets or buprenorphine SL tablets) must be provided; and
6. For new starts, a patient-specific, clinically reason why the member cannot use Brixadi® (buprenorphine ER injection), which is available without a prior authorization, must be provided. Members currently stable on Sublocade® may be approved for continuation of therapy; and
7. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
8. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
9. The following quantity limits will apply:
    a. Sublocade® 100mg/0.5mL and 300mg/1.5mL: 1 monthly dose per 28 days
        i. A quantity limit override will be approved for initial dosing for members who need the second injection 1 week after the first injection when requested.

Recommendation 14: Fiscal Year 2026 Annual Review of Cystic Fibrosis (CF) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Alyftrek® (vanzacaftor/ tezacaftor/deutivacaftor) and Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) approval criteria based on the new FDA approved label expansions and to be consistent with clinical practice (changes shown in red):

Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 variant ~~*F508del* mutation~~ in the CF transmembrane conductance regulator (*CFTR*) gene ~~or a mutation in the *CFTR* gene~~ that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein; and

a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of at least 1 variant in the *CFTR* gene that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein ~~a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use~~; and
b. Documentation must be submitted with results of *CFTR* genetic testing; and

2. Member must be 6 years of age or older; and
3. Members using Alyftrek® must be supervised by a pulmonary specialist; and
~~4. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi®, Symdeko®, or Trikafta® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Alyftrek® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Alyftrek®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Alyftrek®; and
8. ~~Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Alyftrek®, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and~~
~~9. Prescriber must verify that the member does not have severe hepatic impairment; and~~
~~10. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
~~11. Member must not be taking strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Alyftrek®; and~~
12. The following quantity limits will apply:
    a. Alyftrek® 4/20/50mg tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
    b. Alyftrek® 10/50/125mg tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)~~; and
15. Subsequent approvals will be for the duration of 1 year.

Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 variant ~~*F508del* mutation~~ in the CF transmembrane conductance regulator (*CFTR*) gene ~~or a mutation in the *CFTR* gene~~ that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of at least 1 variant in the *CFTR* gene that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein ~~a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use~~; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 2 years of age or older; and
3. Members using Trikafta® must be supervised by a pulmonary specialist; and
4. ~~If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Trikafta®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Trikafta®; and
8. ~~Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Trikafta®, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and~~

~~9. Prescriber must verify that the member does not have severe hepatic impairment; and~~
~~10. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
~~11. Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and~~
12. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
    b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
13. For Trikafta® oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta® tablets cannot be used; and
14. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
15. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor)~~; and
16. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the Kalydeco® (ivacaftor), Orkambi® (lumacaftor/ivacaftor), and Symdeko® (tezacaftor/ivacaftor) approval criteria to be consistent with the other CF transmembrane conductance regulator (CFTR) modulators (changes shown in red):

Kalydeco® (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to ivacaftor based on clinical and/or *in vitro* assay data; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing

when recommended by the mutation test's instructions for use; and
   b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 1 month of age or older; and
3. Members using Kalydeco® must be supervised by a pulmonary disease specialist; and
4. Prescriber must verify the member has been counseled on proper administration of Kalydeco® including taking with a fat-containing food; and
5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Kalydeco®; and
6. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Kalydeco®; and
7. ~~Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Kalydeco®, every 3 months during the first year of treatment, and annually thereafter; and~~
8. ~~Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
9. ~~Member must not be taking any of the following medications concomitantly with Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
10. For members 1 month to younger than 6 months of age:
    a. Member must not have any level of hepatic impairment; and
    b. Member must not be taking concomitant moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
11. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; or
    b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
12. An age restriction of 1 month to 5 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and

15. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing; and
   a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
   b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
3. Member must be 12 months of age or older; and
4. Members using Orkambi® must be supervised by a pulmonary specialist; and
5. Prescriber must verify the member has been counseled on proper administration of Orkambi® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Orkambi®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Orkambi®; and
8. ~~The prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and~~
9. ~~Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
10. ~~Members must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
11. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply; or
    b. Oral granules: A quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
12. An age restriction of 12 months to 5 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
15. Subsequent approvals will be for the duration of 1 year.

Symdeko® (Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 6 years of age or older; and
3. Members using Symdeko® must be supervised by a pulmonary specialist; and
4. ~~If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Symdeko®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Symdeko®; and
8. ~~Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and~~
9. ~~Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
10. ~~Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
11. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable.

For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®~~; and
14. Subsequent approvals will be for the duration of 1 year.

Recommendation 15: Fiscal Year 2026 Annual Review of Amyloidosis Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Amvuttra® (vutrisiran) approval criteria based on net costs and for consistency with the approval criteria for the other amyloidosis medications (changes shown in red):

Amvuttra® (Vutrisiran) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. The treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; or
   b. The treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular (CV) mortality, CV hospitalizations, and urgent heart failure visits; and
2. For the diagnosis of hATTR-PN:
   a. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
   b. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; or
3. For the diagnosis of ATTR-CM:
   a. Diagnosis confirmed by:
      i. Genetic confirmation of transthyretin (*TTR*) gene mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
      ii. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
   b. Presence of amyloid deposits confirmed by:
      i. Nuclear scintigraphy; or
      ii. Endomyocardial biopsy; and
   c. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and

   d. Member must have medical history of heart failure (NYHA Class I to III); and
4. Member must be 18 years of age or older; and
5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
8. Prescriber must confirm the member has not undergone a liver transplant; and
9. Amvuttra® will not be approved for concomitant use with Attruby® (acoramidis), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
10. ~~Authorization for Amvuttra® for the diagnosis of hATTR-PN will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and~~
11. A quantity limit of 0.5mL per 90 days will apply; and
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

The College of Pharmacy also recommends updating the Attruby® (acoramidis), Onpattro® (patisiran), and Vyndamax® (tafamidis) approval criteria for consistency with the approval criteria for the other amyloidosis medications (changes shown in red):

Attruby® (Acoramidis) Approval Criteria:

1. An FDA approved indication for the treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) ~~in adults~~ to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
   a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
   b. Cardiac imaging (including ultrasound or MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
   a. Nuclear scintigraphy; or
   b. Endomyocardial biopsy; and
4. Member must be 18 years of age or older; and
5. Member must have medical history of heart failure (NYHA Class I to III); and

6. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
7. Attruby™ must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Attruby™ will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); 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 approval will be for 1 year; and
10. A quantity limit of 112 tablets per 28 days will apply.

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Member must be 18 years of age or older; and
5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
8. Prescriber must confirm the member has not undergone a liver transplant; and
9. Prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
10. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
11. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Vyndamax® (Tafamidis) Approval Criteria:

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) ~~in adults~~ to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
    b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
    a. Nuclear scintigraphy; or
    b. Endomyocardial biopsy; and
4. Member must be 18 years of age or older; and
5. Member must have medical history of heart failure (NYHA Class I to III); and
6. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Vyndamax® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
9. Vyndamax® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Wainua® (eplontersen); and
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
11. A quantity limit of 1 Vyndamax® capsule per day will apply.

Lastly, the College of Pharmacy recommends updating the Wainua® (eplontersen) criteria based on the approval of the single-dose prefilled syringe and for consistency with the approval criteria for the other amyloidosis medications (changes shown in red).

Wainua® (Eplontersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Member must be 18 years of age or older; and
4. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and

5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. For authorization of the single-dose autoinjector, the prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Wainua®; and
8. For authorization of the single-dose prefilled syringe, the prescriber must verify the injection will be administered by a health care professional; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Wainua® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Vyndamax® (tafamidis); and
11. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
12. A quantity limit of 0.8mL per 28 days will apply.

Recommendation 16: Fiscal Year 2026 Annual Review of Bladder Control Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Bladder Control Medications Product Based Prior Authorization (PBPA) category based on net costs (changes shown in red):

1. Moving oxybutynin patch (Oxytrol®) from the Special PA Tier to Tier-1 and removing the unique criteria; and
2. Moving tolterodine ER (Detrol LA®) from Tier-2 to Tier-1; and
3. Moving fesoterodine (Toviaz®) from Tier-1 to Tier-2; and
4. Moving darifenacin (Enablex®) from Tier-3 to Tier-2; and
5. Updating the approval criteria for Gemtesa® (vibegron) based on net costs and clinical practice.

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
~~**fesoterodine (Toviaz®)**~~	tolterodine (Detrol®)	~~**darifenacin (Enablex®)**~~	oxybutynin 2.5mg tablets+
mirabegron (Myrbetriq®) tablets – **Brand Preferred**	~~**tolterodine ER (Detrol LA®)**~~	mirabegron (Myrbetriq®) granulesß	~~**oxybutynin patch (Oxytrol®)+**~~
oxybutynin (Ditropan®) tablets and syrup	**fesoterodine (Toviaz®)**	trospium ER (Sanctura XR®)	vibegron (Gemtesa®)+

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
oxybutynin ER (Ditropan XL®)	**darifenacin (Enablex®)**		
oxybutynin patch (Oxytrol®)			
solifenacin (VESIcare®)			
tolterodine ER (Detrol LA®)			
trospium (Sanctura®)			

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 specific to Gemtesa® (vibegron), and oxybutynin 2.5mg tablets~~, and Oxytrol® (oxybutynin patch)~~ applies.
ᵝThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
ER = extended-release; PA = prior authorization; susp = suspension

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
   a. For members with a contraindication to anticholinergics, documentation of the contraindication and a patient-specific, clinically significant reason why the member cannot use Myrbetriq® (mirabegron) must be provided; and
   b. For members unable to take Myrbetriq® (mirabegron) due to hypertension, the prescriber must attest that the member has severe, uncontrolled hypertension as defined in the Myrbetriq® package labeling (i.e., systolic blood pressure ≥180mmHg and/or diastolic blood pressure ≥110mmHg) and documentation of member's blood pressure readings must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

~~**Oxytrol® (Oxybutynin 3.9mg/Day Patch) Approval Criteria:**~~

~~1. An FDA approved diagnosis of overactive bladder; and~~
~~2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and~~
~~3. A quantity limit of 8 patches per 30 days will apply.~~

Recommendation 17: Fiscal Year 2026 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Beizray™ (Docetaxel), Beizray™ Kit (Docetaxel/Albumin), Docivyx™ (Docetaxel), Inluriyo™ (Imlunestrant), and Veppanu™ (Vepdegestrant)

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

Recommendation 18: Fiscal Year 2026 Annual Review of Various Ophthalmic Medications and the 30-Day Notice to Prior Authorize Epioxa® HD/Epioxa® (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa® (Veligrotug-vvze)

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

Recommendation 19: Fiscal Year 2026 Annual Review of Antihistamine Medications (Systemic) and 30-Day Notice to Prior Authorize Cetirizine Oral Solution Unit-Dose Cups (UDCs)

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

Recommendation 20: Fiscal Year 2026 Annual Review of Benign Prostatic Hyperplasia (BPH) Medications

NO ACTION REQUIRED.

Recommendation 21: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 22: Future Business

NO ACTION REQUIRED.

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING OCTOBER 14, 2026

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP	X	
Jennifer Boyett, 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	
Lezlie Grimes, Pharm.D.; Clinical Pharmacist	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Whitney Bueno, Pharm.D., BCOP		X
Christine Hughes, Pharm.D., MBA, BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.		X
Mark Wendelboe		X
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Josh Anderson, Chief of Staff		X
Mark Brandenburg, M.D., MSC; Medical Director		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Bradford Eckhart, J.D.; Deput General Counsel		X
Elan Gada, M.D.; Chief Medical Officer		X

Magan Graham, J.D.; General Counsel	X	
Sidney Jones, J.D.; General Counsel	X	
Gentry Kincade, J.D.; General Counsel		X
Melissa Miller, State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Eardie Curry, Genentech	David Mendoza, Otsuka
Bryan Steffan, Boehringer	Julie Vandaveer, Johnson & Johnson
Scott Burns, Johnson & Johnson	JJ Roth, Mirum
Ashlee Waring, Organon	Julie Rhodes, AbbVie
Miranda Ryzenman, Artia Solutions	Kevin Chang, Sanofi
Jama Larose, Dyne Therapeutics	Irene Chung, Aetna
Sergio Mayorga, Concis Labs	Jai Persico, Neurocrine Biosciences
Mike Sullivan, Amgen	Shirley Garza-Gongora, AbbVie
Molly Carson, Creative Capitol Strategies	Payal Tejani, Biogen
Justin Powell, Humana	Shelley Bagwell, Oklahoma Complete Health
Alyse Meyer UCB	Taylor Laffey, LEO Pharma
Mike Thiem, Incyte	Stephen Kim, Incyte
Lee Stout, Chiesi	Susan Oppelt, Tonix Medicines
Alyssa Davenport, Sick Cells	David Large, Galderma
Jim Semans, SK Life Science	Brent Fushimi, UCB
M Shefchyk, Novo Nordisk	John Suelzer, LEO Pharma
Dan Calloway, Bristol Myers Squibb	Todd Dickerson, Jazz Pharma
Gary Parenteau, Dexcom	Allyson Fonte, Agios Pharmaceuticals

PRESENT FOR PUBLIC COMMENT:	
Julie Vandaveer, Johnson & Johnson	

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

1A: ROLL CALL

Dr. Haymore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox did not establish the presence of a quorum.

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO.12 JULIE VANDAVEER

ACTION: NONE REQUIRED

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

3A: SEPTEMPER 9, 2026 DUR MINUTES

Materials included in agenda packet; presented by Dr. Haymore

ACTION: NO ACTION DUE TO LACK OF QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT**

4A: PHARMACY HELPDESK ACTIVITY FOR SEPTEMTER 2026

4B: MEDICATION COVERAGE ACTIVITY FOR SEPTEMBER 2026
4C: CORRESPONDENCE
Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: FALL PIPELINE UPDATE
5A: INTRODUCTION
5B: PRODUCT SUMMARIE
5C: PIPELINE TABLE
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE CETIRIZINE ORAL SOLUTION UNIT DOSE CUPS (UDCS) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIHISTAMINE MEDICATIONS (SYSTEMIC)
6A: COST COMPARISON: CETIRIZINE PRODUCTS
6B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NO ACTION DUE TO LACK OF QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE EPIOXA HD/EPIOXA (RIBOFLAVIN 5'-PHOSPHATE OPHTHALMIC SOLUTION) AND LUMVOA (VELIGROTUG-VVZE) AND UPDATE THE APPROVAL CRITERIA FOR THE VARIOUS OPHTHALMIC MEDICATIONS
7A: MARKET NEWS AND UPDATES
7B: LUMVOA (VELIGROTUG-VVZE) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NO ACTION DUE TO LACK OF QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE BEIZRAY (DOCETAXEL), BEIZRAY KIT (DOCETAXEL/ALBUMIN), DOCIVYX (DOCETAXEL), INLURIYO (IMLUNESTRANT), AND VEPPANU (VEPDEGESTRANT) AND UPDATE THE APPROVAL CRITERIA FOR THE BREAST CANCER MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: PRODUT SUMMARIES
8C: COST COMPARISON
8D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NO ACTION DUE TO LACK OF QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 9: ANNUAL REVIEW OF CONSTIPATION AND DIARRHEA MEDICATIONS
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
9C: PRIOR AUTHORIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: COLLEGE OF PHARMACY RECOMMENDATIONS
9F: UTILIZATION DETAILS OF CONSTIPATION AND DIARRHEA MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer

ACTION: NO ACTION DUE TO LACK OF QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER

<u>AGENDA ITEM NO. 10:</u> ANNUAL REVIEW OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS

10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
10C: PRIOR AUTHORIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS

Materials included in agenda packet; presented by Dr. Grimes

ACTION: NO ACTION DUE TO LACK OF QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF MYELOPROLIFERATIVE NEOPLASM (MPN) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DECNUPAZ (PIVEKIMAB SUNIRINE-PVZY), JAKAFI XR [RUXOLITINIB EXTENDED-RELEASE (ER)], AND MIMRYLO (RUSFERTIDE)

11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF MPN MEDICATIONS
11C: PRIOR AUTHORIZATION OF MPN MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF MPN MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko

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

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF TARGETED IMMUNOMODULATOR AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ICOTYDE (ICOTROKINRA), IMMGOLIS (GOLIMUMAB-SLDI), IMMGOLIS INTRI (GOLIMUMAB-SLDI), LISRAYA (BREPOCITINIB), AND ZIMRIXBY (RITUXIMAB-CDXX)

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF TARGETED IMMUNOMODULATOR AGENTS
12C: PRIOR AUTHORIZATION OF TARGETED IMMUNOMODULATOR AGENTS
12D: MARKET NEWS AND UPDATES
12E: PRODUCT SUMMARIES
12F: COST COMPARISON: RITUXIMAB PRODUCTS
12G: COLLEGE OF PHARMACY RECOMMENDATIONS
12H: UTILIZATION DETAILS OF TARGETED IMMUNOMODULATORY AGENTS

Materials included in agenda packet; presented by Dr. Wilson

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

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF FIBROMYALGIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE TONMYA [CYCLOBENZAPRINE SUBLINGUAL (SL) TABLET]

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF FIBROMYALGIA MEDICATIONS
13C: PRIOR AUTHORIZATION OF FIBROMYALGIA MEDICATIONS

13D: MARKET NEWS AND UPDATES
13E: TONMYA (CYCLOBENZAPRINE SL TABLET) PRODUCT SUMMARY
13F: COST COMPARISON
13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF FIBROMYALGIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ANEMIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AQVESME (MITAPIVAT)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ANEMIA MEDICATIONS
14C: PRIOR AUTHORIZATION OF ANEMIA MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: AQVESME (MITAPIVAT) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF ANEMIA MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 15: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. Grimes
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
16A: ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
16B: ATOPIC DERMATITIS MEDICATIONS
16C: BONE DENSITY REGULATORS
16D: BRINSUPRI (BRENSOCATIB)
16E: GONADOTROPIN-RELEASEING HORMONE (GNRH) MEDICATIONS (NON-ONCOLOGY)
16F: MULTIPLE MYELOMA MEDICATIONS
16G: OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
16H: RHAPSIDO (REMIBRUTINIB)
*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: ADJOURNMENT
The meeting was adjourned at 5:06pm.

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

Memorandum

Date: October 16, 2026

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

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

Subject: DUR Board Recommendations from Meeting on October 14, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Fall Pipeline Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Cetirizine Oral Solution Unit Dose Cups (UDCs) and Update the Approval Criteria for the Antihistamine Medications (Systemic)

NO ACTION TAKEN DUE TO LACK OF A QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER 2026.

Recommendation 4: Vote to Prior Authorize Epioxa HD/Epioxa (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa (Veligrotug-vvze) and Update the Approval Criteria for the Various Ophthalmic Medications

NO ACTION TAKEN DUE TO LACK OF A QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER 2026.

Recommendation 5: Vote to Prior Authorize Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), Docivyx (Docetaxel), Inluriyo (Imlunestrant), and Veppanu (Vepdegestrant) and Update the Approval Criteria for the Breast Cancer Medications

NO ACTION TAKEN DUE TO LACK OF A QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER 2026.

Recommendation 6: Fiscal Year 2026 Annual Review of Constipation and Diarrhea Medications

NO ACTION TAKEN DUE TO LACK OF A QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER 2026.

Recommendation 7: Fiscal Year 2026 Annual Review of Anticoagulants and Platelet Aggregation Inhibitors

NO ACTION TAKEN DUE TO LACK OF A QUORUM; WILL BE AN ACTION ITEM IN NOVEMBER 2026.

Recommendation 8: Fiscal Year 2026 Annual Review of Myeloproliferative Neoplasm (MPN) Medications and 30-Day Notice to Prior Authorize Decnupaz (Pivekimab Sunirine-pvzy), Jakafi XR [Ruxolitinib Extended-Release (ER)], and Mimrylo (Rusfertide)

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

Recommendation 9: Fiscal Year 2026 Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Icotyde (Icotrokinra), Immgolis (Golimumab-sldi), Immgolis Intri (Golimumab-sldi), Lisraya (Brepocitinib), and Zimrixby (Rituximab-cdxx)

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

Recommendation 10: Fiscal Year 2026 Annual Review of Fibromyalgia Medications and 30-Day Notice to Prior Authorize Tonmya [Cyclobenzaprine Sublingual (SL) Tablet]

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

Recommendation 11: Fiscal Year 2026 Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Aqvesme (Mitapivat)

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

Recommendation 12: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 13: Future Business

NO ACTION REQUIRED.



Appendix B

Calendar Year 2027 Drug Utilization Review (DUR) Board Meeting Dates

Oklahoma Health Care Authority
November 2026

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

January 13, 2027

February 10, 2027

March 10, 2027

April 14, 2027

May 12, 2027

June 9, 2027

July 14, 2027

August 11, 2027

September 8, 2027

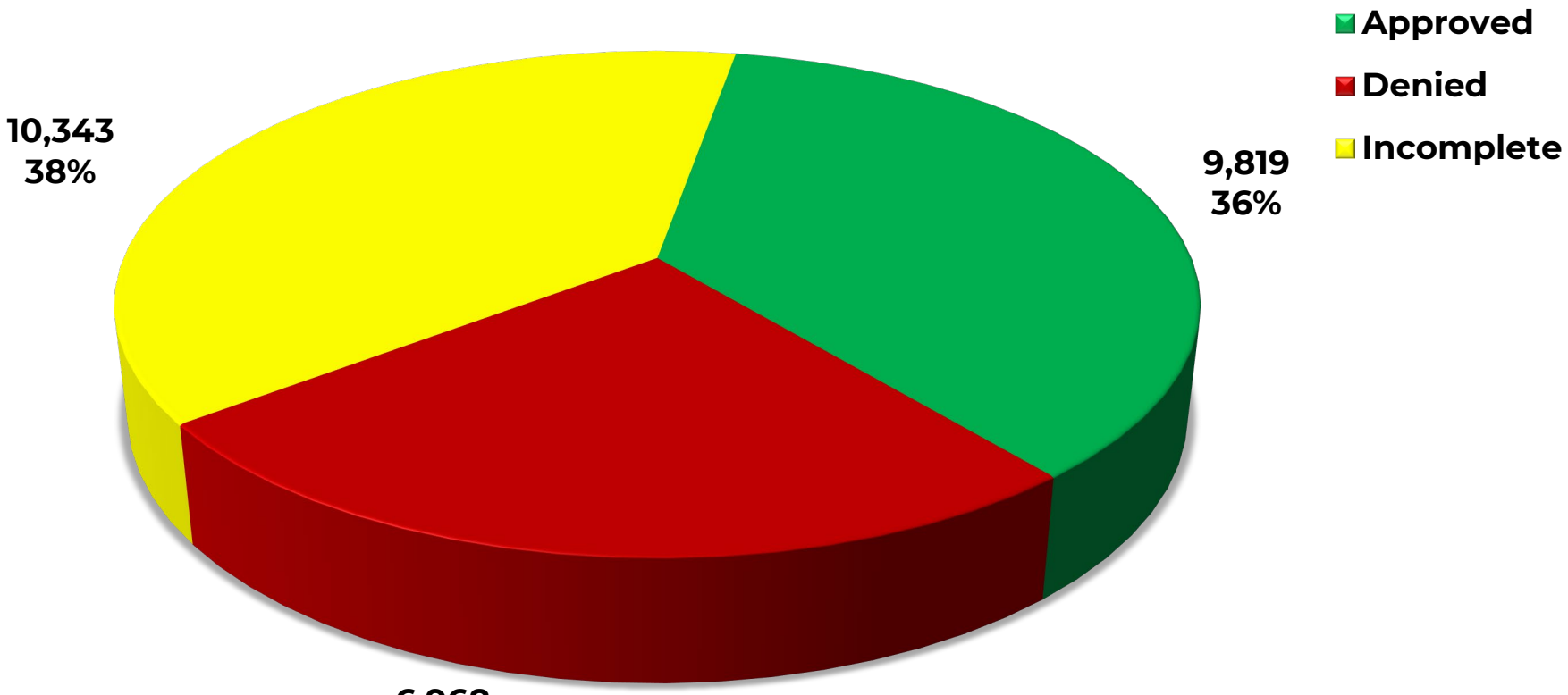
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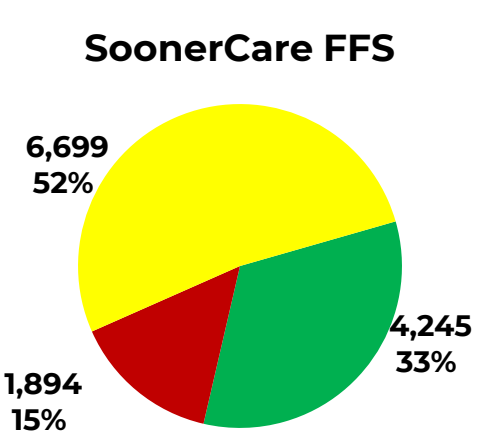
November 10, 2027

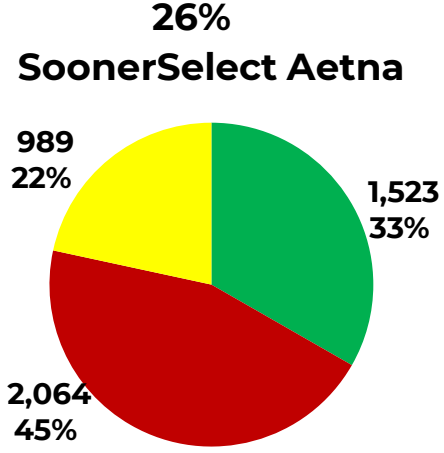
December 8, 2027

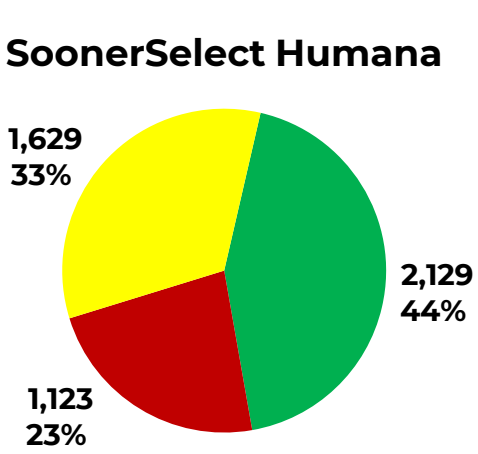
Appendix C

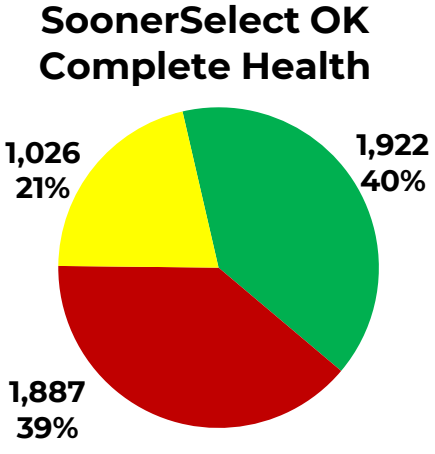
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: OCTOBER 2026





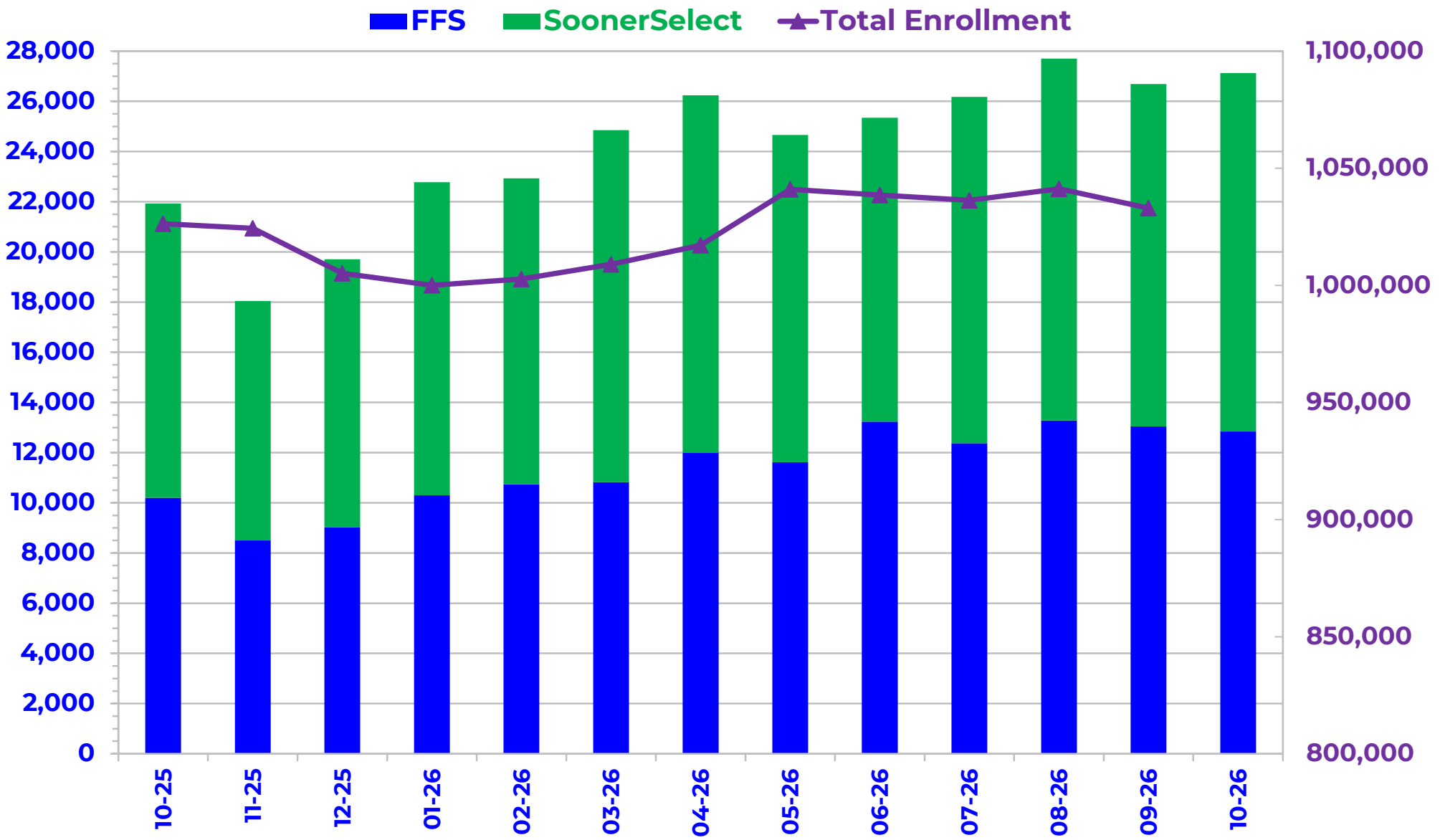






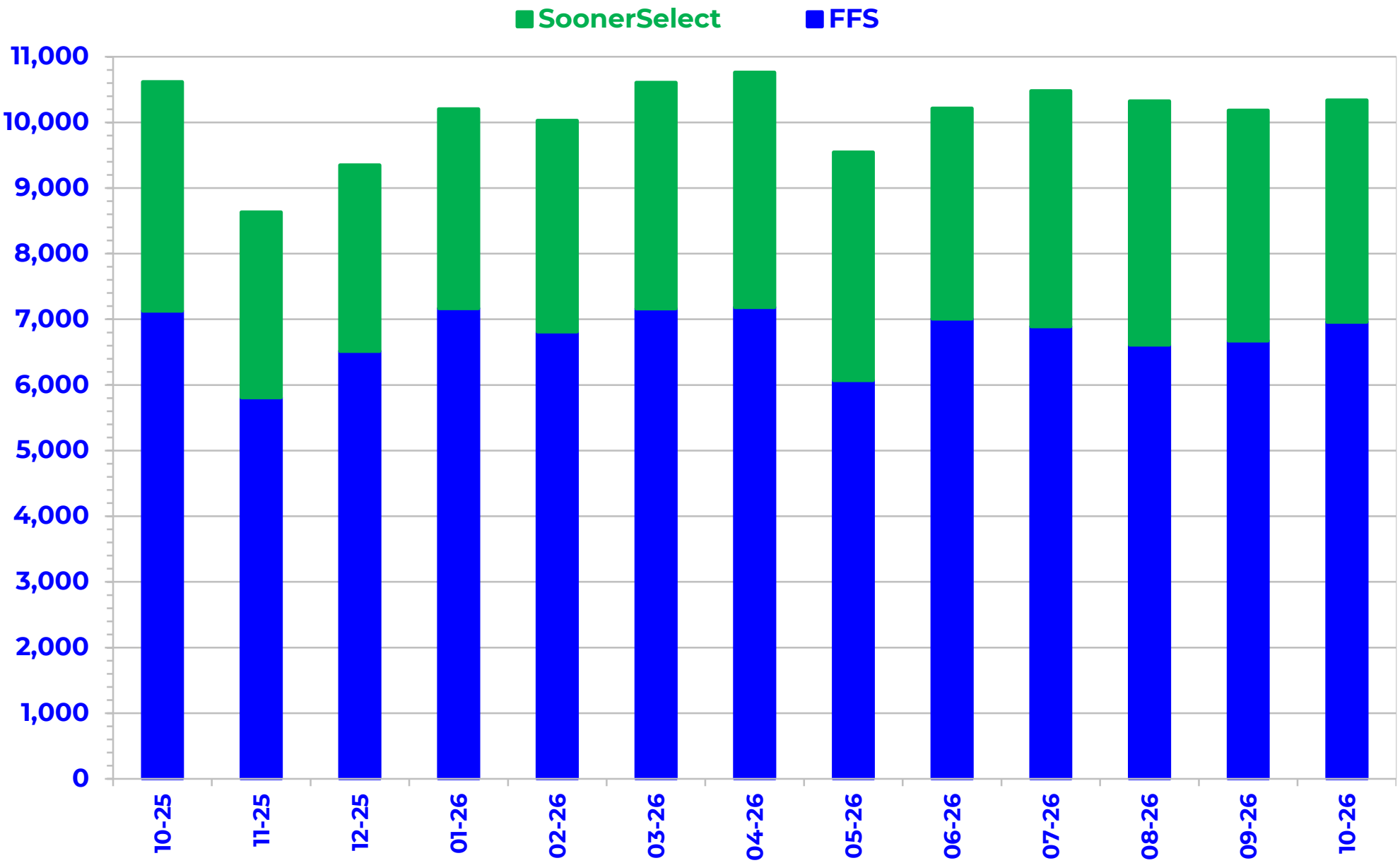
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: OCTOBER 2025 – OCTOBER 2026



SoonerCare FFS Prior Authorization Activity

10/1/2026 Through 10/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	0	0	4	0
Amebicides	2	1	0	1	26
Amphetamines	1,070	580	77	413	361
Analgesics - Anti-inflammatory	248	80	34	134	316
Analgesics - Nonnarcotic	22	0	2	20	0
Analgesics - Opioid	277	114	16	147	176
Androgens - Anabolic	95	6	27	62	284
Anorectal and Related Products	10	0	1	9	0
Anorexiants Non-Amphetamine	1	0	1	0	0
Anthelmintics	16	3	0	13	15
Anti-Infective Agents - Misc.	43	10	9	24	157
Anti-Obesity Agents	618	135	230	253	131
Antianxiety Agents	50	2	4	44	356
Antiarrhythmics	5	0	0	5	0
Antiasthmatic and Bronchodilator Agents	952	150	118	684	477
Antibiotics	53	19	3	31	200
Anticoagulants	20	2	1	17	360
Anticonvulsants	351	135	24	192	363
Antidepressants	453	102	80	271	464
Antidiabetics	1,789	518	272	999	366
Antidotes and Specific Antagonists	3	1	0	2	14
Antiemetics	42	5	3	34	197
Antifungals	9	3	0	6	133
Antihistamines	23	2	4	17	360
Antihyperlipidemics	130	29	18	83	317
Antihypertensives	49	14	7	28	777
Antimalarials	7	0	1	6	0
Antineoplastics and Adjunctive Therapies	235	132	20	83	180
Antiparkinson and Related Therapy Agents	12	1	3	8	360
Antipsychotics/Antimanic Agents	502	161	52	289	410
Antivirals	19	5	2	12	164
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	330	196	29	105	967
Beta Blockers	22	5	3	14	797
Calcium Channel Blockers	9	1	2	6	361
Cardiovascular Agents - Misc.	130	61	13	56	354
Contraceptives	62	22	9	31	338
Corticosteroids	13	5	0	8	236
Cough/Cold/Allergy	2	1	0	1	26
Dermatologicals	648	174	145	329	249
Diagnostic Products	39	20	0	19	178
Digestive Aids	5	4	0	1	359
Diuretics	21	8	0	13	550
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	13	2	5	6	360
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	252	88	31	133	257
Estrogens	32	1	5	26	360

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents - Misc.	473	99	110	264	282
Genitourinary Agents - Misc.	9	2	2	5	268
Gout Agents	6	1	0	5	360
Hematological Agents - Misc.	20	9	1	10	329
Hematopoietic Agents	73	16	18	39	149
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	61	4	15	42	230
Laxatives	22	8	3	11	223
Medical Devices and Supplies	473	91	99	283	303
Migraine Products	524	152	106	266	236
Minerals and Electrolytes	6	2	2	2	25
Miscellaneous Therapeutic Classes	118	38	12	68	319
Mouth/Throat/Dental Agents	1	0	0	1	0
Multivitamins	3	1	0	2	362
Musculoskeletal Therapy Agents	84	3	24	57	360
Nasal Agents - Systemic and Topical	29	3	6	20	270
Neuromuscular Agents	112	47	23	42	351
Ophthalmic Agents	129	25	14	90	167
Other*	74	34	5	35	160
Otic Agents	52	13	6	33	41
Passive Immunizing and Treatment Agents	12	6	0	6	298
Pharmaceutical Adjuvants	1	0	1	0	0
Progestins	5	2	2	1	195
Psychotherapeutic and Neurological Agents - Misc.	353	96	59	198	278
Respiratory Agents - Misc.	58	28	3	27	320
Stimulants - Misc.	259	121	26	112	344
Thyroid Agents	19	6	2	11	1,091
Ulcer Drugs/Antispasmodics/Anticholinergics	126	20	15	91	589
Urinary Antispasmodics	71	17	8	46	752
Vaccines	4	1	0	3	177
Vaginal and Related Products	21	1	7	13	130
Vasopressors	1	1	0	0	360
Vitamins	56	1	36	19	359
Total	**11,944**	**3,646**	**1,856**	**6,442**	

Overrides					
Brand	10	5	0	5	203
Compound	29	25	2	2	69
Dosage Change	197	159	0	38	16
High Dose	1	0	0	1	0
Lost/Broken Rx	55	37	1	17	27
MAT Override	5	3	0	2	36
NDC vs Age	107	72	9	26	491
Nursing Home Issue	27	25	0	2	26
Opioid MME Limit	40	5	5	30	142
Opioid Quantity	12	7	1	4	177
Other	46	34	0	12	29
Quantity vs Days Supply	259	165	12	82	357
STBS/STBSM	27	17	5	5	62

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Step Therapy Exception	9	5	2	2	439
Stolen	4	3	0	1	11
Third Brand Request	66	37	1	28	12
Overrides Total	**894**	**599**	**38**	**257**	
Total Regular PAs + Overrides	**12,838**	**4,245**	**1,894**	**6,699**	

Denial Reasons	
Unable to verify required trials.	6,489
Does not meet established criteria.	1,931
Lack required information to process request.	421
Other PA Activity	
Duplicate Requests	1,774
Letters	65,376
No Process	3
Helpdesk Initiated Prior Authorizations	339
PAs Missing Information	261
Pharmacotherapy	69
Changes to Existing PAs	788

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

SoonerSelect Aetna Prior Authorization Activity

10/1/2026 Through 10/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	424	281	120	23	364
Analgesics - Anti-Inflammatory	127	59	41	27	353
Analgesics - Nonnarcotic	20	3	15	2	168
Analgesics - Opioid	119	49	33	37	156
Androgens - Anabolic	56	1	54	1	365
Anorectal and Related Products	8	1	6	1	30
Anthelmintics	7	2	4	1	22
Antianxiety Agents	37	5	5	27	365
Antiasthmatic and Bronchodilator Agents	227	34	93	100	316
Antibiotics	22	3	2	17	191
Anticoagulants	16	2	3	11	182
Anticonvulsants	80	25	28	27	348
Antidepressants	260	65	106	89	521
Antidiabetics	606	188	318	100	286
Antidiarrheal/Probiotic Agents	1	1	0	0	14
Antiemetics	41	23	3	15	194
Antifungals	1	0	0	1	0
Antihistamines	32	8	23	1	234
Antihyperlipidemics	42	12	20	10	270
Antihypertensives	45	4	6	35	304
Anti-Infective Agents - Misc.	10	3	4	3	30
Antimalarials	1	1	0	0	56
Antineoplastics and Adjunctive Therapies	57	25	5	27	209
Anti-Obesity Agents	324	65	242	17	146
Antiparkinson and Related Therapy Agents	2	0	1	1	0
Antipsychotics/Antimanic Agents	188	52	92	44	355
Antivirals	9	2	4	3	107
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	93	61	24	8	574
Beta Blockers	23	0	1	22	0
Calcium Channel Blockers	12	0	1	11	0
Cardiovascular Agents - Misc.	45	18	22	5	347
Contraceptives	25	2	21	2	365
Corticosteroids	13	6	5	2	289
Dermatologicals	368	134	183	51	211
Diagnostic Products	37	17	14	6	694
Dietary Products/Dietary Management Products	1	1	0	0	359
Digestive Aids	1	1	0	0	365
Diuretics	28	1	0	27	365
Endocrine and Metabolic Agents - Misc.	46	21	20	5	284
Estrogens	23	2	6	15	274
Gastrointestinal Agents - Misc.	110	43	53	14	199
Genitourinary Agents - Misc.	3	3	0	0	320
Gout Agents	8	1	4	3	365
Hematological Agents - Misc.	11	7	1	3	310
Hematopoietic Agents	14	10	1	3	297

*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
Hypnotics/Sedatives/Sleep Disorder Agents	35	5	23	7	201
Laxatives	18	1	7	10	365
Local Anesthetics-Parenteral	1	1	0	0	365
Medical Devices and Supplies	85	25	50	10	706
Migraine Products	243	72	155	16	241
Minerals and Electrolytes	23	12	0	11	365
Miscellaneous Therapeutic Classes	14	10	2	2	335
Multivitamins	2	1	1	0	365
Musculoskeletal Therapy Agents	57	0	28	29	0
Nasal Agents - Systemic and Topical	23	1	12	10	365
Neuromuscular Agents	14	9	1	4	365
Nutrients	3	1	2	0	47
Ophthalmic Agents	37	11	18	8	207
Other	22	4	5	13	365
Otic Agents	26	3	20	3	21
Passive Immunizing and Treatment Agents	2	1	1	0	365
Pharmaceutical Adjuvants	1	1	0	0	182
Progestins	2	0	2	0	0
Psychotherapeutic and Neurological Agents - Misc.	47	22	24	1	212
Respiratory Agents - Misc.	2	1	1	0	365
Stimulants - Misc.	126	84	37	5	334
Thyroid Agents	6	0	3	3	0
Ulcer Drugs/Antispasmodics/Anticholinergics	79	8	24	47	264
Urinary Antispasmodics	14	0	9	5	0
Vaccines	2	1	1	0	182
Vaginal and Related Products	7	0	3	4	0
Vasopressors	3	0	0	3	0
Vitamins	58	7	50	1	291
****Total**	**4,576**	**1,523**	**2,064**	**989**	

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

Overrides					
Brand	3	3	0	0	274
Other	989	0	0	989	0
Quantity Level Limit	31	31	0	0	290
Overrides Total	**1,023**	**34**	**0**	**989**	

Denial Reason	
Benefit	127
Experimental/Investigational	159
Lack Required Infomation to Process Request	148
Medical Necessity	1,630
Other PA Activity	
Duplicate Requests	36
Letters	5,708
No Process	348
Changes to existing PAs	0
PAs missing info	19

*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

10/1/2026 Through 10/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	11	4	1	6	320
Analgesics - Anti-Inflammatory	88	64	7	17	326
Analgesics - Nonnarcotic	3	2	0	1	365
Analgesics - Opioid	52	26	21	5	285
Androgens - Anabolic	86	12	57	17	105
Anorectal and Related Products	2	1	1	0	183
Anthelmintics	8	2	3	3	186
Antianxiety Agents	1	1	0	0	365
Antiasthmatic and Bronchodilator Agents	149	73	58	18	276
Antibiotics	7	0	1	6	0
Anticonvulsants	22	14	3	5	365
Antidepressants	96	49	21	26	411
Antidiabetics	408	149	172	87	214
Antiemetics	13	0	1	12	0
Antifungals	1	1	0	0	365
Antihistamines	2	0	0	2	0
Antihyperlipidemics	31	16	9	6	220
Antihypertensives	3	2	0	1	274
Anti-Infective Agents - Misc.	2	1	0	1	365
Antineoplastics and Adjunctive Therapies	96	66	3	27	205
Anti-Obesity Agents	324	98	97	129	69
Antiparkinson and Related Therapy Agents	2	2	0	0	731
Antipsychotics/Antimanic Agents	18	8	6	4	217
Antivirals	3	1	0	2	56
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	13	8	3	2	694
Beta Blockers	3	1	0	2	183
Calcium Channel Blockers	5	2	0	3	244
Cardiovascular Agents - Misc.	74	49	3	22	347
Chemicals	1	0	0	1	0
Contraceptives	26	5	14	7	130
Corticosteroids	8	2	1	5	274
Dermatologicals	244	158	49	37	245
Diagnostic Products	19	14	3	2	355
Diuretics	3	3	0	0	761
Endocrine and Metabolic Agents - Misc.	67	35	8	24	260
Estrogens	5	3	1	1	274
Gastrointestinal Agents - Misc.	111	56	36	19	271
Genitourinary Agents - Misc.	4	1	0	3	183
Gout Agents	8	4	0	4	304
Hematological Agents - Misc.	5	4	0	1	320
Hematopoietic Agents	29	13	3	13	236
Histamine H3-Receptor Antagonist/Inverse Agonists	7	5	0	2	304
Hypnotics/Sedatives/Sleep Disorder Agents	7	0	7	0	0

*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	4	0	2	2	0
Medical Devices and Supplies	8	7	1	0	1,095
Migraine Products	168	113	42	13	179
Minerals and Electrolytes	1	0	0	1	0
Miscellaneous Therapeutic Classes	13	11	0	2	254
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	29	9	11	9	304
Nasal Agents - Systemic and Topical	3	0	3	0	0
Neuromuscular Agents	50	34	1	15	497
Ophthalmic Agents	21	8	7	6	255
Other	13	4	3	6	110
Passive Immunizing and Treatment Agents	3	0	0	3	0
Pharmaceutical Adjuvants	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	44	31	4	9	239
Respiratory Agents - Misc.	11	9	0	2	388
Stimulants - Misc.	30	16	3	11	295
Thyroid Agents	10	8	0	2	339
Ulcer Drugs/Antispasmodics/Anticholinergics	21	6	13	2	239
Urinary Antispasmodics	16	3	11	2	133
Vaginal and Related Products	5	0	0	5	0
Vitamins	71	6	0	65	154
Total	**2,591**	**1,223**	**690**	**678**	
Overrides					
Dosage Change	136	49	73	14	143
Ingredient Duplication	174	102	42	30	171
NDC vs Age	574	377	33	164	356
NDC vs Sex	1	0	0	1	0
Opioid MME Limit	4	3	0	1	365
Opioid Quantity	7	6	1	0	454
Other	366	59	95	212	91
Quantity vs Days Supply	223	159	34	30	278
STBS/STBSM	595	51	84	460	31
Step Therapy Exception	209	100	71	38	182
Third Brand Request	1	0	0	1	0
Overrides Total	**2,290**	**906**	**433**	**951**	
Total Regular PAs + Overrides	**4,881**	**2,129**	**1,123**	**1,629**	
Denial Reasons					
Alternatives Not Met					333
Medical Necessity					790

*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

10/1/2026 Through 10/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	381	193	136	52	1,094
Analgesics - Anti-Inflammatory	125	59	37	29	894
Analgesics - Nonnarcotic	18	0	14	4	0
Analgesics - Opioid	296	112	118	66	266
Androgens - Anabolic	47	1	36	10	1,095
Anorectal and Related Products	8	0	6	2	0
Anorexiants Non-Amphetamine	4	0	0	4	0
Anthelmintics	6	2	3	1	730
Antianxiety Agents	21	7	14	0	550
Antiasthmatic and Bronchodilator Agents	435	214	135	86	536
Antibiotics	34	12	15	7	476
Anticoagulants	7	5	2	0	279
Anticonvulsants	67	19	28	20	986
Antidepressants	218	58	116	44	994
Antidiabetics	676	315	236	125	905
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antiemetics	28	7	10	11	247
Antifungals	13	1	11	1	365
Antihistamines	16	6	5	5	1,095
Antihyperlipidemics	27	7	17	3	1,095
Antihypertensives	17	3	10	4	451
Anti-Infective Agents - Misc.	5	1	3	1	365
Antineoplastics and Adjunctive Therapies	92	50	20	22	524
Anti-Obesity Agents	306	88	92	126	364
Antipsychotics/Antimanic Agents	164	73	59	32	981
Antivirals	3	1	2	0	71
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	116	64	36	16	1,051
Beta Blockers	9	7	1	1	583
Calcium Channel Blockers	11	6	4	1	754
Cardiovascular Agents - Misc.	32	10	13	9	968
Contraceptives	42	7	30	5	275
Corticosteroids	11	2	1	8	81
Cough/Cold/Allergy	4	3	1	0	156
Dermatologicals	299	93	131	75	563
Diagnostic Products	31	13	15	3	762
Dietary Products/Dietary Management Products	1	0	0	1	0
Diuretics	6	3	2	1	1,095
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	61	15	29	17	918
Estrogens	16	5	10	1	79
Gastrointestinal Agents - Misc.	125	40	63	22	792
Genitourinary Agents - Misc.	2	1	0	1	91
Gout Agents	6	1	4	1	1,095

*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
Hematological Agents - Misc.	16	9	4	3	574
Hematopoietic Agents	33	12	16	5	263
Hypnotics/Sedatives/Sleep Disorder Agents	29	4	20	5	273
Laxatives	18	10	2	6	369
Medical Devices and Supplies	162	95	42	25	964
Migraine Products	220	100	100	20	610
Minerals and Electrolytes	2	0	0	2	0
Miscellaneous Therapeutic Classes	25	19	2	4	786
Multivitamins	4	2	2	0	74
Musculoskeletal Therapy Agents	49	11	32	6	515
Nasal Agents - Systemic and Topical	14	4	9	1	754
Neuromuscular Agents	45	22	9	14	347
Ophthalmic Agents	56	16	28	12	172
Other	47	3	10	34	195
Otic Agents	35	8	18	9	177
Passive Immunizing and Treatment Agents	2	0	1	1	0
Pharmaceutical Adjuvants	2	2	0	0	365
Progestins	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	46	8	23	15	973
Respiratory Agents - Misc.	6	0	4	2	0
Stimulants - Misc.	118	57	45	16	873
Thyroid Agents	11	8	0	3	332
Ulcer Drugs/Antispasmodics/Anticholinergics	60	14	32	14	365
Urinary Antispasmodics	36	12	15	9	162
Vaccines	2	0	2	0	0
Vaginal and Related Products	3	0	2	1	0
Vasopressors	1	1	0	0	86
Vitamins	3	1	2	0	365
****Total**	**4,835**	**1,922**	**1,887**	**1,026**	

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

Denial Reasons	
Medical Necessity	1,887
Benefit	0

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

Appendix D

Journavx (Suzetrigine) Utilization Update

Oklahoma Health Care Authority
November 2026

Introduction[1,2,3,4]

In January 2025, Journavx (suzetrigine) was approved by the U.S. Food and Drug Administration (FDA) to treat moderate to severe acute pain in adults. An estimated 80 million adults in the United States have moderate to severe acute pain each year requiring a prescription medication. Given the serious risks, side effects, and dependency potential with opioids, finding an effective non-opioid pain medication has been a critical area of development that is supported by the FDA. Additionally, the *2022 Center for Disease Control and Prevention (CDC) Clinical Practice Guidelines for Prescribing Opioids for Pain* recommend using non-opioid therapies, when possible, for acute pain. Journavx is a non-opioid analgesic with a new mechanism of action that works by blocking the $Na_V1.8$ voltage-gated sodium channel, which is expressed in the peripheral sensory neurons, where its role is to transmit pain signals to the spinal cord and brain. To increase access to treatment with Journavx for acute pain, on 07/01/2025, the prior authorization (PA) for Journavx was removed for SoonerCare members based on a supplemental rebate agreement with Vertex Pharmaceuticals.

Journavx is indicated to treat acute pain, which is defined as a pain condition that is short-term and occurs from a specific injury, trauma, or surgical procedure that is time-limited, meaning it lasts <3 months. Pain for ≥3 months is typically defined as chronic pain. However, the package labeling states Journavx should be used for the shortest duration, consistent with individual pain treatment goals, and **"use of Journavx for the treatment of acute pain has not been studied beyond 14 days."** Alternative treatment options for Journavx include non-opioid analgesics [acetaminophen (APAP) and nonsteroid anti-inflammatory agents (NSAIDs)] for moderate pain and opioids for severe pain. In clinical trials, Journavx demonstrated greater efficacy than placebo but was not superior to hydrocodone/APAP. Currently, non-opioid analgesics (i.e., APAP and NSAIDs) are used in conjunction with opioids for severe pain to help minimize the dose and side effects seen with opioids. **However, Journavx has not been studied for combination use with opioids; therefore, safety and efficacy for combination therapy are unknown.** Ideally, Journavx would be used short-term (not beyond 14 days) as an alternative to opioids for the treatment of moderate to severe acute pain. The following retrospective drug utilization review (DUR) was

conducted to assess the overall utilization of Journavx within the SoonerCare population.

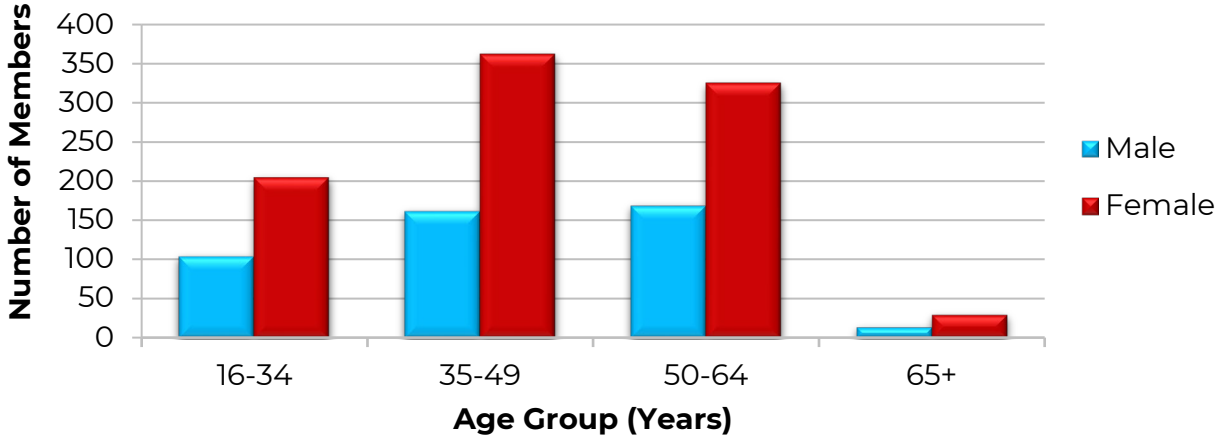
Utilization of Journavx: Fiscal Year 2026

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

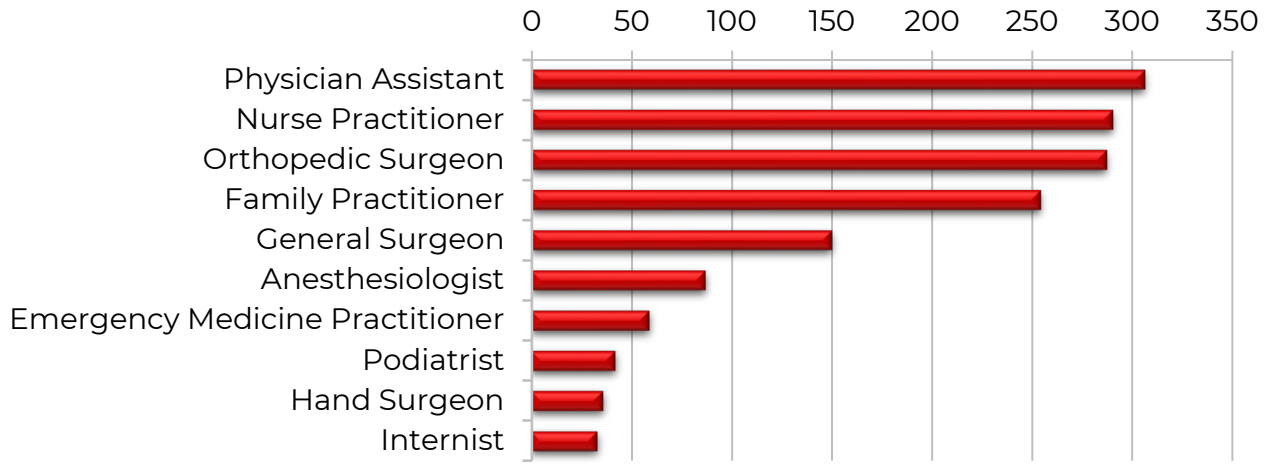
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	3	3	$1,418.23	$472.74	$24.04	90	59
Aetna	3	3	$1,417.82	$472.61	$24.03	90	59
Humana	5	6	$2,284.96	$380.83	$32.64	143	70
OCH	8	10	$5,413.18	$541.32	$35.61	345	152
2025 Total	**19**	**22**	**$10,534.19**	**$478.83**	**$30.98**	**668**	**340**
Fiscal Year 2026							
FFS	560	734	$293,490.51	$399.85	$28.61	19,357	10,260
Aetna	283	332	$135,709.43	$408.76	$29.63	8,886	4,580
Humana	339	396	$162,776.17	$411.05	$30.37	10,660	5,359
OCH	207	216	$89,968.46	$416.52	$29.65	5,895	3,034
2026 Total	**1,369**	**1,678**	**$681,944.57**	**$406.40**	**$29.35**	**44,798**	**23,233**
% Change	**7,105.30%**	**7,527.30%%**	**6,373.60%**	**-15.10%**	**-5.30%**	**6,606.30%**	**6,733.20%**
Change	**1,350**	**1,656**	**$671,410.38**	**-$72.43**	**-$1.63**	**44,130**	**22,893**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Please note: Coverage for Journavx began on 02/04/2025; therefore, the data from fiscal year 2025 does not capture a full year.

Demographics of Members Utilizing Journavx: Pharmacy Claims (All Plans)



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



Utilization Trends of Journavx in the SoonerCare Population

During fiscal year (FY) 2026, there were 1,678 paid claims for Journavx for 1,369 unique members, which accounted for a total cost of $681,944.57 and an average cost per claim of $406.40. A claims analysis was performed to assess utilization trends of Journavx in the SoonerCare population. Members were included in the analysis if they had a paid claim through SoonerCare for Journavx within FY26.

Table 1 below shows the number of members grouped by the number of paid claims for Journavx in FY26. Over 1,200 members (88.09%) had 1 paid claim for Journavx, and the average day supply was 13.85 days. However, there were 163 members (11.9%) with more than 1 paid claim for Journavx and, of those, 45 members (3.29%) had consecutive paid claims for Journavx suggesting potential chronic use.

Table 1: Number of Paid Claims for Journavx in FY26 by # of Members

Number of Paid Claims for Journavx	Total # of Members	% of Total Members (N=1,369) with a Paid Claim for Journavx
1	1,206	88.09%
2	103	7.52%
3	32	2.34%
4	10	0.73%
5	4	0.29%
6	6	0.44%
7+	8	0.58%

Table 2 below shows the opioid utilization for members with paid claims for Journavx. Concomitant use was defined as overlapping days' supply between paid claims for Journavx and an opioid. For example, if a member filled Journavx on 08/06/2025 for a 14-day supply and then filled oxycodone on 08/14/2025 for a 7-day supply, the member could potentially be taking the medications together; therefore, it was considered concomitant use in this analysis. There were 580 members (42.37%) with concomitant use of an opioid and Journavx. Of those members, 114 (8.33%) had a paid claim for Journavx and an opioid on the exact same day.

Table 2: Members with Journavx and Opioid Utilization		
	Total # of Members	**% of Total Members (N=1,369) with a Journavx Paid Claim**
Members with concomitant use of an opioid and Journavx	580	42.37%
Members with a paid claim for an opioid and Journavx on the same day	114	8.33%

To further evaluate Journavx utilization, members with a paid claim for Journavx were assessed to determine whether a subsequent paid claim for an opioid occurred, as shown in Table 3. There were 287 members (20.96%) with a paid claim for an opioid the day after their Journavx paid claim, but within 14 days from the date Journavx was filled, which may indicate the need for alternative or additional pain management.

Table 3: Members with Journavx and Opioid Utilization After Journavx Use		
	Total # of Members	**% of Total Members (N=1,369) with a Journavx Paid Claim**
Members with a paid claim for an opioid after Journavx but within 14 days	287	20.96%

There were 207 members (15.12%) with a documented general acute pain diagnosis code within 15 days before or after their paid claim for Journavx; however, this measure may underestimate appropriate use because acute pain is often documented using procedure-specific diagnosis codes (e.g., hysterectomy or laparoscopy) or codes identifying the location or type of acute pain (e.g., abdominal, shoulder, or dental pain), rather than a general acute pain diagnosis code. Consequently, appropriate use may be associated with a broad range of diagnosis codes that could not be captured by this analysis. Claims data showed 8 members (0.58%) had >6 paid claims of Journavx encompassing >84 days of therapy, which could indicate treatment for chronic pain; however, these claims were not always consecutive. To expand our evaluation of the appropriate use of Journavx, members were identified if they had a documented diagnosis of chronic pain and a paid claim for Journavx. Please note, members may also have acute pain

superimposed on an existing chronic pain diagnosis (e.g., related to an injury or surgery) for which use of Journavx could be appropriate. Table 4 below shows that approximately half of members with a documented chronic pain diagnosis had a paid claim for Journavx. Of those, 540 (39.44%) had use of an opioid at any time during FY26, and 341 (24.91%) had a concomitant paid claim for an opioid with Journavx. However, 5 members (0.37%) had a chronic pain diagnosis and >6 paid claims of Journavx indicating the potential use of Journavx for the treatment of chronic pain, with 2 members (0.15%) also receiving a concomitant opioid.

Table 4: Members with Journavx Utilization and a Chronic Pain Diagnosis		
	Total # of Members	**% of Total Members (N=1,369) with a Journavx Paid Claim**
Members with a chronic pain diagnosis and use of Journavx	681	49.74%
Members with chronic pain diagnosis and use of Journavx and an opioid	540	39.44%
Members with chronic pain diagnosis and use of Journavx and concomitant opioid	341	24.91%
Members with a chronic pain diagnosis and multiple (>6) paid claims for Journavx	5	0.37%
Members with a chronic pain diagnosis and multiple (>6) paid claims for Journavx and a concomitant opioid	2	0.15%

Table 5 below shows the number of members with a paid claim for Journavx and a documented diagnosis of opioid use disorder (OUD) or a medication assisted treatment (MAT) medication in their claims history. Our analysis showed approximately 11% of members with a paid claim for Journavx had a reported OUD diagnosis and/or a MAT medication in their claims summary.

Table 5: Members with Journavx Utilization and Opioid Use Disorder (OUD)		
	Total # of Members	**% of Total Members (N=1,369) with a Journavx Paid Claim**
Members with OUD and Journavx use	123	8.98%
Members with medication assisted treatment (MAT) and Journavx use	78	5.70%
Members with OUD and/or MAT and Journavx use	154	11.25%

Conclusions

After the PA requirement for Journavx was removed in July 2025, the use of Journavx increased from 22 paid claims in FY25 to 1,678 paid claims in FY26. However, it should be noted that coverage for Journavx began on 02/04/2025 following its FDA approval and market launch, so the claims data in FY25 does not capture a full year. One concern identified through the analysis is the frequent use of concomitant opioids with Journavx despite a lack of evidence for the safety and efficacy of this combination. Ideally, Journavx would be used as an alternative to opioids for the treatment of acute pain; however, current clinical practice uses a multimodal analgesia treatment approach for acute pain to minimize the need for opioids with providers typically prescribing both opioids and non-opioid analgesics (i.e., APAP, NSAIDs). Within the SoonerCare population, 8% of members had a paid claim for both Journavx and an opioid on the exact same day, but 42% of members had concomitant use of Journavx and an opioid. However, it is difficult to determine through claims data if this represents true concomitant use. Some members could have failed treatment with Journavx and needed an opioid for additional pain management, or some members could be on chronic pain management with an opioid and needed additional pain control for an acute procedure or injury.

About 88% of members had 1 paid claim for Journavx in FY26 with the majority having ≤6 fills (meaning ≤84 days of treatment). Additionally, 11% of Journavx utilizers had a diagnosis of OUD or a paid claim for a MAT medication in their claims history.

It is important to note that the analysis is based on paid SoonerCare pharmacy claims and does not include whether a member received their medications through a non-SoonerCare source (i.e., private insurance, free clinics, samples). Additionally, paid claims through Indian Health Services (IHS) were excluded from the analysis. Diagnosis data in this analysis is based on SoonerCare medical claims, as SoonerCare pharmacy claims do not require a diagnosis code upon billing.

The purpose of this report was to evaluate the overall utilization of Journavx within the SoonerCare population after the removal of the PA requirement. Future reports could look for trends in opioid fill quantities or morphine milligram equivalent (MME) levels associated with Journavx claims.

Recommendations

The College of Pharmacy will continue to monitor the utilization of Journavx for appropriate use. Currently, Journavx does not require a PA, but does have a quantity limit of 30 tablets for a 14-day supply. Considering there are members most likely using Journavx for chronic pain, additional system limitations are being developed to limit the number of fills within a given time period.

[1] U.S. Food and Drug Administration (FDA). FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-novel-non-opioid-treatment-moderate-severe-acute-pain. Issued 01/30/2025. Last accessed 10/02/2026.

[2] Vertex. Vertex Announces FDA Approval of Journavx (Suzetrigine), a First-in-Class Treatment for Adults with Moderate-to-Severe Acute Pain. Available online at: https://news.vrtx.com/news-releases/news-release-details/vertex-announces-fda-approval-journavxtm-suzetrigine-first-class. Issued 01/30/2025. Last accessed 10/02/2026.

[3] Dowell D, Ragan KR, Jones CM, et al. CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022. *MMWR Recomm Rep* 2022; 71(3):1-95. doi: 10.15585/mmwr.rr7103a1.

[4] Journavx (Suzetrigine) Tablet Prescribing Information. Vertex Pharmaceuticals. Available online at: https://pi.vrtx.com/files/uspi_suzetrigine.pdf. Last revised 01/2026. Last accessed 10/19/2026.



Appendix E

Vote to Prior Authorize Cetirizine Oral Solution Unit-Dose Cups (UDCs) and Update the Approval Criteria for the Antihistamine Medications (Systemic)

Oklahoma Health Care Authority
November 2026

Cost Comparison: Cetirizine Products

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
cetirizine 5mg/5mL oral sol unit-dose cup	**$0.40**	**$120.00**	**$1,440.00**
cetirizine 1mg/mL oral solution	$0.03	$9.00	$108.00
cetirizine 10mg tablet	$0.05	$1.50	$18.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the use of 10mg per day for each product.
Sol = solution; Unit = each tablet or milliliter

Recommendations

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

1. Prior authorization of cetirizine oral solution UDCs and placement into Tier-3 with additional criteria shown below; and
2. Moving levocetirizine tablets from Tier-2 to Tier-1 based on net cost; and
3. Moving desloratadine tablets from Tier-3 to Tier-2 based on net cost; and
4. Updating the Tier-2 and Tier-3 approval criteria based on Drug Utilization Review (DUR) Board recommendations and to clarify the trial requirements for age-appropriate dosage formulations.

Oral Antihistamine Medications		
Tier-1[+]	**Tier-2**	**Tier-3**
OTC cetirizine (Zyrtec) **sol, tab**	**desloratadine (Clarinex) tab**	**cetirizine sol UDC**
OTC levocetirizine (Xyzal) tab	OTC levocetirizine (Xyzal)* **sol**	clemastine **syr, tab**
OTC loratadine (Claritin) **ODT, sol, tab**		desloratadine (Clarinex)[¥] **ODT, sol**

[+]Tier-1 products are covered for pediatric members with no authorization necessary. OTC products are only covered for pediatric members.
*~~Xyzal is only covered for members 0 to 20 years of age.~~ Xyzal solution is available for children 6 months to 6 years of age.
[¥]An age restriction of 6 years to 11 years of age applies for Clarinex ODT ~~RediTabs~~.
ODT = orally disintegrating tablet; OTC = over-the-counter; sol = solution; syr = syrup; tab = tablet; UDC = unit-dose cup

Oral Antihistamine Medications Tier-2 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of 2 ~~all~~ age-appropriate Tier-1 products within the last 30 days; and
3. Approvals will be for the duration of 1 year.

Oral Antihistamine Medications Tier-3 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of 2 ~~all~~ age-appropriate Tier-1 products and 1 age-appropriate Tier-2 product~~s~~ within the last 60 days (unless no age-appropriate Tier-2 product exists); and
    a. Requests for cetirizine unit-dose cups (UDCs) will require a patient-specific, clinically significant reason why the member cannot use cetirizine bulk solution, which is available without a prior authorization; and
3. Approvals will be for the duration of 1 year.

Appendix F

Vote to Update the Approval Criteria for the Constipation and Diarrhea Medications

Oklahoma Health Care Authority
November 2026

Market News and Updates[1]

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

- **November 2025:** Linzess (linaclotide) received an age expansion for the treatment of irritable bowel syndrome with constipation (IBS-C) to include pediatric patients 7 years of age and older.
- **May 2026:** Linzess was approved for an age expansion for the treatment of functional constipation in pediatric patients down to 2 years of age.

Recommendations

The College of Pharmacy recommends the following changes to the Amitiza (lubiprostone) and Movantik (naloxegol) approval criteria based on net costs (changes shown in red):

Amitiza (Lubiprostone) Approval Criteria [Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C) Diagnosis]:

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

6. ~~A patient-specific, clinically significant reason why the member cannot use Linzess (linaclotide) must be provided; and~~
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
8. A quantity limit of 60 capsules per 30 days will apply.

Movantik (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Movantik must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A patient-specific, clinically significant reason why the member cannot use Symproic (naldemedine) must be provided; and
9. A quantity limit of 30 tablets per 30 days will apply.

The College of Pharmacy also recommends updating the Linzess (linaclotide) approval criteria based on the FDA-approved age expansions (changes shown in red):

Linzess (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Chronic idiopathic constipation (CIC) in members 18 years of age or older; or

   b. Irritable bowel syndrome with constipation (IBS-C) in members ~~18~~ 7 years of age or older; or
   c. Functional constipation in members ~~6~~ 2 to 17 years of age; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy (results must be submitted); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 capsules per 30 days will apply.

[1] Linzess (Linaclotide) Prescribing Information. AbbVie and Ironwood Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/202811s023lbl.pdf. Last revised 05/21/2026. Last accessed 10/27/2026.



Appendix G

Vote to Update the Approval Criteria for the Anticoagulants and Platelet Aggregation Inhibitors

Oklahoma Health Care Authority
November 2026

Recommendations

The College of Pharmacy recommends the following changes to the Brilinta (ticagrelor) approval criteria based on net costs (changes shown in red):

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.

Appendix H

Vote to Prior Authorize Epioxa HD/Epioxa (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa (Veligrotug-vvze) and Update the Approval Criteria for the Various Ophthalmic Medications

Oklahoma Health Care Authority
November 2026

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

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

- **October 2025:** The FDA approved Epioxa HD/Epioxa (riboflavin 5'-phosphate) to treat keratoconus in adults and pediatric patients 13 years of age and older, in conjunction with the O_2n System and the Boost Goggles. Epioxa HD/Epioxa does not require the removal of the epithelium like the previously approved Photrexa/Photrexa Viscous (riboflavin 5'-phosphate). The efficacy of Epioxa HD/Epioxa with epithelium-on corneal collagen cross-linking (CXL) with UV-A irradiation and supplemental oxygen in patients with keratoconus was evaluated in 2 prospective, randomized, parallel-group, sham procedure/vehicle-controlled trials. The primary endpoint was a change from baseline in the maximum corneal curvature (K_{max}) in the CXL treatment group and in the sham procedure/vehicle control group. In both studies, the CXL treatment group showed an improvement in K_{max} (decrease in corneal curvature) whereas the sham procedure/vehicle control group showed deterioration (increase in corneal curvature). The treatment difference between groups was about -1.0 diopter in both trials, which was determined to be statistically significant. The Wholesale Acquisition Cost (WAC) of Epioxa HD/Epioxa is $78,500 per kit; therefore, to treat both eyes, the cost would be $157,000.
- **June 2026:** The FDA approved Lumvoa (veligrotug-vvze) for the treatment of thyroid eye disease (TED).

News:

- **January 2026:** Glaukos announced the discontinuation of Photrexa/Photrexa Viscous (riboflavin 5'-phosphate) cross-linking kit.

Lumvoa (Veligrotug-vvze) Product Summary[5,6,7,8,9]

Therapeutic Class: Insulin-like growth factor-1 receptor (IGF-1R) inhibitor

Indication(s): For the treatment of TED regardless of thyroid eye disease activity or duration

How Supplied: 500mg/10mL(50mg/1mL) solution in a single-dose vial

Dosing and Administration:

- The recommended dose of Lumvoa is 10mg/kg every 3 weeks for a total of 5 infusions.
- Lumvoa should be administered by intravenous (IV) infusion over 30 to 45 minutes.

Efficacy: The efficacy of Lumvoa was evaluated in 2 randomized, double masked, placebo-controlled trials, THRIVE (active TED) and THRIVE-2 (chronic TED).

- Key Inclusion Criteria:
  - ≥18 years of age
  - Must agree to use highly effective contraception as specified in the protocol
  - Female TED participants must have a negative serum pregnancy test at screening
  - THRIVE:
    - Moderate to severe active TED with documented evidence of ocular symptoms or signs that began within 15 months prior to screening.
    - Clinical Activity Score (CAS) of ≥3 on the 7-item scale of the study eye
  - THRIVE-2:
    - Moderate to severe chronic TED with documented evidence of ocular symptoms or signs that began greater than 15 months prior to screening
    - A clinical diagnosis of TED, with any CAS (0-7)
- Key Exclusion Criteria:
  - Prior treatment with another anti-IGF-1R therapy
  - Previous orbital irradiation or surgery for TED in the study eye; however, prior orbital decompression surgery was permitted in either study if surgery was limited to the bone
- Intervention:
  - Randomized to receive Lumvoa or placebo in a 2:1 ratio
  - The study eye was the most proptotic eye by exophthalmometry, with the other designated as the non-study eye.
- Primary Outcome: Proptosis responder rate (PRR) in study eye at week 15 which was defined as the percent of patients with ≥2mm reduction in proptosis in the study eye from baseline without ≥2mm increase in the non-study eye measured by exophthalmometer.

- Results:
  - THRIVE:
    - The percent PRR at week 15 was 70% in the Lumvoa treated group and 5% in the placebo treated group with a treatment difference of 65% [95% confidence interval (CI): 52, 78; P<0.01].
    - The proptosis average change from baseline at week 15 was -2.9mm in the Lumvoa treated group versus -0.5mm in the placebo treated group with a treatment difference of -2.4mm (95% CI: -3, -1.8; P<0.01).
  - THRIVE-2:
    - The percent PRR at week 15 was 57% in the Lumvoa treated group and 8% in the placebo treated group with a treatment difference of 49% (95% CI: 38, 60, P<0.01).
    - The proptosis average change from baseline at week 15 was -2.4mm in the Lumvoa treated group versus -0.5mm in the placebo treated group with a treatment difference of -1.9mm (95% CI: -2.4, -1.4; P<0.01).

Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment Course
Lumvoa (veligrotug-vvze) 500mg/10mL sol	**$4,480**	**$448,000¥**
Tepezza (teprotumumab-trbw) 500mg vial	$19,451.83	$447,392.09*

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).
sol = solution; Unit = mL or vial
¥Cost per treatment course is based on a 75kg patient receiving the FDA approved dose of 10mg/kg every 3 weeks for a total of 5 infusions.
*Cost per treatment course is based on a 75kg patient receiving the FDA approved dose of 10mg/kg for the initial dose followed by 20mg/kg every 3 weeks for 7 additional infusions.

Recommendations

The College of Pharmacy recommends the prior authorization of Epioxa HD/ Epioxa (riboflavin 5'-phosphate) with the following criteria (shown in red):

Epioxa HD/Epioxa (Riboflavin 5'-Phosphate) Approval Criteria:

1. A diagnosis of 1 of the following:
   a. Keratoconus; or
   b. Corneal ectasia following refractive surgery; and
2. Member must be 13 years of age or older; and
3. Must be administered by an optometrist or ophthalmologist trained in the corneal cross-linking procedure; and
4. Must be used in combination with the O_2n System and Boost Goggles in the corneal cross-linking (CXL) procedure; and

5. Must be administered using the epithelial-on procedure as specified in the package labeling; and
6. Member must not have any contraindications to Epioxa HD/Epioxa or to the CXL procedure or have any current or previous ocular conditions in the eye to be treated that may predispose the eye for future complications after the procedure; or
    a. The prescriber has assessed the member and determined the risks outweigh the benefits of the procedure and has counseled the member on the potential risks; and
7. Member must not have previous use of Photrexa/Photrexa Viscous (riboflavin 5'-phosphate) with the CXL procedure in the eye to be treated; and
8. A quantity limit of 1 kit (4mL) per eye per lifetime will apply.

The College of Pharmacy recommends the prior authorization of Lumvoa (veligrotug-vvze) with the following criteria (shown in red):

Lumvoa (Veligrotug-vvze) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease (TED) in adult members 18 years of age and older; and
    a. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Lumvoa, and for at least 6 months after the last dose of Lumvoa; and
4. Member must not have had prior surgical treatment for TED unless eye surgery was limited to the bone; or
    a. A prior authorization request with patient-specific information may be submitted for consideration of Lumvoa for members who have had prior surgical treatment for TED, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Lumvoa; and
~~5. Member must have medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of TED; and~~
    a. ~~The name of the ophthalmologist and endocrinologist recommending treatment with Lumvoa must be provided on the prior authorization request; and~~
6. Must be prescribed by, or in consultation with, an endocrinologist, ophthalmologist, or specialist with expertise in the treatment of TED; and

7. Lumvoa must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
8. Lumvoa must be administered by a health care professional. Prior authorization requests must indicate how Lumvoa will be administered; and
    a. Lumvoa must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Lumvoa must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Lumvoa; and
9. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Member must not have received previous treatment with Tepezza (teprotumumab-trbw); and
11. Approvals will be for a maximum of 5 total infusions.

The College of Pharmacy also recommends updating the approval criteria for Tepezza (teprotumumab-trbw) based on the FDA approval of Lumvoa (veligrotug-vvze) (changes shown in red):

Tepezza (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease (TED) in adult members 18 years of age and older; and
    a. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza, and for at least 6 months after the last dose of Tepezza; and
4. Member must not have had prior surgical treatment for TED; or
    a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza for members who have had prior surgical treatment for TED, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza; and
~~5. Member must have medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of TED; and~~

~~a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza must be provided on the prior authorization request; and~~

6. Must be prescribed by, or in consultation with, an endocrinologist, ophthalmologist, or specialist with expertise in the treatment of TED; and
7. Tepezza must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
8. Tepezza must be administered by a health care professional. Prior authorization requests must indicate how Tepezza will be administered; and
    a. Tepezza must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tepezza must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza; and
9. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Member must not have received previous treatment with Lumvoa (veligrotug-vvze); and
11. Approvals will be for a maximum of 8 total infusions.

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Appendix I

Vote to Prior Authorize Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), Docivyx (Docetaxel), Inluriyo (Imlunestrant), and Veppanu (Vepdegestrant) and Update the Approval Criteria for the Breast Cancer Medications

Oklahoma Health Care Authority
November 2026

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

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

- **November 2022:** The FDA approved Docivyx (docetaxel) as a new formulation of docetaxel. It is indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, non-small cell lung cancer (NSCLC), castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck.
- **October 2024:** The FDA approved Beizray (docetaxel) as a new formulation of docetaxel. It is indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck. Beizray was not covered by SoonerCare until October 2025, when the current manufacturer began marketing the product.
- **September 2025:** The FDA approved Inluriyo (imlunestrant) for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy.
- **December 2025:** The FDA approved Enhertu (fam-trastuzumab deruxtecan-nxki) for a new indication, in combination with pertuzumab, as first-line treatment of adult patients with unresectable or metastatic HER2-positive immunohistochemistry (IHC) 3+ or in situ hybridization (ISH)-positive breast cancer, as determined by an FDA-authorized test.
- **May 2026:** The FDA approved Veppanu (vepdegestrant) for the treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy.

- **May 2026:** The FDA approved Enhertu (fam-trastuzumab deruxtecan-nxki) for 2 new indications for early breast cancer. The first new indication is as neoadjuvant treatment of adult patients with HER2-positive IHC 3+ or ISH-positive Stage II or III breast cancer, as determined by an FDA-authorized test, followed by a taxane, trastuzumab, and pertuzumab (THP). The second new indication is as adjuvant treatment of adult patients with HER2-positive IHC 3+ or ISH-positive breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment.
- **May 2026:** The FDA approved Datroway (datopotamab deruxtecan-dlnk) for a new indication for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for programmed death 1 (PD-1)/programmed death ligand 1 (PD-L1) inhibitor therapy.
- **June 2026:** The FDA approved Truqap (capivasertib) for a new indication, in combination with abiraterone and prednisone, for the treatment of adult patients with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.
- **June 2026:** The FDA approved Ibrance (palbociclib) for a new indication, in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with hormone receptor (HR)-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment.
- **June 2026:** The FDA approved Trodelvy (sacituzumab govitecan-hziy) for 2 new indications for the first-line treatment of TNBC. The first new indication is as a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC who are not candidates for PD-1 or PD-L1 inhibitor-based therapy. The second new indication is for use in combination with pembrolizumab or pembrolizumab/berahyaluronidase alfa-pmph for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 combined positive score (CPS) ≥10 as determined by an FDA-authorized test.
- **September 2026:** The FDA approved Inluriyo (imlunestrant) for a new indication, in combination with Verzenio (abemaciclib), for the treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy.
- **October 2026:** The FDA approved Tukysa (tucatinib) for a new indication, in combination with trastuzumab and pertuzumab, for the

maintenance treatment of adults with unresectable locally advanced or metastatic HER2-positive breast cancer following induction treatment.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for colon and rectal cancer no longer recommend the use of lapatinib in combination with trastuzumab for a diagnosis of unresectable, advanced, or metastatic HER2-amplified colorectal cancer.

Beizray (Docetaxel) and Beizray Kit (Docetaxel/Albumin) Product Summary[15]

Therapeutic Class: Microtubule inhibitor

Indication(s): Indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck

How Supplied:

- Single-dose vials (SDVs):
  - 20mg/mL SDV
  - 80mg/4mL SDV
- Kits containing the following:
  - 80mg Kit: 1 SDV of Beizray 80mg/4mL plus 1 SDV of intravenous (IV) solution stabilizer (50mL, 25% albumin human USP solution)
  - 160mg Kit: 2 SDVs of Beizray 80mg/4mL plus 1 SDV of IV solution stabilizer (50mL, 25% albumin human USP solution)

Dosing and Administration: The recommended dosage depends on the specific indication. Please refer to the full *Prescribing Information* for dosage and administration details.

Docivyx (Docetaxel) Product Summary[16]

Therapeutic Class: Microtubule inhibitor

Indication(s): Indicated for all of the same indications as Taxotere (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck

How Supplied:

- 20mg/2mL SDV
- 80mg/8mL SDV
- 160mg/16mL SDV

Dosing and Administration: The recommended dosage depends on the specific indication. Please refer to the full *Prescribing Information* for dosage and administration details.

Cost Comparison: Docetaxel Products

Product	Cost Per mg	Cost Per 21 Days*	Cost Per 6 Doses
Beizray (docetaxel) vial or kit J9174	**$46.53**	**$7,444.80**	**$44,668.80**
Docivyx (docetaxel) vial J9172	**$46.19**	**$7,390.40**	**$44,342.40**
docetaxel vial (generic) J9171	$0.47	$75.20	$451.20

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), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost based on use of up to 160mg per dose every 3 weeks and continued for 6 doses.

Inluriyo (Imlunestrant) Product Summary[17]

Therapeutic Class: Estrogen receptor antagonist

Indication(s):

- Treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy
- Treatment, in combination with abemaciclib, of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, with disease progression following at least 1 line of endocrine therapy

How Supplied: 200mg oral tablet

Dosing and Administration: The recommended dosage is 400mg orally once daily, on an empty stomach, until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is $401.79 per 200mg tablet. This would result in an estimated cost of $22,500.24 per 28 days or $292,503.12 per year based on recommended dosing.

Veppanu (Vepdegestrant) Product Summary[18]

Therapeutic Class: Heterobifunctional protein degrader

Indication(s): Treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy

How Supplied: 100mg and 200mg oral tablets

Dosing and Administration: The recommended dose is 200mg orally once daily with food continued until disease progression or unacceptable toxicity.

Cost: The WAC is $980.00 per 200mg tablet. This would result in an estimated cost of $29,400.00 per 30 days or $352,800.00 per year based on recommended dosing.

Cost Comparison: Trastuzumab Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Herceptin (trastuzumab) J9355	$68.87	$3,099.15	$52,685.55
Kanjinti (trastuzumab-anns) Q5117	$63.87	$2,874.15	$48,860.55
Herzuma (trastuzumab-pkrb) Q5113	$55.30	$2,488.50	$42,304.50
Ontruzant (trastuzumab-dttb) Q5112	$32.79	$1,475.55	$25,084.35
Hercessi (trastuzumab-strf) Q5146	$30.26	$1,361.70	$23,148.90
Ogivri (trastuzumab-dkst) Q5114	$29.51	$1,327.95	$22,575.15
Trazimera (trastuzumab-qyyp) Q5116	$11.27	$507.15	$8,621.55

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), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 21 days based on use of (3) 150mg vials per dose (6mg/kg every 3 weeks for a 75kg member)

Recommendations

The College of Pharmacy recommends the prior authorization of Beizray (docetaxel), Beizray Kit (docetaxel/albumin), Docivyx (docetaxel), Inluriyo (imlunestrant), and Veppanu (vepdegestrant) with the following criteria (shown in red):

Beizray (Docetaxel), Beizray Kit (Docetaxel/Albumin), and Docivyx (Docetaxel) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use generic docetaxel formulations, which are available without a prior authorization, must be provided.

Inluriyo (Imlunestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and
3. Tumor is positive for estrogen receptor-1 (ESR-1) mutation; and
4. Disease has progressed following at least 1 line of endocrine therapy; and

5. Meets 1 of the following:
    a. Used as a single agent; or
    b. Used in combination with abemaciclib; and
6. Member must be 18 years of age or older.

Veppanu (Vepdegestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Disease is recurrent unresectable (local or regional), or metastatic; and
3. Estrogen receptor (ER)-positive, human epidermal growth factor 2 (HER2)-negative disease; and
4. Tumor is positive for estrogen receptor-1 (ESR1) mutation; and
5. Has progressed after at least 1 line of endocrine therapy; and
6. Member is 18 years of age or older.

The College of Pharmacy also recommends updating the approval criteria for Datroway (datopotamab deruxtecan-dlnk), Enhertu (fam-trastuzumab deruxtecan-nxki), Ibrance (palbociclib), Trodelvy (sacituzumab govitecan-hziy), Truqap (capivasertib), and Verzenio (abemaciclib) based on recent FDA approvals with the following changes (shown in red):

Datroway (Datopotamab Deruxtecan-dlnk) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of unresectable or metastatic breast cancer; and
2. Used in 1 of the following settings:
    a. Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative; and
        i. Member has received prior endocrine-based therapy and chemotherapy; ~~and~~ or
    b. Disease is triple-negative breast cancer (TNBC); and
        i. Member has received no prior systemic therapy; and
        ii. Member is not a candidate for programmed death 1 (PD-1)/programmed death ligand 1 (PD-L1) inhibitor therapy; and
        iii. No germline BRCA 1/2 pathogenic variant; and
3. Used as a single agent.

Enhertu (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Breast Cancer Diagnosis]:

1. Adult members with unresectable or metastatic disease; and
    a. For human epidermal growth factor receptor 2 (HER2)-positive [immunohistochemistry (IHC) 3+ or in situ hybridization (ISH)-positive] disease, must meet the following:
        i. Used as first-line treatment, in combination with pertuzumab; or
        ii. Used as monotherapy; and

1. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and
2. Member has received ≥1 prior anti-HER2-based regimens; or

iii. Stage II or III disease, used as neoadjuvant treatment, and followed by a taxane, trastuzumab, and pertuzumab (THP); or
iv. Residual invasive disease following neoadjuvant treatment with trastuzumab (with or without pertuzumab) and taxane-based treatment; or

b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet 1 of the following:
   i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; or
   ii. Disease is hormone receptor (HR)-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy; or
c. For HER-2 ultralow (IHC 0 with membrane staining) disease, must meet the following:
   i. Disease is HR-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy.

Ibrance (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic, hormone receptor positive~~, human epidermal growth factor receptor 2 (HER2) negative~~ breast cancer; and
2. For human epidermal growth factor receptor 2 (HER2)-negative disease:
   a. Used in combination with:
      i. An aromatase inhibitor in female members; or
      ii. Fulvestrant in women with disease progression following endocrine therapy; or
      iii. An aromatase inhibitor or fulvestrant in male patients; or
      iv. Inavolisib and fulvestrant in patients with disease progression following endocrine therapy; or
3. For HER2-positive disease:
   a. Used in combination with trastuzumab, with or without pertuzumab, and endocrine therapy; and
   b. Used as maintenance treatment following induction treatment.

Trodelvy (Sacituzumab Govitecan-hziy) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of triple-negative breast cancer; and
    a. Used as first line therapy:
        i. Used as monotherapy if member is not a candidate for PD-1 or PD-L1 inhibitor therapy; or
        ii. Used in combination with pembrolizumab for tumors expressing PD-L1 (CPS ≥10) as determined by an FDA-authorized test; or
    b. Used as second line or later therapy:
        i. Unresectable locally advanced or metastatic disease; and
        ii. Member must have received ≥2 prior therapies, at least 1 of which was for metastatic disease; or
2. Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
    a. Unresectable locally advanced or metastatic disease; and
    b. Member has previously received endocrine-based therapy and ≥2 additional systemic therapies in the metastatic setting.

Truqap (Capivasertib) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer; and
2. Used in combination with abiraterone and prednisone; and
3. Disease is PTEN-deficient as detected by FDA-authorized test; and
4. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member is 18 years of age or older.

Tukysa (Tucatinib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced unresectable or metastatic breast cancer; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Used in combination with trastuzumab and capecitabine; and
    a. Following progression of ≥1 prior anti-HER2 regimen(s) in the metastatic setting; or
4. Used in combination with trastuzumab and pertuzumab; and
    a. For maintenance treatment following induction treatment.

Verzenio (Abemaciclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
    a. Hormone receptor positive disease; and
    b. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in 1 of the following settings:
            1. In combination with an aromatase inhibitor as initial endocrine-based therapy; or

2. In combination with fulvestrant with disease progression following endocrine therapy; or
3. In combination with imlunestrant in estrogen receptor 1 (ESR1)-mutated disease that has progressed following at least 1 line of endocrine therapy; or
4. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or

2. Diagnosis of early-stage breast cancer; and
   a. Hormone receptor positive disease; and
   b. HER2-negative disease; and
   c. Node-positive disease high risk for recurrence; and
   d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the Tykerb (lapatinib) approval criteria based on NCCN recommendations (changes shown in red):

~~**Tykerb (Lapatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:**~~

~~1. Diagnosis of unresectable, advanced, or metastatic disease; and~~
~~2. Member has human epidermal receptor 2 (HER2)-amplified disease; and~~
~~3. Member has wild-type RAS and BRAF disease; and~~
~~4. Member meets 1 of the following:~~
   ~~a. Has tried at least 1 chemotherapy regimen; or~~
   ~~b. Is not a candidate for intensive therapy, according to the prescriber; and~~
~~5. Used in combination with trastuzumab; and~~
~~6. Member has not been previously treated with a HER2-inhibitor.~~

Lastly, the College of Pharmacy recommends updating the approval criteria for the trastuzumab products based on net costs to remove the prior authorization requirement for the preferred trastuzumab products Hercessi (trastuzumab-strf), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp) and to replace the existing criteria for clarity (changes and additions shown in red):

~~**Herceptin (Trastuzumab), Herceptin Hylecta (Trastuzumab/ Hyaluronidase-oysk), Hercessi (Trastuzumab-strf), Herzuma (Trastuzumab-pkrb), Kanjinti (Trastuzumab-anns), Ogivri (Trastuzumab-dkst), Ontruzant (Trastuzumab-dttb), and Trazimera (Trastuzumab-qyyp) Approval Criteria [Breast Cancer Diagnosis]:**~~

~~1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and~~

2. Preferred trastuzumab products include Hercessi, Kanjinti, Ontruzant, and Trazimera. Authorization of non-preferred trastuzumab products (Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, or Ogivri) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi, Kanjinti, Ontruzant, or Trazimera). 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.

Herceptin (Trastuzumab), Hercessi (Trastuzumab-strf), Herzuma (Trastuzumab-pkrb), Kanjinti (Trastuzumab-anns), Ogivri (Trastuzumab-dkst), Ontruzant (Trastuzumab-dttb), and Trazimera (Trastuzumab-qyyp) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with pertuzumab, lapatinib, or tucatinib; and
4. Used in 1 of the following settings:
    a. If first-line therapy, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression; and
5. Preferred trastuzumab products include Hercessi, Kanjinti, Ontruzant, and Trazimera. Authorization of non-preferred trastuzumab products (Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, or Ogivri) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi, Kanjinti, Ontruzant, or Trazimera). 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.

Herceptin (Trastuzumab), Hercessi (Trastuzumab-strf), Herzuma (Trastuzumab-pkrb), Kanjinti (Trastuzumab-anns), Ogivri (Trastuzumab-dkst), Ontruzant (Trastuzumab-dttb), and Trazimera (Trastuzumab-qyyp) Approval Criteria [Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include Hercessi, Kanjinti, Ontruzant, and Trazimera. Authorization of non-preferred trastuzumab products

~~(Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, or Ogivri) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi, Kanjinti, Ontruzant, or Trazimera). 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.~~

Herceptin (Trastuzumab), Herceptin Hylecta (Trastuzumab/ Hyaluronidase-oysk), Herzuma (Trastuzumab-pkrb), and Kanjinti (Trastuzumab-anns) Approval Criteria [Breast Cancer Diagnosis]:

1. A patient-specific, clinically significant reason why the member cannot use Hercessi (trastuzumab-strf), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dttb), and Trazimera (trastuzumab-qyyp), which are available without prior authorization, 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.

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Appendix J

Vote to Prior Authorize Decnupaz (Pivekimab Sunirine-pvzy), Jakafi XR [Ruxolitinib Extended-Release (ER)], and Mimrylo (Rusfertide) and Update the Approval Criteria for the Myeloproliferative Neoplasm (MPN) Medications

Oklahoma Health Care Authority
November 2026

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

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

- **May 2026:** The FDA approved Jakafi XR (ruxolitinib ER) as a new once-daily formulation of oral ruxolitinib for the treatment of all the same indications as the existing twice-daily formulation of Jakafi (ruxolitinib), including indications for the treatment of myelofibrosis, polycythemia vera, and graft-versus-host disease. Jakafi XR is available as oral tablets in 11mg, 22mg, 33mg, 44mg, and 55mg strengths.
- **May 2026:** The FDA approved Decnupaz (pivekimab sunirine-pvzy) for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- **August 2026:** The FDA approved Besremi (ropeginterferon alfa-2b-njft) for a new indication for the treatment of adults with essential thrombocythemia.
- **August 2026:** The FDA approved Mimrylo (rusfertide) for the treatment of erythrocytosis in adults with polycythemia vera.

Decnupaz (Pivekimab Sunirine-pvzy) Product Summary[5]

Therapeutic Class: CD123-directed antibody and alkylating agent conjugate

Indication(s): Treatment of adult patients with BPDCN

How Supplied: 2mg lyophilized cake in a single-dose vial (SDV)

Dosing and Administration: The recommended dose is 0.045mg/kg administered as an intravenous (IV) infusion over approximately 15-30 minutes once every 3 weeks until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is $92,325.40 per SDV. For a member weighing 75kg, this would result in an estimated cost of $184,650.80 per dose or $3,139,063.60 per year based on recommended dosing.

Mimrylo (Rusfertide) Product Summary[6]

Therapeutic Class: Hepcidin mimetic

Indication(s): Treatment of erythrocytosis in adults with polycythemia vera

How Supplied: Lyophilized powder in SDVs in 9.5mg, 19mg, 28mg, 41mg, and 54mg strengths

Dosing and Administration:

- Mimrylo should be administered subcutaneously (sub-Q) on a weekly dosing schedule.
- The recommended weekly dosage range of Mimrylo is 9.5mg to 108mg.
- The recommended starting dose is 19mg once a week.
- The dose should be adjusted based on efficacy or safety.
- Doses higher than 54mg are administered as 2 injections. If the weekly dosage is greater than 82mg, the first injection should be administered on day 1 and the second injection should be administered on day 4 or 5.

Cost: The WAC is $4,231 per SDV, regardless of strength. For a member using 1 SDV per week, this would result in an estimated cost of $16,924 per 28 days or $220,012 per year. For a member needing 2 SDVs per week, this would result in an estimated cost of $33,848 per 28 days or $440,024 per year.

Recommendations

The College of Pharmacy recommends the prior authorization of Decnupaz (pivekimab sunirine-pvzy), Jakafi XR (ruxolitinib ER), and Mimrylo (rusfertide) with the following criteria based on recent FDA approvals and net costs (shown in red):

Decnupaz (Pivekimab Sunirine-pvzy) Approval Criteria [Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) Diagnosis]:

1. Diagnosis of BPDCN; and
2. Member must be 18 years of age or older; and
3. Must be used as a single-agent.

Jakafi (Ruxolitinib) and Jakafi XR [Ruxolitinib Extended-Release (ER)] Approval Criteria [Graft-Versus-Host Disease (GVHD) Diagnosis]:

1. Diagnosis of acute or chronic Graft-Versus-Host Disease (GVHD); and
2. Failure of at least 1 prior line of systemic therapy; and
3. Member must be 12 years of age or older; and
4. Requests for Jakafi XR will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of Jakafi.

Jakafi (Ruxolitinib) and Jakafi XR [Ruxolitinib Extended-Release (ER)] Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of myelofibrosis; and
2. Used in 1 of the following settings:
   a. Symptomatic lower-risk myelofibrosis with no response or loss of response to peginterferon alfa-2a or hydroxyurea; or
   b. Intermediate to high-risk myelofibrosis; and
3. Member must be 18 years of age or older; and
4. Requests for Jakafi XR will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of Jakafi.

Jakafi (Ruxolitinib) and Jakafi XR [Ruxolitinib Extended-Release (ER)] Approval Criteria [Polycythemia Vera Diagnosis]:

1. Diagnosis of polycythemia vera; and
2. Inadequate response or loss of response to hydroxyurea or peginterferon alfa-2a therapy; and
3. Member must be 18 years of age or older; and
4. Requests for Jakafi XR will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of Jakafi.

Mimrylo (Rusfertide) Approval Criteria [Polycythemia Vera (PV) Diagnosis]:

1. Diagnosis of PV; and
2. Member has not achieved adequate control with at least 1 prior therapy.

The College of Pharmacy also recommends updating the approval criteria for Besremi (ropeginterferon alfa-2b-njft) based on recent FDA approvals with the following changes (shown in red):

Besremi (Ropeginterferon Alfa-2b-njft) Approval Criteria ~~[Polycythemia Vera (PV) Diagnosis]~~:

1. Diagnosis of 1 of the following:
   a. Essential thrombocythemia; or
   b. Polycythemia vera; and
2. Used as a single agent.

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Appendix K

Vote to Prior Authorize Icotyde (Icotrokinra), Immgolis (Golimumab-sldi), Immgolis Intri (Golimumab-sldi), Lisraya (Brepocitinib), and Zimrixby (Rituximab-cdxx) and Update the Approval Criteria for the Targeted Immunomodulator Agents

Oklahoma Health Care Authority
November 2026

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

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

- **March 2026:** The FDA approved Icotyde (icotrokinra) for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40kg who are candidates for systemic therapy or phototherapy.
- **April 2026:** The FDA approved Saphnelo (anifrolumab-fnia) for a new subcutaneous (sub-Q) pen formulation for the treatment of adult patients with moderate-to-severe systemic lupus erythematosus (SLE) who are receiving standard therapy. Previously, Saphnelo was only available in a single-dose vial (SDV) for intravenous (IV) administration.
- **May 2026:** The FDA approved Immgolis (golimumab-sldi) and Immgolis Intri (golimumab-sldi) as new interchangeable biosimilars to Simponi (golimumab) and Simponi Aria (golimumab), respectively. Immgolis and Immgolis Intri are FDA approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate. Additionally, Immgolis is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC). The manufacturer plans to announce the commercial launch of these biosimilars later in 2026.
- **May 2026:** The FDA approved Tofidence (tocilizumab-bavi) for a new indication for the treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS) in adults and pediatric patients 2 years of age and older.
- **July 2026:** The FDA approved Zimrixby (rituximab-cdxx), a new biosimilar to Rituxan (rituximab), for the treatment of adults with the following indications: non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), RA, and granulomatosis with polyangiitis (GPA; Wegener's granulomatosis) and microscopic polyangiitis (MPA). Zimrixby contains rituximab, which is a CD20-directed cytolytic antibody.

- **August 2026:** The FDA approved Lisraya (brepocitinib) for the treatment of dermatomyositis in adults.
- **September 2026:** The FDA approved Olumiant (baricitinib) for an age expansion down to 12 years of age for the treatment of severe alopecia areata. Previously, Olumiant was only FDA approved for adults with this indication.

Guideline Update(s):

- **National Alopecia Areata Foundation (NAAF) and American Hair Research Society (AHRS):** The NAAF and AHRS released updated consensus statements on the treatment of severe alopecia areata in adults. Consensus was achieved if there was at least 70% agreement based on systematic literature review and the expert opinion of 31 United States-based alopecia areata experts. Key areas where consensus was achieved include:
  - FDA approved oral Janus kinase (JAK) inhibitors are recommended as the primary (initial) treatment for all adult patients with severe alopecia areata.
  - JAK inhibitors should be continued for at least 6 months. For patients who do not experience the treatment goal within that time frame, the dose may be increased, when multiple doses are available, or the patient may be switched to a different oral JAK inhibitor.
  - Other therapies, such as oral minoxidil, topical minoxidil, intralesional corticosteroids, high potency topical corticosteroids, or oral corticosteroids are now considered as adjunctive or supplemental therapies to the primary alopecia areata treatment.

Icotyde (Icotrokinra) Product Summary[8]

Therapeutic Class: Interleukin-23 (IL-23) receptor antagonist

Indication(s): Treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh ≥40kg who are candidates for systemic therapy or phototherapy

How Supplied: 200mg oral tablets

Dosing and Administration:

- The recommended dose is 200mg orally once daily.
- Icotyde should be administered upon waking on an empty stomach with water, at least 30 minutes before eating food.
- Tablets should be swallowed whole and should not be crushed, split, or chewed.

Efficacy: The efficacy of Icotyde was evaluated in 4 multicenter, randomized, double-blind, placebo and/or active comparator-controlled trials (Trial PSO-1, Trial PSO-2, Trial PSO-3, and Trial PSO-4). These trials included a total of 2,500 patients, of whom 72 were pediatric patients 12 years of age and older and the remainder were adults.

- Key Inclusion Criteria:
  - Trial PSO-1 and PSO-2:
    - 18 years of age or older
    - Moderate-to-severe plaque psoriasis [Investigator's Global Assessment (IGA) score ≥3, Psoriasis Area and Severity Index (PASI) score ≥12, and body surface area (BSA) involvement ≥10%]
  - Trial PSO-3:
    - 12 years of age or older
    - Moderate-to-severe plaque psoriasis (IGA score ≥3, PASI score ≥12, and BSA involvement ≥10%)
  - Trial PSO-4:
    - 12 years of age or older
    - Moderate-to-severe plaque psoriasis (IGA score ≥2 and BSA involvement ≥1%)
    - Presence of at least moderate plaque psoriasis of the scalp, genital area, or hands/feet at baseline
    - Previous failure of at least 1 topical therapy for the treatment of plaque psoriasis
- Intervention(s):
  - Trial PSO-1 and PSO-2: Patients were randomized to receive Icotyde 200mg, deucravacitinib 6mg, or placebo once daily for 16 weeks.
  - Trial PSO-3 and PSO-4: Patients were randomized to receive Icotyde 200mg or placebo once daily for 16 weeks.
- Primary Endpoint(s):
  - Trial PSO-1, PSO-2, and PSO-3 Co-Primary Endpoints:
    - Proportion of patients achieving an IGA score of 0 or 1 with a ≥2-grade improvement from baseline at week 16 compared to placebo
    - Proportion of patients achieving at least a 90% improvement in PASI scores from baseline (PASI 90) at week 16 compared to placebo
  - Trial PSO-4:
    - Proportion of patients achieving an IGA score of 0 or 1 with a ≥2-grade improvement from baseline at week 16 compared to placebo
- Results:
  - Trial PSO-1:

        - IGA 0 or 1 with ≥2-grade improvement: Achieved by 68% of patients who received Icotyde compared to 11% of patients who received placebo [treatment difference: 58%; 95% confidence interval (CI): 50, 64]
        - PASI 90: Achieved by 55% of patients who received Icotyde compared to 4% of patients who received placebo (treatment difference: 51%; 95% CI: 44, 57)
    - Trial PSO-2:
        - IGA 0 or 1 with ≥2-grade improvement: Achieved by 71% of patients who received Icotyde compared to 9% of patients who received placebo (treatment difference: 63%; 95% CI: 53, 70)
        - PASI 90: Achieved by 58% of patients who received Icotyde compared to 1% of patients who received placebo (treatment difference: 57%; 95% CI: 49, 62)
    - Trial PSO-3:
        - IGA 0 or 1 with ≥2-grade improvement: Achieved by 65% of patients who received Icotyde compared to 8% of patients who received placebo (treatment difference: 56%; 95% CI: 50, 62)
        - PASI 90: Achieved by 50% of patients who received Icotyde compared to 4% of patients who received placebo (treatment difference: 45%; 95% CI: 40, 50)
    - Trial PSO-4:
        - IGA 0 or 1 with ≥2-grade improvement: Achieved by 57% of patients who received Icotyde compared to 6% of patients who received placebo (treatment difference: 51%; 95% CI: 42, 59)

Cost: The Wholesale Acquisition Cost (WAC) is $280.03 per tablet, resulting in an estimated cost of $8,400.90 per month or $100,810.80 per year based on recommended dosing.

Lisraya (Brepocitinib) Product Summary[9]

Therapeutic Class: JAK and tyrosine kinase 2 (TYK2) inhibitor

Indication(s): Treatment of dermatomyositis in adult patients

How Supplied: 30mg oral tablets

Dosing and Administration:

- The recommended dose is 30mg orally once daily with or without food.

Efficacy: The efficacy of Lisraya was evaluated in a Phase 3, randomized, double-blind, multicenter, placebo-controlled trial that enrolled 241 adult patients with dermatomyositis.

- Key Inclusion Criteria:
  - Confirmed diagnosis of dermatomyositis
  - 18 years of age to less than 75 years of age
  - Active muscle and skin disease at screening and baseline
  - Prior or current use of at least 1 corticosteroid or non-steroid immunomodulatory/immunosuppressive therapy (hydroxychloroquine alone is not sufficient to meet this)
- Intervention(s):
  - Patients were randomized 1:1:1 to receive brepocitinib 30mg, brepocitinib 15mg, or placebo once daily for 52 weeks.
  - Patients were able to continue receiving standard background therapies (at stable dosages) for dermatomyositis, such as oral corticosteroids, non-steroid immunosuppressive therapy, and anti-malarial therapies. Brepocitinib 15mg is not an FDA approved or recommended dosage.
- Primary Endpoint(s):
  - Mean Total Improvement Score (TIS) at week 52 on a scale ranging from 0 to 100, with higher scores representing greater myositis improvement on a composite index reflecting changes in 6 core set measures
- Results:
  - The least squares mean TIS score was 47.5 in the brepocitinib group compared to 33.3 in the placebo group (treatment difference: 14.2; 95% CI: 5.5, 22.9), demonstrating greater improvement in the brepocitinib group.

Cost: The WAC is $1,166.67 per tablet, resulting in an estimated cost of $35,000.10 per month or $420,001.20 per year based on recommended dosing.

Cost Comparison: Rituximab Products

Product	Cost Per 10mg	Cost Per Dose*	Cost Per Year*
Rituxan (rituximab) (J9312)	**$72.09**	**$7,209.00**	**$28,836.00**
Truxima (rituximab-abbs) (Q5115)	$35.99	$3,599.00	$14,396.00
Riabni (rituximab-arrx) (Q5123)	$21.08	$2,108.00	$8,432.00
Ruxience (rituximab-pvvr) (Q5119)	$5.79	$579.00	$2,316.00

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), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per dose and cost per year based on the FDA approved dosing for rheumatoid arthritis (RA), using (2) 1,000mg doses separated by 2 weeks and repeated every 24 weeks (4 doses per year)
Please note: Cost information is not yet available for Zimrixby (rituximab-cdxx).

Recommendations[10,11]

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. Removing the current Tier-1 products, shifting the current Tier-2 and Tier-3 products down by 1 Tier, and removing the PA requirement for the new Tier-1 products based on net cost and to allow earlier access, when appropriate, to the preferred targeted immunomodulator agents based on net cost and current guideline recommendations; and
2. Moving selected Special PA products to Tier-3 for clarity; and
3. Prior authorization and placement of Icotyde (icotrokinra) into Tier-3 based on net cost; and
4. Prior authorization and placement of Immgolis (golimumab-sldi), Immgolis Intri (golimumab-sldi), Lisraya (brepocitinib), and Zimrixby (rituximab-cdxx) into the Special PA Tier based on net costs; and
5. Updating the Saphnelo (anifrolumab-fnia) and Tofidence (tocilizumab-bavi) approval criteria based on recent FDA approvals; and
6. Updating the Benlysta (belimumab) criteria to be consistent with the Saphnelo criteria; and
7. Moving Rituxan (rituximab) from Tier-2 to the Special PA Tier and updating the rituximab approval criteria based on net costs; and
8. Moving branded Remicade (infliximab), Renflexis (infliximab-abda), and Avsola (infliximab-axxq) from Tier-3 to the Special PA Tier and updating the infliximab approval criteria based on net costs; and
9. Moving Litfulo (ritlecitinib) from the Special PA Tier to Tier-2 and updating the unique alopecia areata criteria based on net costs and guideline recommendations; and
10. Updating the hidradenitis suppurativa criteria based on clinical practice and current guideline recommendations; and
11. Updating the Ilaris (canakinumab) criteria for clarity.

Targeted Immunomodulator Agents*				
~~Tier-1 (DMARDs appropriate to disease state)~~	Tier-~~1~~ ~~2~~*	Tier-~~2~~ ~~3~~	Tier-3	Special Prior Authorization (PA)
~~6-mercapto-purine~~	adalimumab (Humira)[+±] - **Branded Only**	abatacept (Orencia, Orencia ClickJect)[¤]	**baricitinib (Olumiant)[€]**	adalimumab (Humira)[+±] - **Unbranded Only**
~~azathioprine~~	adalimumab-adaz (Hyrimoz)[+±] - **Unbranded Only**	certolizumab pegol (Cimzia)	**bimekizumab-bkzx (Bimzelx)[Δ]**	adalimumab-aacf (Idacio)[+±]

Targeted Immunomodulator Agents*				
~~Tier-1 (DMARDs appropriate to disease state)~~	Tier-~~1~~ ~~2~~*	Tier-~~2~~ ~~3~~	Tier-3	Special Prior Authorization (PA)
~~Hydroxychloroquine~~	adalimumab-aqvh (Yusimry)[+±]	deucravacitinib (Sotyktu)	**deuruxolitinib (Leqselvi)[€]**	adalimumab-aaty (Yuflyma)[+±]
~~leflunomide~~	adalimumab-bwwd (Hadlima)[+±] - **Branded Only**	golimumab (Simponi, Simponi Aria)[±]	**etrasimod (Velsipity)**	adalimumab-adaz (Hyrimoz)[+±] - **Branded Only**
~~mesalamine~~	adalimumab-fkjp (Hulio)[+±] - **Unbranded Only**	~~infliximab (Remicade)[±] – Branded Only~~	**guselkumab (Tremfya)**	adalimumab-adbm (Cyltezo)[+±]
~~methotrexate~~	adalimumab-ryvk (Simlandi)[+±] - **Branded Only**	~~infliximab-abda (Renflexis)[±]~~	**icotrokinra (Icotyde)**	adalimumab-afzb (Abrilada)[+±]
~~minocycline~~	anakinra (Kineret)	~~infliximab-axxq (Avsola)[±]~~	**ixekizumab (Taltz)**	adalimumab-atto (Amjevita)[+±]
~~NSAIDs~~	apremilast (Otezla)[ß]	**ritlecitinib (Litfulo)[€]**	**mirikizumab-mrkz (Omvoh)**	adalimumab-bwwd (Hadlima)[+±] - **Unbranded Only**
~~oral corticosteroids~~	etanercept (Enbrel)[±]	sarilumab (Kevzara)[§]	**risankizumab-rzaa (Skyrizi)**	adalimumab-fkjp (Hulio)[+±] - **Branded Only**
~~sulfasalazine~~	infliximab (Remicade)[±] - **Unbranded Only**	tocilizumab-aazg (Tyenne)[π±] - **Branded Only**	**secukinumab (Cosentyx)[Δ]**	adalimumab-ryvk (Simlandi)[+±] - **Unbranded Only**
~~topical corticosteroids~~	infliximab-dyyb (Inflectra)[±]	tofacitinib (Xeljanz, Xeljanz XR, Xeljanz oral solution)[**]	**tildrakizumab-asmn (Ilumya)**	anifrolumab-fnia (Saphnelo)**
	~~rituximab (Rituxan)[~±]~~	vedolizumab intravenous (IV) (Entyvio)	**upadacitinib (Rinvoq, Rinvoq LQ)[#]**	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)[±]			**brepocitinib (Lisraya)****
	ustekinumab-kfce (Yesintek)[±]			brodalumab (Siliq)**
	ustekinumab-srlf (Imuldosa)[±]			canakinumab (Ilaris)[¥**]

Targeted Immunomodulator Agents*				
~~Tier-1 (DMARDs appropriate to disease state)~~	Tier-~~1~~ 2*	Tier-2 ~~3~~	Tier-3	Special Prior Authorization (PA)
	ustekinumab-stba (Steqeyma)± - **Branded Only**			~~deuruxolitinib (Leqselvi)€~~
	ustekinumab-ttwe (Pyzchiva)± - **Branded Only**			etanercept-szzs (Erelzi)±
				etanercept-ykro (Eticovo)±
				~~etrasimod (Velsipity)~~
				golimumab-sldi (Immgolis, Immgolis Intri)±
				~~guselkumab (Tremfya)~~
				infliximab (Remicade)± - Branded Only
				infliximab-abda (Renflexis)±
				infliximab-axxq (Avsola)±
				infliximab-dyyb (Zymfentra)±
				~~ixekizumab (Taltz)~~
				~~mirikizumab-mrkz (Omvoh)~~
				rilonacept (Arcalyst)**
				~~risankizumab-rzaa (Skyrizi)~~
				~~ritlecitinib (Litfulo)€~~
				rituximab (Rituxan)~±
				rituximab-cdxx (Zimrixby)±
				~~secukinumab (Cosentyx)Δ~~
				spesolimab-sbzo (Spevigo)**
				~~tildrakizumab-asmn (Ilumya)~~

Targeted Immunomodulator Agents*				
~~Tier-1 (DMARDs appropriate to disease state)~~	Tier-~~1~~ ~~2~~*	Tier-~~2~~ ~~3~~	Tier-3	Special Prior Authorization (PA)
				tocilizumab (Actemra)[π±]
				tocilizumab-aazg (Tyenne)[π±] - **Unbranded Only**
				tocilizumab-anoh (Avtozma)[π±]
				tocilizumab-bavi (Tofidence)[π±]
				~~**upadacitinib (Rinvoq, Rinvoq LQ)**~~[#]
				ustekinumab (Stelara)[±]
				ustekinumab-aauz (Otulfi)[±]
				ustekinumab-aekn (Selarsdi)[±] - **Unbranded Only**
				ustekinumab-auub (Wezlana)[±]
				ustekinumab-stba (Steqeyma)[±] - **Unbranded Only**
				ustekinumab-ttwe (Pyzchiva)[±] - **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.

[β] 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).~~
ᵀUnique 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).
ᵍUnique 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.

Targeted Immunomodulator Agents Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. 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 for the requested product; and
3. Recent trials (within the last 360 days) ~~of 1 Tier-1 medication (appropriate to the member's disease state) and at least 2 Tier-2 medications~~ of at least 3 lower-tiered medications (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-3 medication documented within the last 100 days; or
5. A unique FDA-approved indication not covered by Tier-2 medications (unique approval criteria may apply).

~~**Targeted Immunomodulator Agents Special Prior Authorization (PA) Approval Criteria:**~~

~~1. An FDA approved diagnosis; and~~
~~2. 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 for the requested product; and~~
~~3. Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state), at least 2 Tier-2 medications (appropriate to the member's disease state), and 1 Tier-3 medication (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or~~
~~4. Prior stabilization on the Special PA medication documented within the last 100 days; or~~
~~~

~~5. A unique FDA-approved indication not covered by lower-tiered medications (unique approval criteria may apply).~~

Adalimumab Non-Preferred (Special Prior Authorization Tier) Products ~~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 a preferred ~~Tier 2~~ Tier-1 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.

Adalimumab Non-Preferred (Special Prior Authorization Tier) 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~~ 1 of the following categories (can refer to a recent trial or historical trial prior to biologic therapy):
   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~~ Tier-1 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.

Adalimumab Non-Preferred (Special Prior Authorization Tier) 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~~ Tier-1 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), 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), Tofidence (Tocilizumab-bavi), 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, 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.

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.

Benlysta (Belimumab) Approval Criteria:

1. ~~The intravenous (IV) formulation will be covered as a medical only benefit while the subcutaneous (sub-Q) formulation will be covered as a pharmacy only benefit; and~~
2. An FDA approved indication of 1 of the following:
    a. The treatment of members 5 years of age and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) already receiving standard therapy; or
    b. The treatment of members 5 years of age and older with active lupus nephritis (LN) who are receiving standard therapy; and
3. Documented inadequate response to at least 2 of the following medications appropriate to member's specific disease state:
    a. High-dose oral corticosteroids; or
    b. Methotrexate; or
    c. Azathioprine; or
    d. Mycophenolate; or
    e. Cyclophosphamide; or
    f. Hydroxychloroquine/chloroquine; and
4. Member must not have severe active central nervous system lupus; and

5. Benlysta will not be approved for concomitant use with biologic therapies; and
6. For the intravenous (IV) formulation, Benlysta must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
    a. Must be shipped to the health care facility where the member is scheduled to receive treatment; and
7. Benlysta will not be approved for concomitant use with IV cyclophosphamide (exception for induction treatment with IV cyclophosphamide for members with a diagnosis of LN).

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~~ 1 of the following categories (can refer to a recent trial or historical trial prior to biologic therapy):
    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~~ Tier-1 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 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~~ 1 of the following categories (can refer to a recent trial or historical trial prior to biologic therapy):
    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~~ Tier-1 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. 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
3. A quantity limit of 108mg every 2 weeks will apply for the sub-Q formulation; and
4. 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.

Ilaris (Canakinumab) Approval Criteria [Active Systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD) Diagnosis]:

1. An FDA approved indication of SJIA or AOSD; and
2. The member should not be using a tumor necrosis factor (TNF) blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Ilaris should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. Dosing should not be more often than once every 4 weeks; and
   a. Weight-based dosing in members 2 years of age and older (the member's recent weight must be provided):
      i. Body weight ≥7.5kg: 4mg/kg subcutaneous injection every 4 weeks (maximum 300mg/dose); and
5. ~~Recent trials of 1 Tier-1 medication and all appropriate Tier-2 medications that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or~~
6. Recent trial of Tyenne (tocilizumab-aazg) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
7. Prior stabilization on the ~~Tier-3~~ Special Prior Authorization medication documented within the last 100 days; and

8. Approvals will be for the duration of 1 year.

Immgolis (Golimumab-sldi) and Immgolis Intri (Golimumab-sldi) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Simponi (golimumab) and Simponi Aria (golimumab) 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.

Leqselvi (Deuruxolitinib), Litfulo (Ritlecitinib), and Olumiant (Baricitinib) Approval Criteria [Alopecia Areata Diagnosis]:

1. An FDA approved diagnosis of severe alopecia areata; and
2. For Litfulo or Olumiant, member must be 12 to 20 years of age; or
3. For Leqselvi ~~or Olumiant~~, member must be 18 to 20 years of age; and
4. Prescriber must confirm the member or caregiver has been counseled regarding the covered age range for the requested product and that the medication will no longer be covered once the member turns 21 years of age; and
5. Member's baseline Severity of Alopecia Tool (SALT) score must be provided and must be ≥50; and
6. Must be prescribed by a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. ~~Prescriber must agree to screen for tuberculosis and viral hepatitis prior to initiating treatment; and~~
8. 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 for the requested product; and
9. Prescriber must provide documentation of patient-specific, clinically significant information (e.g., impacting member's mental health or ability to function in day-to-day living, reason why no treatment or cosmetic solutions are not appropriate) to demonstrate the medical necessity of this medication for this member; and
10. ~~Member must have documented trials within the last 6 months that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance to all alternatives):~~
    - a. ~~Medium potency to very high potency Tier 1 topical corticosteroid used for at least 12 weeks; or~~
    - b. ~~Oral corticosteroid used for at least 6 weeks; or~~
    - c. ~~Cyclosporine; or~~
    - d. ~~Methotrexate; or~~

~~e. Contact immunotherapy (e.g., diphenylcyclopropenone, squaric acid dibutyl ester); and~~

11. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
12. Prescriber must verify female members are not breastfeeding; and
13. 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 pregnancy registry; and
14. Requests for Leqselvi (deuruxolitinib) or Olumiant (baricitinib) will require a patient-specific, clinically significant reason why the member cannot use Litfulo (ritlecitinib); and
15. Initial approvals will be for a duration of 24 weeks of treatment; and
16. Reauthorization may be considered if the prescriber documents the member is responding well to treatment as indicated by a reduction in the member's SALT score (current SALT score must be provided).

Lisraya (Brepocitinib) Approval Criteria:

1. An FDA approved diagnosis of dermatomyositis meeting both of the following based on American College of Rheumatology (ACR)/ European League Against Rheumatism (EULAR) classification criteria:
   a. Definite or probable idiopathic inflammatory myopathy (IIM); and
   b. Dermatomyositis subtype; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by a dermatologist, neurologist, rheumatologist, or other specialist with expertise in the treatment of dermatomyositis; and
4. 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
5. Member must be receiving treatment with a corticosteroid and at least 1 of the following other immunomodulatory/immunosuppressive therapies (unless there is documented previous failure or intolerance):
   a. Methotrexate; or
   b. Azathioprine; or
   c. Mycophenolate mofetil or mycophenolic acid; or
   d. Leflunomide; or
   e. Sulfasalazine; or
   f. Hydroxychloroquine; and
6. A patient-specific, clinically significant reason why the member cannot use guideline-recommended, second-line treatments (e.g., abatacept, intravenous immunoglobulin, rituximab); and
7. Concurrent use with other Janus kinase (JAK) inhibitors, other tyrosine kinase 2 (TYK2) inhibitors, or biologic disease modifying anti-rheumatic drugs (DMARDs) will not be approved; and

8. Initial approvals will be for a duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

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.

~~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. ~~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. ~~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 LQ (Upadacitinib Oral Solution) Approval Criteria:

1. Member must meet ~~Special Prior Authorization (PA)~~ Tier-3 approval criteria; and
2. An age restriction of 2 years of age to 10 years of age will apply. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Rituxan (Rituximab) and Zimrixby (Rituximab-cdxx) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), and Truxima

(rituximab-abbs) 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.

Saphnelo (Anifrolumab-fnia) Approval Criteria:

1. An FDA approved indication for the treatment of adult patients with moderate-to-severe systemic lupus erythematosus (SLE), who are receiving standard therapy; and
2. Member must be 18 years of age or older; and
3. Documented inadequate response to at least 1 of the following medications appropriate to member's specific disease state:
   a. High-dose oral corticosteroids; or
   b. Methotrexate; or
   c. Azathioprine; or
   d. Mycophenolate; or
   e. Cyclophosphamide; or
   f. Hydroxychloroquine/chloroquine; and
4. Member must not have severe active lupus nephritis (LN) or severe active central nervous system lupus; and
5. Saphnelo will not be approved for combination use with biologic therapies or cyclophosphamide; and
6. For the intravenous (IV) formulation, Saphnelo must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
   a. Must be shipped to the health care facility where the member is scheduled to receive treatment; and
7. 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.

Ustekinumab Non-Preferred (Special Prior Authorization Tier) Products ~~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 a preferred Tier-1 ustekinumab product ~~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.

Xeljanz (Tofacitinib Oral Solution) Approval Criteria:

1. Member must meet ~~Tier-3~~ Tier-2 approval criteria; and
2. An age restriction of 2 years of age to 10 years of age will apply. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

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[1] Johnson & Johnson. FDA Approval of Icotyde (Icotrokinra) Ushers in New Era for First-Line Systemic Treatment of Plaque Psoriasis with a Targeted Oral Peptide. Available online at: https://www.jnj.com/media-center/press-releases/fda-approval-of-icotyde-icotrokinra-ushers-in-new-era-for-first-line-systemic-treatment-of-plaque-psoriasis-with-a-targeted-oral-peptide. Issued 03/18/2026. Last accessed 10/27/2026.

[2] AstraZeneca. Saphnelo Approved in the US for Subcutaneous Self-Administration as a New Autoinjector for the Treatment of Systemic Lupus Erythematosus. Available online at: https://www.astrazeneca.com/media-centre/press-releases/2026/saphnelo-self-administration-approved-in-the-US.html. Issued 04/27/2026. Last accessed 10/27/2026.

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Appendix L

Vote to Prior Authorize Tonmya [Cyclobenzaprine Sublingual (SL) Tablet] and Update the Approval Criteria for the Fibromyalgia Medications

Oklahoma Health Care Authority
November 2026

Market News and Updates[1,2,3]

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

- **August 2025:** The FDA approved Tonmya (cyclobenzaprine SL tablet) for the treatment of fibromyalgia through the 505(b)(2) pathway.

Guidelines:

- **European Alliance of Associations for Rheumatology (EULAR):**
  - In 2016, EULAR published the *EULAR Revised Recommendations for the Management of Fibromyalgia*. Within the guidelines, recommended pharmacological therapy includes low-dose amitriptyline, duloxetine, milnacipran, tramadol, pregabalin, or cyclobenzaprine tablets. Selective serotonin reuptake inhibitors (SSRIs), including fluoxetine, received a "weak against" recommendation for the treatment of fibromyalgia. The evaluated trials demonstrated moderate effects on pain and sleep, but no significant effect on fatigue.

Tonmya (Cyclobenzaprine SL Tablet) Product Summary[4]

Therapeutic Class: Skeletal muscle relaxant

Indication(s): Treatment of fibromyalgia in adults

How Supplied: 2.8mg SL tablet

Dosing and Administration:

- The recommended dose is 5.6mg administered SL once daily at bedtime.
  - Tonmya should be initiated at 2.8mg once daily at bedtime for days 1 through 14, then the dose should be increased to 5.6mg once daily at bedtime.
  - The FDA maximum approved dose is 5.6mg once daily.
- The mouth should be moist before SL administration; therefore, the patient should take sips of water before administration.
- Tonmya should not be swallowed whole, cut, crushed, or chewed.

- The maximum recommended dose for geriatric patients 65 years of age and older is 2.8mg.
- In patients with mild hepatic impairment, the maximum recommended daily dose is 2.8mg. Tonmya is not recommended in patients with moderate or severe hepatic impairment.

Efficacy: The efficacy of Tonmya for fibromyalgia was evaluated in 3 randomized, 2-arm, parallel-group, double-blind, placebo-controlled multicenter trials (Trial 1, Trial 2, and Trial 3). All 3 trials had the same study design and enrolled a total of 1,474 patients.

- Key Inclusion Criteria:
  - 18-65 years of age
  - Diagnosis of fibromyalgia based on the 2016 American College of Rheumatology (ACR) criteria
  - Minimum numeric pain rating scale (NPRS) of 4
- Intervention: Randomized to receive bedtime SL treatment of either of the following:
  - Tonmya 2.8mg nightly for the first 2 weeks, then Tonmya 5.6mg through week 14
  - Placebo administered through week 14
- Primary Outcome: The primary endpoint in all 3 trials was the change from baseline to week 14 in the weekly average of daily 24-hour recall pain intensity scores measured by the 11-point (0-10) NPRS.
- Results: Trials 1 and 3 demonstrated a statistically significant reduction in pain intensity scores when compared to placebo; however, Trial 2 showed no statistically significant treatment difference between Tonmya and placebo. The full results of Trial 2 were not listed in the package insert. The results of Trial 1 and Trial 3 were included and are summarized below.
  - Trial 1:
    - The baseline mean NPRS score [standard deviation (SD)] in the Tonmya group was 6.1 (1.06) and the placebo group was 6.0 (1.08).
    - At week 14, the NPRS score (SD) was 4.2 (0.12) in the Tonmya group with a change from baseline of -1.9 (0.12) and 4.6 (0.12) in the placebo group with a change from baseline of -1.5 (0.12).
    - The difference in least squared (LS)-Mean [Standard Error (SE)] in the change from baseline between groups was -0.4 (0.16), [95% confidence interval (CI): -0.7, -0.1, P=0.010].
  - Trial 3:
    - The baseline mean NPRS score (SD) in the Tonmya group was 5.9 (1.05) and the placebo group was 5.9 (1.08).

- At week 14, the NPRS score (SD) was 4.1 (0.12) in the Tonmya group with a change from baseline of -1.8 (0.12) and 4.7 (0.12) in the placebo group with a change from baseline of -1.2 (0.12).
- The difference in LS-Mean (SE) in the change from baseline between groups was -0.7 (0.16), (95% CI: -1.0, -0.3, P<0.001).

Cost Comparison

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Tonmya (cyclobenzaprine 2.8mg SL tablet)	**$29.59**	**$1,775.40***	**$21,304.80**
cyclobenzaprine 10mg tablet (generic)	$0.02	$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).
SL = sublingual; Unit = tablet
*Cost per 30 days based on the FDA approved maximum dose of 5.6mg per day.
¥Cost per 30 days based on the EULAR guideline maximum recommended dose of 40mg per day.

Recommendations

The College of Pharmacy recommends the following changes to the Fibromyalgia Product Based Prior Authorization (PBPA) category based on guidelines and net cost (changes noted in red in the following Tier chart and approval criteria):

1. The removal of fluoxetine from the Tier-1 medications; and
2. The creation of a Special PA Tier; and
3. The prior authorization of Tonmya (cyclobenzaprine SL tablet) with placement into the Special PA Tier with the following additional criteria.

Fibromyalgia Medications		
Tier-1	**Tier-2**	**Special PA**
amitriptyline	milnacipran (Savella) – **Brand Preferred**	**cyclobenzaprine SL tablet (Tonmya)**
cyclobenzaprine		
duloxetine		
~~**fluoxetine**~~		
pregabalin		
tramadol		

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).
PA = Prior Authorization; SL = sublingual

Fibromyalgia Medications Tier-2 Approval Criteria:

1. Member must have a documented, recent (within the last 6 months) trial of 2 Tier-1 medications (must include 1 trial with duloxetine) at least 3 weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; or

2. Contraindication(s) to all available lower tiered medications; or
3. Current stabilization on a Tier-2 medication; and
4. Savella is brand preferred. Requests for generic milnacipran will require a patient-specific, clinically significant reason why the brand name cannot be used.

Tonmya (Cyclobenzaprine Sublingual Tablet) Approval Criteria:

1. An FDA approved diagnosis of fibromyalgia; and
2. Member must have a documented, recent (within the last 6 months) trial of 3 lower tiered medications (must include 1 trial with cyclobenzaprine tablets) at least 3 weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; and
3. Contraindication(s) to all lower tiered products will be taken into consideration; and
4. For the member's cyclobenzaprine tablet trial, the following information must be provided:
    a. If the member had an improvement in fibromyalgia symptoms, but intolerable adverse effects, please provide detailed information regarding the adverse effects occurring with cyclobenzaprine tablets that are not expected to occur with Tonmya; and
    b. If the member did not have an improvement in fibromyalgia symptoms, please provide clinical justification as to why Tonmya would be expected to confer a different response since it contains the same active ingredient; and
5. Initial approvals will be for 1 month. Subsequent approvals will be for 1 year if the provider documents the member is responding well to treatment; and
6. A quantity limit of 60 tablets for 30 days will apply.

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Appendix M

Vote to Prior Authorize Aqvesme (Mitapivat) and Update the Approval Criteria for the Anemia Medications

Oklahoma Health Care Authority
November 2026

Market News and Updates[1,2]

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

- **December 2025:** The FDA approved Aqvesme for the treatment of anemia in adults with alpha or beta thalassemia. With this approval, Aqvesme becomes the only FDA-approved medication for anemia in both non-transfusion-dependent and transfusion-dependent alpha or beta thalassemia.
- **July 2026:** The FDA approved Casgevy for an age expansion in patients 2 years of age or older with either sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or transfusion-dependent beta thalassemia (TDT). Previously, Casgevy was only FDA approved in patients 12 years of age or older for the same indications.

Aqvesme (Mitapivat) Product Summary[3]

Therapeutic Class: Pyruvate kinase (PK) activator

Indication(s): Treatment of anemia in adults with alpha or beta thalassemia

How Supplied: 100mg oral tablet

Dosing and Administration:

- The recommended dose is 100mg twice daily.
- Treatment with Aqvesme is intended to be long-term and should be discontinued if no benefit in hemolytic anemia has been observed, based on the totality of laboratory results and clinical status of the patient, unless there is another explanation for response failure.
- Baseline liver tests including alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin with fractionation should be assessed before the first Aqvesme dose, every 4 weeks for 24 weeks, and as clinically indicated thereafter.
- See the full *Prescribing Information* for recommendations when drug-induced liver injury is suspected, interruptions due to non-liver causes, and drug interactions.

Efficacy: Aqvesme was studied in 2 randomized, double-blind, placebo-controlled trials, ENERGIZE-T and ENERGIZE, comparing Aqvesme to placebo.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Documented diagnosis of thalassemia [beta thalassemia with or without alpha-globin gene mutations, hemoglobin (Hgb) E/beta thalassemia, or alpha thalassemia/Hgb H disease] based on DNA analysis
  - If taking hydroxyurea, must be on a stable dose for ≥16 weeks
  - ENERGIZE-T:
    - Transfusion dependent, defined as 6-20 red blood cell (RBC) units transfused and ≤6-week transfusion-free period during the 24-week period before randomization
  - ENERGIZE:
    - Non-transfusion-dependent, defined as ≤5 RBC units during the 24-week period before randomization
    - No RBC transfusions ≤8 weeks before providing informed consent
    - No RBC transfusions during the screening period
    - Hgb concentration ≤10g/dL, based on an average of at least 2 Hgb concentration measurements
- Key Exclusion Criteria:
  - Patients with a documented history of homozygous or heterozygous sickle Hgb or Hgb C
  - Prior exposure to gene therapy or prior bone marrow or stem cell transplantation
  - Currently receiving treatment with Reblozyl or hematopoietic stimulating agents
- Intervention(s): Patients were randomized to receive Aqvesme 100mg twice daily or placebo for 48 weeks in ENERGIZE-T and 24 weeks in ENERGIZE.
- Primary Endpoint(s):
  - ENERGIZE-T: Transfusion reduction response defined as ≥50% reduction from baseline in RBC units transfused in any consecutive 12 weeks, with a reduction of at least 2 units
  - ENERGIZE: Hgb response defined as ≥1g/dL increase in average Hgb concentration from week 12–week 24 vs. baseline
- Results:
  - ENERGIZE-T:
    - Transfusion reduction response was achieved by 52 patients in the Aqvesme group vs. 11 for placebo [adjusted rate

difference: 17.6%; 95% confidence interval (CI): 8, 27.2; P=0.0003].

- ENERGIZE:
  - Hgb response was achieved by 55 patients in the Aqvesme group vs. 1 for placebo (adjusted rate difference: 40.9%; 95% CI: 32, 49.8; P<0.0001).

Cost: The Wholesale Acquisition Cost (WAC) of Aqvesme is $599.79 per tablet. This would result in an estimated cost of $33,588.24 per 28 days or $436,647.12 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Aqvesme (mitapivat) with the following criteria and recommends updating the Reblozyl (luspatercept-aamt) approval criteria based on the FDA approval of Aqvesme (changes shown in red):

Aqvesme (Mitapivat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia with alpha or beta thalassemia; and
2. Member must be 18 years of age or older; and
3. Member must have 1 of the following:
   a. A baseline hemoglobin (Hgb) level of ≤10g/dL; or
   b. Transfusion-dependent thalassemia requiring regular red blood cell (RBC) transfusions as defined by the following:
      i. Member has received at least 6 RBC units within the preceding 24 weeks; and
      ii. Member has not had any transfusion-free period >35 days within the preceding 24 weeks; and
4. Aqvesme must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of alpha or beta thalassemia (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating alpha or beta thalassemia); and
5. Member must not have liver cirrhosis; and
6. Prescriber must evaluate the potential for drug interactions, including the need for increased monitoring according to package labeling, prior to and during treatment with Aqvesme; and
7. For transfusion-dependent beta thalassemia, member must not have previously received treatment with Zynteglo (betibeglogene autotemcel) or Casgevy (exagamglogene autotemcel); and
8. Aqvesme will not be approved for concomitant use with Reblozyl (luspatercept-aamt); and

9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year if the provider documents the member is responding well to therapy (i.e., reduction in number of transfusions or RBC units, Hgb increase, improvements in quality of life or clinical status); and
10. Aqvesme should be discontinued in members who do not show evidence of therapeutic benefit in hemolytic anemia.

Reblozyl (Luspatercept-aamt) Approval Criteria [Beta Thalassemia Diagnosis]:

1. An FDA approved indication for the treatment of adult members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must require regular RBC transfusions (no transfusion-free period >35 days during the prior 6-month period); and
3. Member must not have previously received treatment with Zynteglo (betibeglogene autotemcel) or Casgevy (exagamglogene autotemcel); and
4. Reblozyl will not be approved for concomitant use with Aqvesme (mitapivat); and
5. Reblozyl must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of beta thalassemia (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating beta thalassemia); and
6. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl administration; and
7. Prescriber must verify Reblozyl will be administered by a trained health care provider; and
8. A recent (within the last 3 months) 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. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
10. Initial approvals will be for the duration of 4 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.25mg/kg (allows for initial dosing of 6 weeks at 1mg/kg). Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the Casgevy (exagamglogene autotemcel) and Zynteglo (betibeglogene autotemcel)

approval criteria based on the approval of Aqvesme (mitapivat) and the FDA approved age expansion for Casgevy (changes shown in red):

Casgevy (Exagamglogene Autotemcel) Approval Criteria [Sickle Cell Disease (SCD) Diagnosis]:

1. An FDA approved diagnosis of SCD with recurrent vaso-occlusive crises (VOCs); and
2. Member must be 2 ~~12~~ years of age or older; and
3. Member must have evidence of severe disease as demonstrated by 1 of the following (based on prescriber attestation):
   a. ≥2 severe VOCs per year in the last 2 years; or
   b. Currently receiving chronic transfusion therapy for recurrent VOCs; and
4. Casgevy must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Casgevy; and
5. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Lyfgenia (lovotibeglogene autotemcel); and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Casgevy); and
11. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
12. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy administration; and
14. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy; and
15. Prescriber must verify male and female 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; and

16. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy; and
17. Casgevy must be administered at a Casgevy authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Casgevy (Exagamglogene Autotemcel) Approval Criteria [Transfusion-Dependent Beta Thalassemia (TDT) Diagnosis]:

1. An FDA approved diagnosis of TDT; and
2. Member must be 2 ~~12~~ years of age or older; and
3. Member must require regular red blood cell (RBC) transfusions as demonstrated by the following:
   a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
   b. 10 units of packed RBCs per year in the last 2 years; and
4. Casgevy must be prescribed by a hematologist with expertise in the treatment of TDT and the administration of Casgevy; and
5. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
6. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
7. Member must not have previously received treatment with Zynteglo (betibeglogene autotemcel); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to 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 Casgevy); and
10. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy administration; and
11. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy; and
12. Prescriber must verify male and female 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; and
13. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy; and

14. Member will not be approved for treatment with Reblozyl (luspatercept-aamt) or Aqvesme (mitapivat) following Casgevy infusion (current authorizations for luspatercept-aamt or mitapivat will be discontinued upon Casgevy approval); and
15. Casgevy must be administered at a Casgevy authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy dose from receipt to storage to administration; and
16. Approvals will be for 1 dose per member per lifetime.

Zynteglo (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must be 4 years of age or older; and
3. Member must weigh ≥6kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
    a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
    b. ≥8 transfusions of packed RBCs per year in the last 2 years; and
5. Zynteglo must be prescribed by a hematologist or transplant specialist with expertise in the treatment of beta thalassemia and the administration of Zynteglo; and
6. Member must not have a known and available human leukocyte antigen (HLA) fully-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Casgevy (exagamglogene autotemcel) for the transfusion-dependent beta thalassemia (TDT) indication; and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Zynteglo); and
11. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo administration; and
12. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Zynteglo; and
13. Prescriber must verify male and female 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; and
14. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo; and
15. Member will not be approved for treatment with Reblozyl (luspatercept-aamt) or Aqvesme (mitapivat) following Zynteglo infusion (current authorizations for luspatercept-aamt or mitapivat will be discontinued upon Zynteglo approval); and
16. 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 Zynteglo, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
17. Zynteglo must be administered at a Zynteglo qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zynteglo dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Finally, the College of Pharmacy recommends updating the Siklos (hydroxyurea tablets) and Xromi (hydroxyurea oral solution) approval criteria for clarity (changes shown in red):

Siklos (Hydroxyurea Tablets) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Member must be 2 years of age or older; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. A trial of hydroxyurea capsules or a patient-specific, clinically significant reason why hydroxyurea capsules are not appropriate for the member must be provided; and
5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling; and
6. ~~Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and~~
7. ~~Prescriber must agree to monitor the member for the development of secondary malignancies; and~~
8. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
9. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Siklos for at least 6 months after therapy; and

10. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Xromi (Hydroxyurea Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Xromi will not require a prior authorization for members 6 years of age and younger. For members 7 years of age and older, a patient-specific, clinically significant reason why the member cannot use hydroxyurea capsules or tablets must be provided; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling; and
5. ~~Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and~~
6. ~~Prescriber must agree to monitor the member for the development of secondary malignancies; and~~
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Xromi for at least 6 months after therapy; and
9. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

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[1] Agios Pharmaceuticals. U.S. FDA Approves Agios' Aqvesme (Mitapivat) for the Treatment of Anemia in Adults with Alpha- or Beta-Thalassemia. Available online at: https://investor.agios.com/news-releases/news-release-details/us-fda-approves-agios-aqvesmetm-mitapivat-treatment-anemia. Issued 12/23/2025. Last accessed 10/20/2026.

[2] U.S. Food and Drug Administration (FDA). FDA Approves First Gene Therapy for Young Children with Sickle Cell Disease. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-young-children-sickle-cell-disease. Issued 07/01/2026. Last accessed 10/20/2026.

[3] Aqvesme (Mitapivat) Prescribing Information. Agios. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/216196Orig1s003lbl.pdf. Last revised 12/2025. Last accessed 10/20/2026.

Appendix N

Fiscal Year 2026 Annual Review of Rhapsido (Remibrutinib)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

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) the following:
    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. 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.

Utilization of Rhapsido (Remibrutinib): Fiscal Year 2026

Fiscal Year 2026 Utilization: Pharmacy Claims (All Plans)

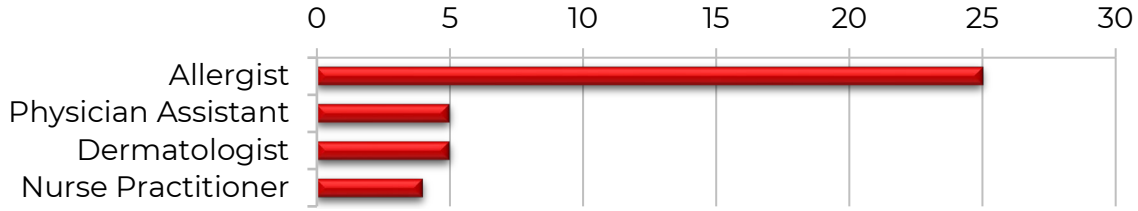
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2026							
FFS	2	2	$9,064.82	$4,532.41	$151.08	120	60
Aetna	5	11	$49,069.97	$4,460.91	$148.70	660	330
Humana	5	18	$80,396.10	$4,466.45	$148.88	1,080	540
OCH	4	8	$36,259.28	$4,532.41	$151.08	480	240
2026 Total	**16**	**39**	**$174,790.17**	**$4,481.80**	**$149.39**	**2,340**	**1,170**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; N/A = not applicable; OCH = Oklahoma Complete Health
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Demographics of Members Utilizing Rhapsido (Remibrutinib): Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing Rhapsido (remibrutinib) during fiscal year 2026, detailed demographic information could not be provided.

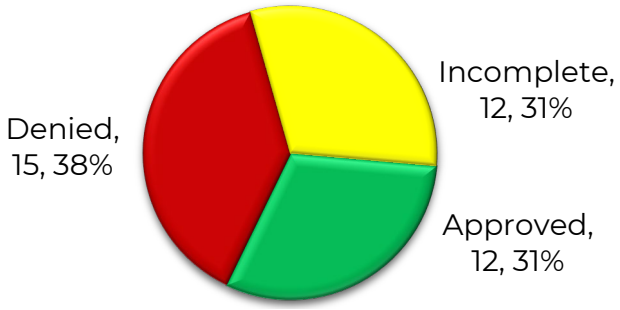
Top Prescriber Specialties of Rhapsido (Remibrutinib): by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Rhapsido (Remibrutinib)

There 39 prior authorization requests submitted for Rhapsido (remibrutinib) during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	2	17%	6	50%	4	33%	**12**
Aetna	4	57%	0	0%	3	43%	**7**
Humana	3	38%	3	38%	2	25%	**8**
OCH	3	25%	3	25%	6	50%	**12**
Total	**12**	**31%**	**12**	**31%**	**15**	**38%**	**39**

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

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

Anticipated Patent Expiration(s):

- Rhapsido (remibrutinib tablets): December 2043

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

- **October 2026:** The FDA approved Rhapsido (remibrutinib) for a new indication for the treatment of symptomatic dermographism (SD) in adults inadequately controlled by histamine-1 (H1) antihistamines. SD is a form of chronic inducible urticaria (CindU) characterized by itching and/or burning skin and the development of itchy wheals due to shearing forces on the skin. First line therapy for SD is trigger avoidance and nonsedating second-generation H1 antihistamines which may be increased up to 4 times the recommended dose in patients who do not obtain complete control with the typical FDA approved dosing. The approval was based on data from the SD cohort of the Phase 3 RemIND trial in patients who remained symptomatic on second-generation H1 antihistamines. Rhapsido demonstrated higher rates of complete response from hives compared to placebo as measured by the Total Fric Score. At week 12, 29.3% of patients on Rhapsido vs. 14% on placebo achieved complete response from hives [treatment difference: 15; 95% confidence interval (CI): 0.3, 29.7; P=0.0229].

Guideline Updates:

- **International Guideline for Urticaria Update:** The *International Guideline for the Definition, Classification, Diagnosis, and Management of Urticaria* was updated in February 2026. Some notable updates include:
  - Patients should be assessed for disease activity, impact, and control at all visits using validated Patient-Reported Outcome Measures (PROMs) such as the urticaria activity score (UAS), angioedema activity score (AAS), chronic urticaria quality of life questionnaire (CU-Q2oL), angioedema quality of life questionnaire (AE-QoL), urticaria control test (UCT), and angioedema control test (AECT).

    - The UCT was developed and validated to determine the level of disease control in all forms of chronic urticaria (CSU and CIndU). It is a simple 4-item tool with a clearly defined cut off for patients with "well-controlled" vs. "poorly controlled" disease, and it is thus suited for the management of patients in routine clinical practice.
- Treatment should follow the basic principles of treating as much as needed and as little as possible, taking into consideration that the activity of the disease may vary. This implies stepping up or stepping down in the treatment algorithm according to the course of disease. It is important to highlight that patients need good counseling regarding continuous treatment and using PROMs, especially about using the UAS.
- First line treatment for all types of urticaria continues to be a second-generation H1 antihistamine and then dosing up to 4-fold in patients with chronic urticaria unresponsive to a standard-dosed second-generation H1 antihistamine as second-line treatment before other treatments are considered.
- For patients who are unresponsive to high doses of second-generation H1 antihistamines, the following are recommended: omalizumab (strong recommendation), dupilumab (conditional recommendation), or remibrutinib (conditional recommendation).

Recommendations

The College of Pharmacy recommends the following changes to the Rhapsido (remibrutinib) approval criteria based on the new FDA approved indication and clinical practice (changes shown in red):

Rhapsido (Remibrutinib) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Chronic spontaneous urticaria (CSU); and
        i. Member must have an Urticaria Activity Score (UAS) ≥16; or
    b. Symptomatic dermographism (SD); and
        i. Member has a positive response to provocation testing, defined as the presence of a pruritic palpable wheal within 10 minutes of provocation; and
        ii. Numerical rating score (NRS) of ≥5 for itch; and
2. Member must be 18 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. 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

5. Member must have a documented trial of (or have a contraindication or documented intolerance to) the following:
    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
6. 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 or NRS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

Utilization Details of Rhapsido (Remibrutinib): Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RHAPSIDO TAB 25MG	39	16	$174,790.17	$4,481.80	2.44	100%
TOTAL	**39**	**16***	**$174,790.17**	**$4,481.80**	**2.44**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[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 10/2026. Last accessed 10/20/2026.
[2] Novartis. Novartis Rhapsido (Remibrutinib) Receives FDA Approval as First Treatment for Symptomatic Dermographism (SD), Expanding Its Use Beyond Chronic Spontaneous Urticaria (CSU). Available online at: https://www.novartis.com/news/media-releases/novartis-rhapsido-remibrutinib-receives-fda-approval-first-treatment-symptomatic-dermographism-sd-expanding-its-use-beyond-chronic-spontaneous-urticaria-csu. Issued 10/07/2026. Last accessed 10/20/2026.
[3] Magerl M, Altrichter S, Borzova E, et al. The Definition, Diagnostic Testing, and Management of Chronic Inducible Urticarias – The EAACI/GA2LEN/EDF/UNEV Consensus Recommendations 2016 Update and Revision. *Allergy* 2016; 71: 780–802. doi: 10.1111/all.12884.
[4] Rhapsido (Remibrutinib) Prescribing Information. Novartis. Available online at: https://www.novartis.com/us-en/sites/novartis_us/files/rhapsido.pdf. Last revised 10/2026. Last accessed 10/20/2026.
[5] Zuberbier T, Ansari Z, Latiff A, et al. The International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria. *Allergy* 2026; 81: 2582-2632. doi: 10.1111/all.70210.

Appendix O

Fiscal Year 2026 Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Sarclisa Escena (Isatuximab-irfc) and Zenbexus (Iberdomide)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

Utilization data for Venclexta (venetoclax) and approval criteria for indications other than multiple myeloma can be found in the March 2026 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the leukemia and lymphoma medications.

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 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
3. Approvals will be for 1 dose per member per lifetime.

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.

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.

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 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
3. Approvals will be for 1 dose per member per lifetime.

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

1. Relapsed/refractory light chain amyloidosis; 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. 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.

Elrexfio (Elranatamab-bcmm) 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. 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.

Empliciti (Elotuzumab) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of previously treated multiple myeloma with relapsed or progressive disease; and
2. Used in combination with 1 of the following regimens:
    a. Lenalidomide and dexamethasone in members who have received 1 to 3 prior therapies; or
    b. Bortezomib and dexamethasone; or
    c. Pomalidomide and dexamethasone in members who have received ≥2 prior therapies, including an immunomodulatory agent and a proteasome inhibitor (PI).

Hemady (Dexamethasone 20mg Tablet) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use dexamethasone 4mg tablets to achieve the required dose in place of Hemady must be provided.

IVRA (Melphalan 90mg/mL) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason why the member cannot use generic melphalan 50mg/10mL vial which is available without a prior authorization.

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.

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.

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

1. Diagnosis of multiple myeloma; and
    a. As primary therapy; and
        i. Used in combination with bortezomib, lenalidomide, and dexamethasone; 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
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 received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; 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 received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; 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.

Venclexta (Venetoclax) Approval Criteria [Multiple Myeloma Diagnosis]

1. Diagnosis of relapsed or progressive multiple myeloma and
2. Presence of t(11;14) translocation; and
3. In combination with dexamethasone; or
4. In combination with dexamethasone and daratumumab; or
5. In combination with dexamethasone and either bortezomib, carfilzomib, or ixazomib.

Xpovio (Selinexor) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed/refractory DLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma; and
2. Member has received ≥2 prior lines of systemic therapy.

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.

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 Multiple Myeloma Medications: Fiscal Year 2026

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 2025							
FFS	2	2	$26,357.32	$13,178.66	$470.67	6	56
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	1	1	$66.37	$66.37	$66.37	2	1
OCH	0	0	$0.00	$0.00	$0.00	0	0
2025 Total	**3**	**3**	**$26,423.69**	**$8,807.90**	**$463.57**	**8**	**57**
Fiscal Year 2026							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2026 Total	**0**	**0**	**$0.00**	**$0.00**	**$0.00**	**0**	**0**
% Change	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**
Change	**-3**	**-3**	**-$26,423.69**	**-$8,807.90**	**-$463.57**	**-8**	**-57**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Medical Claims (All Plans)

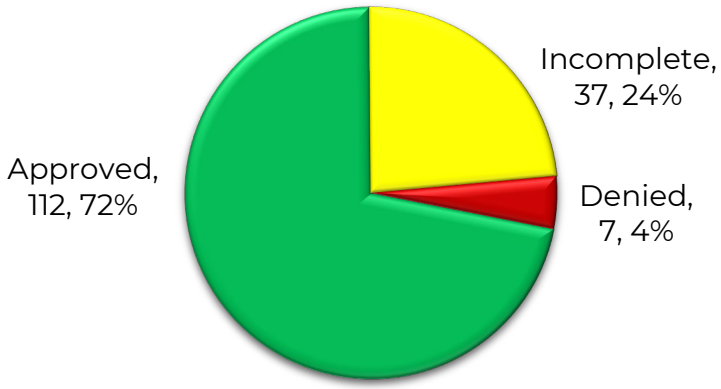
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	40	737	$2,650,753.29	$3,596.68	18.43
Aetna	4	31	$75,166.97	$2,424.74	7.75
Humana	8	149	$366,930.98	$2,462.62	18.63
OCH	8	141	$349,673.06	$2,479.95	17.63
2025 Total	**57**	**1,058**	**$3,442,524.30**	**$3,253.80**	**18.56**
Fiscal Year 2026					
FFS	41	504	$3,526,123.46	$6,996.28	12.29
Aetna	7	48	$208,435.84	$4,342.41	6.86
Humana	11	140	$599,471.65	$4,281.94	12.73
OCH	17	389	$1,479,964.76	$3,804.54	22.88
2026 Total	**61**	**1,081**	**$5,813,995.71**	**$5,378.35**	**17.72**
% Change	**7.02%**	**2.17%**	**68.89%**	**65.29%**	**-4.53%**
Change	**4**	**23**	**$2,371,471.41**	**$2,124.55**	**-0.84**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Prior Authorization of Multiple Myeloma Medications

There were 156 prior authorization requests submitted for multiple myeloma medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	63	68%	27	29%	2	2%	**92**
Aetna	0	0%	2	50%	2	50%	**4**
Humana	23	88%	3	12%	0	0%	**26**
OCH	26	76%	5	15%	3	9%	**34**
Total	**112**	**72%**	**37**	**24%**	**7**	**4%**	**156**

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

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

Anticipated Patent Expiration(s):

- Ninlaro (ixazomib): November 2029
- Xpovio (selinexor): August 2035
- IVRA (melphalan): June 2036
- Hemady (dexamethasone): December 2037
- Zenbexus (iberdomide): September 2039

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

- **January 2026:** The FDA approved Darzalex Faspro (daratumumab/hyaluronidase-fihj) for a new indication, in combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- **March 2026:** The FDA approved Tecvayli (teclistamab-cqyv) for a new indication, in combination with daratumumab/hyaluronidase-fihj, for

the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.

- **July 2026:** The FDA approved Sarclisa Escena (isatuximab-irfc), a new subcutaneous (sub-Q) formulation of isatuximab, for the treatment of 3 different multiple myeloma indications. Sarclisa (isatuximab-irfc) was previously only available as an intravenous (IV) formulation.
- **August 2026:** The FDA granted accelerated approval to Zenbexus (iberdomide), in combination with daratumumab/hyaluronidase-fihj and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for systemic light chain amyloidosis allow for the use of elranatamab and isatuximab in relapsed/refractory light chain amyloidosis as a single agent.
- The NCCN guidelines for multiple myeloma allow for the use of talquetamab in combination with daratumumab and dexamethasone with or without pomalidomide in those who have received at least 1 prior line of therapy.
- The NCCN guidelines for multiple myeloma recommend a lower category for ixazomib when used as a single agent in maintenance therapy following response to primary therapy or hematopoietic cell transplant.
- The NCCN guidelines for multiple myeloma allow the use of Abecma (idecabtagene vicleucel) and Carvykti (ciltacabtagene autoleucel) in relapsed/refractory disease after 1-3 prior therapies without any specific requirements for assessing measurable disease.

Sarclisa Escena (Isatuximab-irfc) Product Summary[8]

Therapeutic Class: CD38-directed cytolytic antibody

Indication(s):

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy

- In combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant

How Supplied: 1,400mg/10mL (140mg/mL) solution in a single-dose vial (SDV)

Dosing and Administration:

- The recommended dose is 1,400mg administered as a sub-Q injection with the CirCLIQ On-Body Delivery System (OBDS) or with a syringe and infusion set for manual administration, in combination with pomalidomide and dexamethasone, in combination with carfilzomib and dexamethasone, or in combination with bortezomib, lenalidomide, and dexamethasone.
- See the full *Prescribing Information* for the recommended dosing frequency, which depends on the cycle and which concomitant medications are being administered.

Cost: The Wholesale Acquisition Cost (WAC) is $8,796 per SDV. The recommended dosing frequency varies depending on the concomitant medications used. For a member receiving a dose on days 1 and 15 of each 28-day cycle, this would result in an estimated cost of $17,592 per 28 days or $228,696 per year based on recommended dosing.

Zenbexus (Iberdomide) Product Summary[9]

Therapeutic Class: Cereblon-modulating protein degrader

Indication(s): Treatment, in combination with daratumumab/hyaluronidase-fihj and dexamethasone, of adult patients with multiple myeloma who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent

- This indication is approved under accelerated approval based on minimal residual disease (MRD)-negative complete response (CR) at any time. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

How Supplied: 0.75mg and 1mg oral capsules

Dosing and Administration: The recommended dosage is 1mg orally once daily with or without food on days 1 to 21 of a 28-day cycle, until disease progression or unacceptable toxicity, in combination with daratumumab/ hyaluronidase-fihj and dexamethasone.

Cost: The WAC is $1,404.76 per capsule. This would result in an estimated cost of $29,499.96 per 28 days or $383,499.48 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Zenbexus (iberdomide) with the following criteria (shown in red):

Zenbexus (Iberdomide) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
2. Member has received ≥1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent; and
3. Used in combination with daratumumab/hyaluronidase-fihj and dexamethasone; and
4. Member is 18 years of age or older.

The College of Pharmacy also recommends the prior authorization of Sarclisa Escena (isatuximab-irfc) with criteria similar to Sarclisa (isatuximab-irfc) for a diagnosis of multiple myeloma, with additional updates based on NCCN guideline recommendations (shown in red):

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

1. Diagnosis of multiple myeloma; and
    a. As primary therapy; and
        i. Used in combination with bortezomib, lenalidomide, and dexamethasone; 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
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; or
        iii. Used in combination with lenalidomide and dexamethasone if bortezomib refractory.

Sarclisa (Isatuximab-irfc) Approval Criteria [Light Chain Amyloidosis Diagnosis]:

1. Diagnosis of relapsed or refractory light chain amyloidosis; and
2. Used as a single agent.

Next, the College of Pharmacy recommends updating the approval criteria for Tecvayli (teclistamab-cqyv) based on recent FDA approvals (changes shown in red):

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 in combination with daratumumab in those who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent; or
    b. Used as a single agent in those who have received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; and
    c. Used in combination with talquetamab-tgvs in those who have received at least 3 prior lines of therapy; or
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.

Next, the College of Pharmacy recommends updating the approval criteria for Darzalex (daratumumab) and Darzalex Faspro (daratumumab/ hyaluronidase-fihj) based on recent FDA approvals and 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; 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; and
3. For Darzalex Faspro, member must not have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB disease.

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
        iii. Bortezomib, lenalidomide, and dexamethasone; 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
    iii. Cyclophosphamide, bortezomib, lenalidomide, and dexamethasone and member has high risk disease or plasma cell leukemia (PCL); 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. For relapsed or refractory disease 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
    viii. Iberdomide and dexamethasone; or
    ix. Teclistamab-cqyv (if prior therapy included a proteasome inhibitor and an immunomodulatory agent); or
    x. Talquetamab-tgvs and dexamethasone, with or without pomalidomide; 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.

Next, the College of Pharmacy recommends updating the approval criteria for Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel), Elrexfio (elranatamab-bcmm), Ninlaro (ixazomib), and Talvey (talquetamab-tgvs) based on NCCN recommendations (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~~ ≥1 prior line~~s~~ 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 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
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); and
    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 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
3. Approvals will be for 1 dose per member per lifetime.

Elrexfio (Elranatamab-bcmm) Approval Criteria [Light Chain Amyloidosis Diagnosis]:

1. Diagnosis of relapsed or refractory light chain amyloidosis; and
2. 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.

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.~~

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 received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; or
   b. Used in combination with teclistamab-cgyv in those who have received at least 3 prior lines of therapy; ~~and~~ or

c. Used in combination with daratumumab and dexamethasone, with or without pomalidomide, in those who have received at least 1 prior line 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.

Utilization Details of Multiple Myeloma Medications: Fiscal Year 2026

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9041 BORTEZOMIB INJ	484	34	$20,400.94	$42.15	14.24
J9144 DARATUM/HYALURON INJ	405	51	$3,954,305.13	$9,763.72	7.94
J9145 DARATUMUMAB INJ	86	3	$287,113.14	$3,338.52	28.67
J3055 TALQUETAMAB-TGVS INJ	57	2	$827,994.24	$14,526.21	28.5
J9380 TECLISTAMAB-CQYV INJ	31	2	$251,898.70	$8,125.76	15.5
J9227 ISATUXIMAB-IRFC INJ	16	1	$92,820.00	$5,801.25	16
Q2056 CILTACABTAGENE AUTOLEUCEL	1	1	$374,251.96	$374,251.96	1
J9246 MELPHALAN (EVOMELA) INJ	1	1	$5,211.60	$5,211.60	1
TOTAL	**1,081**	**61**	**$5,813,995.71**	**$5,378.35**	**17.72**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated members.
DARATUM/HYALURON = daratumumab/hyaluronidase; INJ = injection
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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[4] U.S. FDA. FDA Approves Isatuximab-irfc for Subcutaneous Injection for Multiple Myeloma Indications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-isatuximab-irfc-subcutaneous-injection-multiple-myeloma-indications. Issued 07/09/2026. Last accessed 10/20/2026.
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Appendix P

Fiscal Year 2026 Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Adquey (Difamilast 1% Ointment)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

Approval criteria for Dupixent (dupilumab injection) for indications other than AD can be found in the Fiscal Year 2026 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications report, which is also being presented at the November 2026 Drug Utilization Review (DUR) Board meeting. Dupixent is reviewed annually with the asthma and COPD maintenance medications. However, utilization data for Dupixent is included in this report due to significant use for AD. Utilization data for Rinvoq (upadacitinib) and approval criteria for indications other than AD can be found in the October 2026 DUR Board packet. This medication and criteria are reviewed annually with the targeted immunomodulator agents.

Adbry (Tralokinumab-ldrm Injection) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be:
    a. 12 years of age or older for use of the prefilled syringe; or
    b. 18 years of age or older for use of the autoinjector; and
3. Member must have a documented trial 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'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
5. Adbry 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. Requests for concurrent use of Adbry with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Adbry has not been studied in combination with other biologic therapies); and
7. Initial approvals will be for the duration of 16 weeks. 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.

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.

Cibinqo (Abrocitinib) and Rinvoq (Upadacitinib) Approval Criteria [Atopic Dermatitis (AD) Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
2. For Cibinqo, member must be 12 years of age or older; and
3. For Rinvoq, member must be 12 years of age or older; and
4. Member must have a documented trial 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
5. Member must have a documented 16-week trial with an FDA approved biologic medication for atopic dermatitis that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. 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
7. Requested medication 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. For Cibinqo, prescriber must verify the member will not use antiplatelet therapies (e.g., clopidogrel, prasugrel, ticagrelor) concurrently with Cibinqo, except for low-dose aspirin, during the first 3 months of treatment; and
9. Cibinqo and Rinvoq will not be approved for use in combination with other Janus kinas (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
10. For Rinvoq, a patient-specific, clinically significant reason why the member cannot use Cibinqo must be provided; and
11. 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. Additionally, compliance will be evaluated for continued approval; and
12. For Rinvoq, the maximum approvable dose for AD is 30mg once daily.

Dupixent (Dupilumab Injection) 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 6 months 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 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'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
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. 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
7. Initial approvals will be for the duration of 16 weeks. 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.

Ebglyss (Lebrikizumab-lbkz) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be 12 years of age or older and weigh ≥40kg; 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'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
5. 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. Requests for concurrent use of Ebglyss with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Ebglyss has not been studied in combination with other biologic therapies); and
7. Initial approvals will be for a quantity limit override for the initial dosing for the duration of 16 weeks; and
8. Reauthorization may be granted for the maintenance dosing of 250mg every 4 weeks for a duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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. 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.

Eucrisa (Crisaborole Ointment) Approval Criteria:

1. An FDA approved indication for treatment of mild-to-moderate atopic dermatitis (eczema); and

2. Member must be at least 3 months of age or older; and
3. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with a topical corticosteroid or topical calcineurin inhibitor (or have a contraindication or documented intolerance); and
4. A quantity limit of 1 tube per 30 days will apply; 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. Clinical exceptions for the trial requirement may be considered for the following:
    a. Documented adverse effect, drug interaction, or contraindication to topical corticosteroids; or
    b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids; or
7. Clinical exceptions for the age restriction (for members younger than the FDA approved age) may be considered for the following:
    a. Prescribed by a dermatologist.

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. 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

7. 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
8. Initial approvals will be for the initial dosing for the duration of 16 weeks; and
9. 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.

Nemluvio (Nemolizumab-ilto) Approval Criteria [Prurigo Nodularis (PN) Diagnosis]:

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have severe pruritus as defined by a Peak Pruritus Numeric Rating Scale (PP-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. 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. A patient-specific, clinically significant reason why the member cannot use Dupixent (dupilumab) must be provided; and
9. 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
10. The member's recent weight must be provided, and approval quantities will be based on the FDA approved dosing regimen; and

11. Initial approvals will be for the duration of 16 weeks. Reauthorization (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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 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 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); or
    b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]; 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.

Opzelura (Ruxolitinib 1.5% Cream) Approval Criteria [Nonsegmental Vitiligo Diagnosis]:

1. An FDA approved indication of nonsegmental vitiligo; and
2. The member's body surface area (BSA) involvement must be provided and must be ≤10%; and
3. Member must be 12 to 20 years of age; and

4. Member must have documented trials within the last 6 months for a minimum of 12 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 (used continuously or intermittently); and
    b. 1 topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]; and
5. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and
6. Prescriber must verify female members are not breastfeeding; and
7. 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
8. Initial approvals will be for a duration of 24 weeks of treatment; and
9. Reauthorization for an additional 28 weeks of treatment (to complete 1 year of treatment) may be considered if the prescriber documents both of the following:
    a. The member had a positive response to and tolerated previous treatment with Opzelura; and
    b. The member has been evaluated by the prescriber and continues to require treatment with Opzelura; and
10. Further approval beyond 1 year of treatment will require patient-specific, clinically significant information to support the member's need for additional treatment.

Prudoxin and Zonalon (Doxepin Cream) Approval Criteria:

1. An FDA approved indication for the short-term (up to 8 days) management of moderate pruritus in members with atopic dermatitis or lichen simplex chronicus; and
2. Requests for longer use than 8 days will not generally be approved. Chronic use beyond 8 days may result in higher systemic levels and should be avoided.

Vtama (Tapinarof 1% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of atopic dermatitis; and
2. Member must be 2 years of age or older; and
3. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); 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 2 months. 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.

Vtama (Tapinarof 1% Cream) Approval Criteria [Plaque Psoriasis Diagnosis]:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 18 years of age or older; and
3. Member must have a body surface area (BSA) involvement of ≤20%; and
4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. 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
6. 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
7. A quantity limit of 60 grams per 30 days will apply.

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. 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
3. 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

4. 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
5. 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. 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
3. Member must have a body surface (BSA) involvement of ≤20% (or ≤25% if both the scalp and body are being treated); and
4. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
5. 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
6. 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
7. 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. 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

7. 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
8. 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
9. A quantity limit of 60 grams per 30 days will apply.

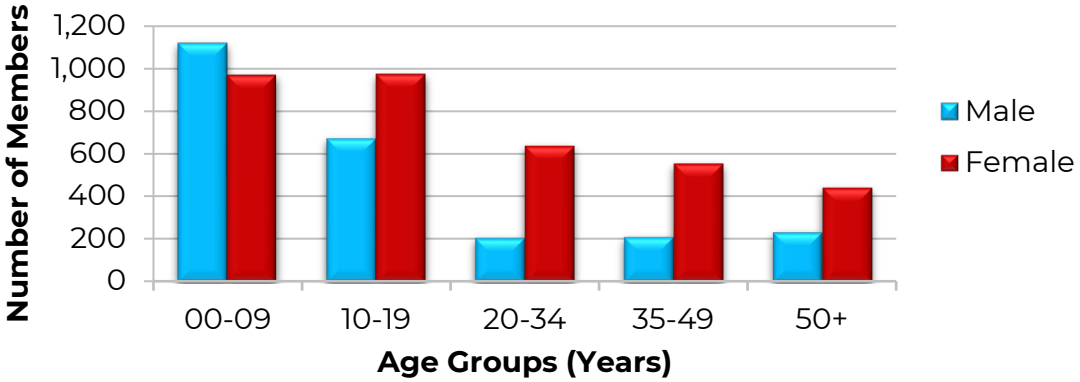
Utilization of AD Medications: Fiscal Year 2026

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

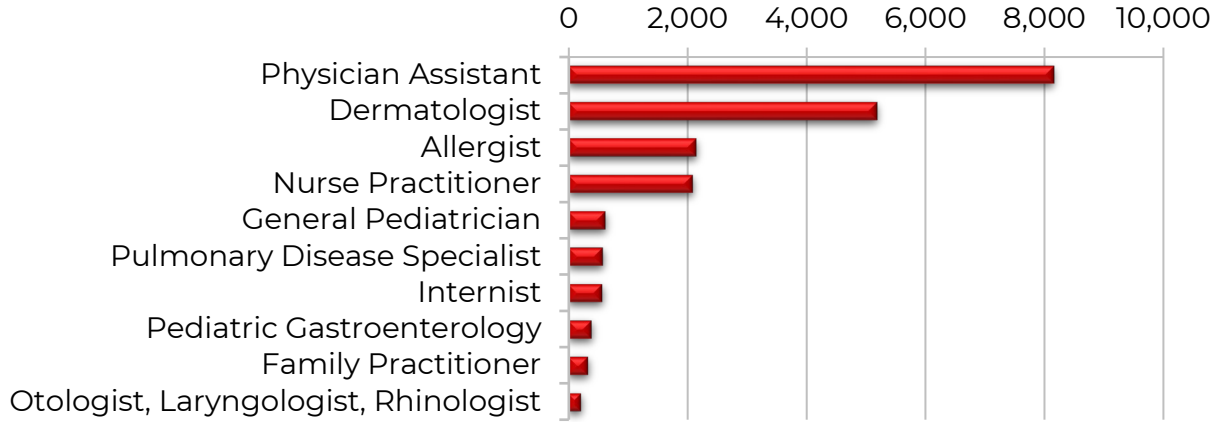
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	1,552	5,080	$14,038,981.95	$2,763.58	$87.24	92,195	160,925
Aetna	1,254	3,807	$9,179,706.81	$2,411.27	$81.10	96,518	113,185
Humana	1,303	4,384	$11,274,567.96	$2,571.75	$88.72	102,746	127,084
OCH	1,114	3,507	$9,159,883.47	$2,611.89	$82.46	75,441	111,089
2025 Total	**4,903**	**16,778**	**$43,653,140.19**	**$2,601.81**	**$85.21**	**366,900**	**512,283**
Fiscal Year 2026							
FFS	1,777	5,808	$16,874,332.58	$2,905.36	$92.10	111,263	183,212
Aetna	1,476	4,668	$12,227,256.69	$2,619.38	$86.08	115,750	142,040
Humana	1,630	5,431	$14,304,773.54	$2,633.91	$88.83	138,348	161,032
OCH	1,488	4,874	$13,606,340.18	$2,791.62	$88.83	104,465	153,177
2026 Total	**6,011**	**20,781**	**$57,012,702.99**	**$2,743.50**	**$89.16**	**469,827**	**639,461**
% Change	**22.60%**	**23.90%**	**30.60%**	**5.40%**	**4.60%**	**28.10%**	**24.80%**
Change	**1,108**	**4,003**	**$13,359,562.80**	**$141.69**	**$3.95**	**102,927**	**127,178**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Utilization data includes products used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.

Demographics of Members Utilizing AD Medications (All Plans)



Top Prescriber Specialties of AD Medications by Number of Claims (All Plans)



Prior Authorization of AD Medications

There were 7,847 prior authorization requests submitted for AD medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	1,347	39%	1,488	43%	650	19%	**3,485**
Aetna	910	55%	215	13%	516	31%	**1,641**
Humana	677	73%	81	9%	166	18%	**924**
OCH	960	53%	340	19%	497	28%	**1,797**
Total	**3,894**	**50%**	**2,124**	**27%**	**1,829**	**23%**	**7,847**

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

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

Anticipated Patent Expiration(s):

- Eucrisa (crisaborole): July 2030
- Anzupgo (delgocitinib 2% cream): September 2031
- Cibinqo (abrocitinib): January 2036
- Adquey (difamilast 1% ointment): December 2036
- Zoryve (roflumilast cream): June 2037
- Vtama (tapinarof 1% cream): December 2039
- Opzelura (ruxolitinib): May 2041
- Zoryve (roflumilast 0.3% foam): August 2042

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

- **February 2026:** The FDA approved Adquey (difamilast 1% ointment) for the topical treatment of adults and pediatric patients 2 years of age and older with mild to moderate atopic dermatitis.
- **June 2026:** The FDA approved Ebglyss (lebrikizumab-lbkz) for an updated maintenance dosing regimen. The maintenance dose of 250mg may now be administered every 4 or 8 weeks. Previously, the recommended maintenance dose was 250mg every 4 weeks.
- **June 2026:** The FDA approved Zoryve (roflumilast 0.3% cream) for an age expansion for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 2 years of age and older. Previously, Zoryve 0.3% cream was approved for use in patients 6 years of age and older with this indication.

Adquey (Difamilast 1% Ointment) Product Summary[5]

Therapeutic Class: Phosphodiesterase 4 (PDE-4) inhibitor

Indication(s): Topical treatment of mild-to-moderate atopic dermatitis in patients 2 years of age and older

How Supplied: 1% ointment (10mg difamilast per gram) in 85g tubes

Dosing and Administration:

- A thin layer should be applied to affected areas and rubbed in completely twice daily.
- Not for ophthalmic, oral, or intravaginal use

Efficacy: The efficacy of Adquey was assessed primarily in 3 multicenter, randomized, double-blind, parallel-group, vehicle-controlled studies. The studies enrolled a total of 612 patients with atopic dermatitis.

- Key Inclusion Criteria:
  - Diagnosis of atopic dermatitis meeting the following age requirements:
    - Trial 1: Adult and pediatric patients 10 years of age and older
    - Trial 2: Adult and pediatric patients 15 years of age and older
    - Trial 3: Pediatric patients 2 to 14 years of age
  - Disease is mild to moderate [e.g., Investigator's Global Assessment (IGA) score of 2 or 3 at baseline on a scale from 0-4]
- Intervention(s):
  - Patients were randomized 1:1 to receive Adquey or vehicle ointment twice daily for at least 4 weeks
- Primary Endpoint(s):
  - Proportion of patients achieving IGA success, defined as an IGA score of 0 ("clear") or 1 ("almost clear") and at least a 2-point improvement from baseline at week 4
- Results:
  - Trial 1: IGA success achieved in 21% of patients who received Adquey vs. 3% of patients who received vehicle [treatment difference: 18%; 95% confidence interval (CI): 5%, 31%]
  - Trial 2: IGA success achieved in 38% of patients who received Adquey vs. 13% of patients who received vehicle (treatment difference: 26%; 95% CI: 17%, 34%)
  - Trial 3: IGA success achieved in 40% of patients who received Adquey vs. 15% of patients who received vehicle (treatment difference: 29%; 95% CI: 15%, 42%)

Cost Comparison: Topical Products

Product	Cost Per Gram	Cost Per Tube	Cost Per Year*
Adquey (difamilast 1% ointment) 85g tube	**$13.45**	**$1,143.25**	**$13,719.00**
Zoryve (roflumilast 0.05% cream) 60g tube	$15.39	$923.40	$11,080.80
Zoryve (roflumilast 0.15% cream) 60g tube	$15.40	$924.00	$11,088.00
Eucrisa (crisaborole 2% ointment) 60g tube	$12.64	$758.40	$9,100.80
pimecrolimus 1% cream 60g tube	$3.00	$180.00	$720.00
tacrolimus 0.1% ointment 60g tube	$1.05	$63.00	$252.00
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 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 Adquey (difamilast 1% ointment) with the following criteria (shown in red):

Adquey (Difamilast 1% Ointment) Approval Criteria:

1. An FDA approved diagnosis of mild-to-moderate atopic dermatitis; and
2. Member must be 2 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 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
4. 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
5. A quantity limit of 85 grams per 30 days will apply.

The College of Pharmacy also recommends updating the Ebglyss (lebrikizumab-lbkz) and Zoryve (roflumilast) approval criteria based on recent FDA approvals (changes shown in red):

Ebglyss (Lebrikizumab-lbkz) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and

2. Member must be 12 years of age or older and weigh ≥40kg; 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'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
5. 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. Requests for concurrent use of Ebglyss with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Ebglyss has not been studied in combination with other biologic therapies); and
7. Initial approvals will be for a quantity limit override for the initial dosing for the duration of 16 weeks; and
8. Reauthorization may be granted for the maintenance dosing of 250mg every 4 or 8 weeks for a duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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

1. An FDA approved diagnosis of plaque psoriasis; and
2. Requested product must be FDA approved for the member's age; and
    a. 0.3% Cream: Member must be ~~6~~ 2 years of age or older; or
    b. 0.3% Foam: Member must be 12 years of age or older; and
3. Member must have a body surface (BSA) involvement of ≤20% (or ≤25% if both the scalp and body are being treated); and
4. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
5. 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

6. 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
7. A quantity limit of 60 grams per 30 days will apply.

Utilization Details of AD Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	6,869	1,245	$28,890,963.98	$4,205.99	5.52	50.67%
DUPIXENT INJ 300MG/2ML SYR	1,696	339	$7,181,920.77	$4,234.62	5	12.60%
DUPIXENT INJ 200MG/1.14ML PEN	1,618	305	$6,395,746.79	$3,952.87	5.3	11.22%
DUPIXENT INJ 200MG/1.14ML SYR	1,316	280	$5,201,860.44	$3,952.78	4.7	9.12%
ADBRY INJ 300MG/2ML AUTO	797	161	$3,293,421.63	$4,132.27	4.95	5.78%
ADBRY INJ 150MG/ML SYR	561	95	$1,322,003.50	$2,356.51	5.91	2.32%
EBGLYSS INJ 250MG/2ML PEN	153	46	$1,115,096.07	$7,288.21	3.33	1.96%
NEMLUVIO INJ 30MG PEN	95	31	$527,193.95	$5,549.41	3.06	0.92%
EBGLYSS INJ 250MG/2ML SYR	4	1	$29,445.64	$7,361.41	4	0.05%
SUBTOTAL	**13,109**	**2,242***	**$53,957,652.77**	**$4,116.08**	**5.85**	**94.64%**
TOPICAL PRODUCTS						
TACROLIMUS OIN 0.1%	2,340	1,588	$134,975.66	$57.68	1.47	0.24%
TACROLIMUS OIN 0.03%	2,149	1,414	$115,657.48	$53.82	1.52	0.20%
PIMECROLIMUS CREAM 1%	1,126	863	$156,831.51	$139.28	1.3	0.28%
EUCRISA OIN 2%	984	610	$797,083.18	$810.04	1.61	1.40%
ZORYVE FOAM 0.3%	356	161	$329,326.15	$925.07	2.21	0.58%
VTAMA CREAM 1%	169	88	$251,788.38	$1,489.87	1.92	0.44%
ZORYVE CREAM 0.15%	140	83	$131,895.95	$942.11	1.69	0.23%
OPZELURA CREAM 1.5%	125	60	$255,073.58	$2,040.59	2.08	0.45%
ZORYVE CREAM 0.3%	111	46	$101,907.22	$918.08	2.41	0.18%
ZORYVE CREAM 0.05%	46	26	$44,482.00	$967.00	1.77	0.08%
ANZUPGO CREAM 2%	6	4	$11,984.46	$1,997.41	1.5	0.02%
SUBTOTAL	**7,552**	**4,530***	**$2,331,005.57**	**$308.66**	**1.67**	**4.09%**
ORAL PRODUCTS						
CIBINQO TAB 100MG	83	18	$500,580.24	$6,031.09	4.61	0.88%
CIBINQO TAB 200MG	24	4	$145,393.05	$6,058.04	6	0.26%
CIBINQO TAB 50MG	13	2	$78,071.36	$6,005.49	6.5	0.14%
SUBTOTAL	**120**	**21***	**$724,044.65**	**$6,033.71**	**5.71**	**1.27%**
TOTAL	**20,781**	**6,011***	**$57,012,702.99**	**$2,743.50**	**3.46**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; INJ = injection; OIN = ointment; SYR = syringe; TAB = tablet
Utilization data includes products used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 10/2026. Last accessed 10/21/2026.
[2] Adquey (Difamilast) – New Drug Approval. *OptumRx*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval-adquey-022426.pdf. Issued 02/12/2026. Last accessed 10/21/2026.
[3] Eli Lilly and Company. FDA Approves Lilly's Ebglyss (Lebrikizumab-lbkz) for One Maintenance Dose Every Eight Weeks in Patients with Moderate-to-Severe Atopic Dermatitis. Available online at: https://investor.lilly.com/news-releases/news-release-details/fda-approves-lillys-ebglyssr-lebrikizumab-lbkz-one-maintenance. Issued 06/09/2026. Last accessed 10/21/2026.
[4] Arcutis Biotherapeutics, Inc. FDA Approves Arcutis' Zoryve (Roflumilast) Cream 0.3% for the Treatment of Plaque Psoriasis in Children as Young as Age 2. Available online at: https://www.arcutis.com/fda-approves-arcutis-zoryve-roflumilast-cream-0-3-for-the-treatment-of-plaque-psoriasis-in-children-as-young-as-age-2/. Issued 06/29/2026. Last accessed 10/21/2026.
[5] Adquey (Difamilast) Prescribing Information. Acrotech Biopharma, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/219474Orig1s000lbl.pdf. Last revised 02/2026. Last accessed 10/21/2026.



Appendix Q

Fiscal Year 2026 Annual Review of Bone Density Regulators and 30-Day Notice to Prior Authorize Aukelso (Denosumab-kyqq), Bosaya (Denosumab-kyqq), Enoby (Denosumab-qbde), Jubereq (Denosumab-desu), Osvyrti (Denosumab-desu) and Xtrenbo (Denosumab-qbde)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax)	alendronate + vitamin D tabs (Fosamax Plus 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

Osteoporosis Medications Tier-2 Approval Criteria:

1. A trial of at least 1 Tier-1 bisphosphonate medication, compliantly used for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
2. Hypersensitivity to or intolerable adverse effect(s) with all Tier-1 bisphosphonate medications (including oral and intravenous routes of administration); and
3. Quantity limits apply based on FDA approved maximum doses.

Actonel (Risedronate 30mg Tablets), Atelvia [Risedronate Delayed-Release (DR) Tablets], and Binosto (Alendronate Effervescent Tablets) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other available Tier-1 and Tier-2 bisphosphonate medications must be provided; or
2. Members with a diagnosis of Paget's disease in claims history will not require prior authorization.

Bildyos (Denosumab-nxxp), Boniva [Ibandronate Intravenous (IV) Solution], Conexxence (Denosumab-bnht), Jubbonti (Denosumab-bbdz), 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, 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.

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 therapy; and
2. For Bilprevda, Bomyntra, and Osenvelt 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.

Bonsity (Teriparatide) and Forteo (Teriparatide) Approval Criteria:

1. Diagnosis of 1 of the following:
    a. Treatment of postmenopausal women with osteoporosis at high risk for fracture; or
    b. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or
    c. Treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy at high risk for fracture; or
    d. Treatment of non-healing fracture (this indication only pertains to Forteo); and
2. A minimum 12-month trial with a bisphosphonate plus adequate calcium and vitamin D or a patient-specific, clinically significant reason why the member cannot use a bisphosphonate must be provided; and
3. Use of generic teriparatide will require a patient-specific, clinically significant reason why the member cannot use the brand formulation, Forteo (teriparatide); and
4. Use of Bonsity (teriparatide) will require a patient-specific, clinically significant reason why the member cannot use Forteo (teriparatide) or generic teriparatide formulations; and
5. The diagnosis of non-healing fracture may be approved for 6 months; and
6. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime; and
7. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy.

Evenity (Romosozumab-aqqg) Approval Criteria:

1. An FDA approved diagnosis of osteoporosis in postmenopausal women at high-risk for fracture; and
2. Member meets 1 of the following:
    a. History of osteoporotic fracture; or
    b. Multiple risk factors for fracture (e.g., T-score ≤-2.5 at the total hip or femoral neck, smoking, corticosteroid use, rheumatoid arthritis); or
    c. Failure of or intolerance to other available osteoporosis therapies; and
3. Prescriber must verify member has not had a myocardial infarction or stroke within the preceding year; and
4. Prescriber must verify calcium levels will be monitored and pre-existing hypocalcemia will be corrected prior to starting therapy; and
5. Prescriber must verify that the member will take adequate calcium and vitamin D supplements during treatment with Evenity to reduce the risk of hypocalcemia; and
6. Evenity must be administered by a health care provider; and
7. Approval will be limited to a total duration of 1 year of therapy.

Fosamax (Alendronate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of osteoporosis or Paget's disease; and
2. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation must be provided.

Tymlos (Abaloparatide) Approval Criteria:

1. Diagnosis of postmenopausal osteoporosis confirmed by the following:
    a. History of vertebral fracture(s) or low trauma or fragility fracture(s) (e.g., prior fracture from minor trauma such as falling from standing height or less) within the past 5 years; or
    b. A bone mineral density (BMD) test (T-score at or below -2.5) within the last month in the spine, femoral neck, total hip, or 33% radius; or
    c. A T-score between -1.0 and -2.5 in the spine, femoral neck, total hip, or 33% radius, with a FRAX 10-year probability for major osteoporotic fracture ≥20% or the 10-year probability of hip fracture ≥3%; and
2. One of the following [if a 12-month bisphosphonate trial is inappropriate for the member, the member must have a trial of Prolia or a selective estrogen receptor modulator (SERM) or a patient-specific, clinically significant reason why Prolia or a SERM is not appropriate must be provided]:
    a. A minimum 12-month trial with a bisphosphonate medication plus adequate calcium and vitamin D; or
    b. A 12-month trial of Prolia (denosumab), unless contraindicated, intolerant, or allergic, that did not yield adequate results; or

c. A 12-month trial of a SERM, unless contraindicated, intolerant, or allergic, that did not yield adequate results; and

3. A patient-specific, clinically significant reason why the member cannot use Forteo (teriparatide) must be provided; and
4. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the member's lifetime; and
5. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy; and
6. A quantity limit of 1 pen per 30 days will apply.

Utilization of Bone Density Regulators: Fiscal Year 2026

Comparison of Fiscal Years: Bone Density Regulators: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	619	1,780	$260,700.21	$146.46	$2.55	18,389	102,319
Aetna	143	425	$40,495.40	$95.28	$1.76	3463	23,035
Humana	207	732	$130,194.38	$177.86	$3.67	5377	35,440
OCH	155	449	$62,856.58	$139.99	$2.93	3875	21,472
2025 Total	**1,044**	**3,386**	**$494,246.57**	**$145.97**	**$2.71**	**31,103**	**182,266**
Fiscal Year 2026							
FFS	680	1,942	$296,871.58	$152.87	$2.69	18,464	110,382
Aetna	155	402	$64,842.14	$161.30	$2.82	3,495	22,997
Humana	222	738	$287,376.27	$389.40	$7.14	5,387	40,254
OCH	155	429	$58,748.01	$136.94	$2.54	3,545	23,128
2026 Total	**1,132**	**3,511**	**$707,838.00**	**$201.61**	**$3.60**	**30,890**	**196,761**
% Change	**8.40%**	**3.70%**	**43.20%**	**38.10%**	**32.80%**	**-0.70%**	**8.00%**
Change	**88**	**125**	**$213,591.43**	**$55.64**	**$0.89**	**-213**	**14,495**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

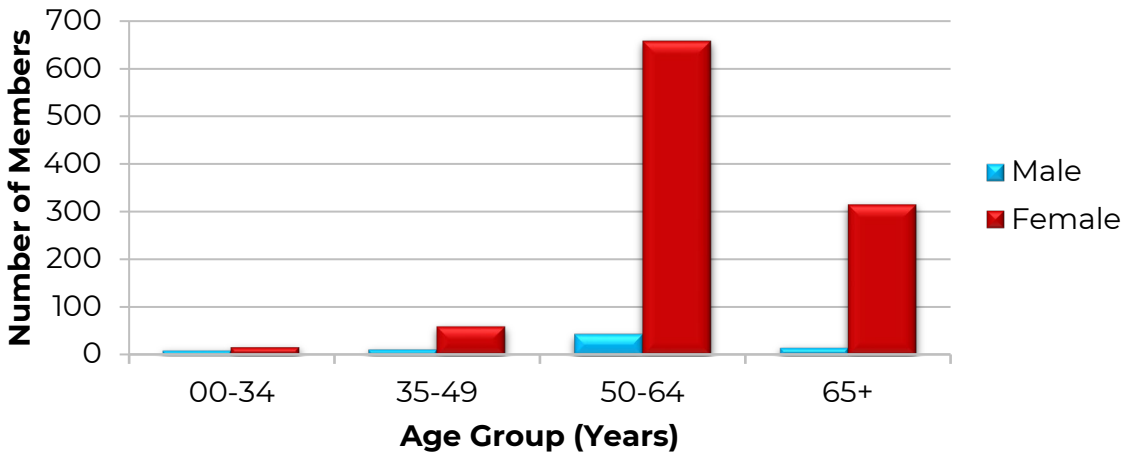
Comparison of Fiscal Years: Bone Density Regulators: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	234	529	$678,443.54	$1,282.50	2.26
Aetna	56	93	$112,722.05	$1,212,07	1.66
Humana	50	96	$185,405.72	$1,931.31	1.92
OCH	59	106	$128,263.89	$1,210.04	1.80
2025 Total	**385**	**824**	**$1,104,835.20**	**$1,340.82**	**2.14**
Fiscal Year 2026					
FFS	262	586	$974,911.41	$1,663.67	2.24
Aetna	52	108	$164,026.32	$1,518.76	2.08
Humana	74	173	$294,791.48	$1,704.00	2.34
OCH	68	167	$258,497.33	$1,547.89	2.46
2026 Total	**435**	**1,034**	**$1,692,226.54**	**$1,636.58**	**2.38**
% Change	**12.99%**	**25.49%**	**53.17%**	**22.06%**	**11.21%**
Change	**50**	**210**	**$587,391.34**	**$295.76**	**1.81**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

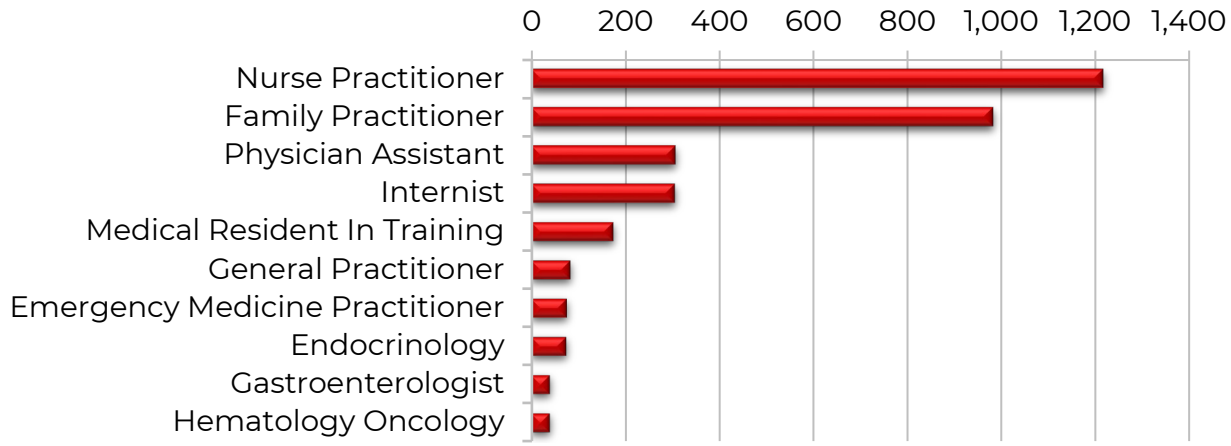
- Aggregate drug rebates collected during fiscal year 2026 for the bone density regulators totaled $2,730,985.06.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Bone Density Regulators: 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.

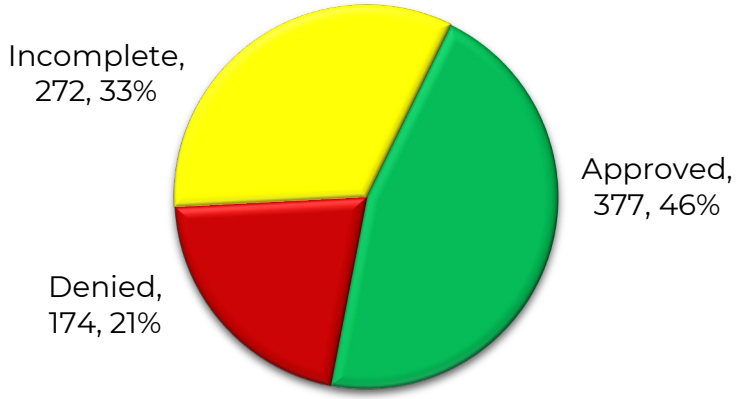
Top Prescriber Specialties of Bone Density Regulators by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Bone Density Regulators

There were 823 prior authorization requests submitted for bone density regulators during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	233	43%	229	41%	90	17%	**552**
Aetna	39	50%	7	40%	22	10%	**68**
Humana	67	62%	28	0%	23	38%	**118**
OCH	38	43%	8	17%	39	40%	**85**
Total	**377**	**46%**	**272**	**33%**	**174**	**21%**	**823**

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

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

Anticipated Patent Expiration(s):

- Atelvia [risedronate sodium delayed-release (DR) tablet]: January 2028
- Binosto (alendronate effervescent tablet): December 2031
- Tymlos (abaloparatide injection): January 2040

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

- **September 2025:** The FDA approved Bosaya (denosumab-kyqq) and Aukelso (denosumab-kypp) as biosimilars to Prolia (denosumab) and Xgeva (denosumab), respectively, for the same indications currently approved for the reference products.
- **September 2025:** The FDA approved Enoby (denosumab-qbde) and Xtrenbo (denosumab-qbde) as biosimilars to Prolia and Xgeva, respectively, for the same indications currently approved for the reference products.
- **November 2025:** The FDA approved Osvyrti (denosumab-desu) and Jubereq (denosumab-desu) 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. Updating the Tier-2 approval criteria for consistency with other criteria within the category; and
2. Moving Fosamax Plus D (alendronate + vitamin D) to the Special PA Tier with the following additional criteria based on net costs; and
3. Prior authorizing Enoby (denosumab-qbde) with placement into Tier-2; and
4. Moving Actonel (risedronate 5mg) tablets from Tier-2 to the Special PA Tier based on net cost and updating the additional approval criteria for clarity; and
5. Prior authorizing Bosaya (denosumab-kyqq) and Osvyrti (denosumab-desu) with placement into the Special PA Tier with additional criteria similar to Prolia (denosumab); and
6. Moving Bildyos (denosumab-qbde) and Jubbonti (denosumab-bbdz) from the Special PA Tier to Tier-2 based on net costs; and
7. Designating teriparatide (unbranded Bonsity) as non-preferred to brand Forteo (teriparatide) and adding it to the Special PA Tier for clarity.

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax)	~~**alendronate + vitamin D tabs (Fosamax + D)**~~	abaloparatide inj (Tymlos)
calcium + vitamin D†	**denosumab-bbdz inj (Jubbonti)**	alendronate effervescent tabs (Binosto)
ibandronate tabs (Boniva)	**denosumab-nxxp inj (Bildyos)**	alendronate soln (Fosamax)
zoledronic acid inj (Reclast)	**denosumab-qbde inj (Enoby)**	**alendronate + vitamin D tabs (Fosamax + D)**
	risedronate **35mg & 150mg** tabs (Actonel)	denosumab inj (Prolia)
		~~**denosumab-bbdz inj (Jubbonti)**~~
		denosumab-bmwo inj (Stoboclo)
		denosumab-bnht inj (Conexxence)
		denosumab-desu inj (Osvyrti)
		denosumab-kyqq inj (Bosaya)
		~~**denosumab-nxxp inj (Bildyos)**~~
		ibandronate inj (Boniva IV)
		risedronate **5mg &** 30mg tabs (Actonel)
		risedronate DR tabs (Atelvia)
		romosozumab-aqqg (Evenity)
		teriparatide inj (Forteo) – **Brand Preferred**
		teriparatide inj (Bonsity)
		teriparatide inj (unbranded 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

Osteoporosis Medications Tier-2 Approval Criteria:

1. A trial of at least 1 Tier-1 bisphosphonate medication, compliantly used for at least ~~6~~ 12 months concomitantly with calcium and vitamin D, that

failed to prevent fracture or improve bone mineral density (BMD) scores; or
2. Hypersensitivity to or intolerable adverse effect(s) with all Tier-1 bisphosphonate medications (including oral and intravenous routes of administration); and
3. Quantity limits apply based on FDA approved maximum doses.

Actonel (Risedronate 5mg & 30mg Tablets), Atelvia [Risedronate Delayed-Release (DR) Tablets], and Binosto (Alendronate Effervescent Tablets) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other available Tier-1 and Tier-2 bisphosphonate medications must be provided; or
2. Actonel (risedronate 5mg tablets) will be approved for members with a diagnosis of glucocorticoid-induced osteoporosis; or
3. Actonel (risedronate 30mg tablets) will be approved for ~~M~~members with a diagnosis of Paget's disease ~~in claims history will not require prior authorization~~.

~~Bildyos (Denosumab-nxxp),~~ Boniva [Ibandronate Intravenous (IV) Solution], Bosaya (Denosumab-kyqq), Conexxence (Denosumab-bnht), ~~Jubbonti (Denosumab-bbdz),~~ Osvyrti (Denosumab-desu), 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 and Stoboclo a patient-specific, clinically significant reason why the member cannot use Jubbonti or Prolia must be provided.~~
4. For Bosaya, Conexxence, Osvyrti, Prolia, and Stoboclo, a patient-specific, clinically significant reason why the member cannot use the preferred Tier-2 denosumab products 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.

Bonsity (Teriparatide), ~~and~~ Forteo (Teriparatide), and Teriparatide (Unbranded Bonsity) Approval Criteria:

1. Diagnosis of 1 of the following:
    a. Treatment of postmenopausal women with osteoporosis at high risk for fracture; or

   b. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or
   c. Treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy at high risk for fracture; or
   d. Treatment of non-healing fracture (this indication only pertains to Forteo); and
2. A minimum 12-month trial with a bisphosphonate plus adequate calcium and vitamin D or a patient-specific, clinically significant reason why the member cannot use a bisphosphonate must be provided; and
3. Use of generic teriparatide will require a patient-specific, clinically significant reason why the member cannot use the brand formulation, Forteo (teriparatide); and
4. Use of Bonsity (teriparatide) and teriparatide (unbranded Bonsity) will require a patient-specific, clinically significant reason why the member cannot use Forteo (teriparatide) or generic teriparatide formulations; and
5. The diagnosis of non-healing fracture may be approved for 6 months; and
6. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime; and
7. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy.

Fosmax Plus D (Alendronate + Vitamin D) Approval Criteria:

1. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all other available Tier-1 and Tier-2 bisphosphonate medications in combination with over-the-counter (OTC) vitamin D must be provided.

The College of Pharmacy also recommends the prior authorization of Aukelso (denosumab-kyqq), Jubereq (denosumab-desu), and Xtrenbo (denosumab-qbde) with criteria similar to Xgeva (denosumab); to designate Bilprevda as a preferred oncology-indicated denosumab product based on net costs; and to designate Xgeva as a nonpreferred oncology-indicated denosumab product based on net costs (changes shown in red):

Aukelso (Denosumab-kyqq), Bilprevda (Denosumab-nxxp), Bomyntra (Denosumab-bnht), Jubereq (Denosumab-desu), Osenvelt (Denosumab-bmwo), Wyost (Denosumab-bbdz), ~~and~~ Xgeva (Denosumab), and Xtrenbo (Denosumab-qbde) 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 therapy; and .

2. For Aukelso, ~~Bilprevda,~~ Bomyntra, Jubereq, Osenvelt, and Xgeva, a patient-specific, clinically significant reason why the member cannot use Bilprevda, Wyost, or Xtrenbo ~~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.

Utilization Details of Bone Density Regulators: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ALENDRONATE PRODUCTS						
ALENDRONATE TAB 70MG	2,759	910	$40,979.82	$14.85	3.03	5.79%
ALENDRONATE TAB 35MG	160	43	$1,994.10	$12.46	3.72	0.28%
ALENDRONATE TAB 10MG	72	31	$1,937.58	$26.91	2.32	0.27%
SUBTOTAL	**2,991**	**984**	**$44,911.50**	**$15.02**	**3.04**	**6.34%**
IBANDRONATE PRODUCTS						
IBANDRONATE TAB 150MG	282	84	$4,209.80	$14.93	3.36	0.59%
SUBTOTAL	**282**	**84**	**$4,209.80**	**$14.93**	**3.36**	**0.59%**
TIER-1 SUBTOTAL	**3,273**	**1,068**	**$49,121.30**	**$15.01**	**3.06**	**6.94%**
TIER-2 PRODUCTS						
RISEDRONATE PRODUCTS						
RISEDRONATE TAB 35MG	6	2	$92.93	$15.49	3	0.01%
RISEDRONATE TAB 5MG	3	1	$323.39	$107.80	3	0.05%
RISEDRONATE TAB 150MG	1	1	$23.94	$23.94	1	0.00%
TIER-2 SUBTOTAL	**10**	**4**	**$440.26**	**$44.03**	**2.5**	**0.06%**
SPECIAL PA PRODUCTS						
TERIPARATIDE PRODUCTS						
FORTEO INJ 600MCG/2.4ML	96	22	$398,009.88	$4,145.94	4.36	56.23%
TERIPARATIDE INJ 600MCG/2.4ML	17	7	$31,458.02	$1,850.47	2.43	4.44%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**113**	**29**	**$429,467.90**	**$2,696.01**	**3.9**	**62.66%**
DENOSUMAB PRODUCTS						
PROLIA INJ 60MG/ML	62	42	$111,964.35	$1,805.88	1.48	15.82%
JUBBONTI INJ 60MG/ML	3	3	$4,641.66	$1,547.22	1	0.66%
SUBTOTAL	**65**	**45**	**$116,606.01**	**$1,793.94**	**1.44**	**16.47%**
ABALOPARATIDE PRODUCTS						
TYMLOS INJ 3,120MCG/1.56ML	25	6	$72,189.41	$2,887.58	4.17	10.20%
SUBTOTAL	**25**	**6**	**$72,189.41**	**$2,887.58**	**4.17**	**10.20%**
ROMOSOZUMAB PRODUCTS						
EVENITY INJ 105MG	14	7	$37,604.37	$2,686.03	2	5.31%
SUBTOTAL	**14**	**7**	**$37,604.37**	**$2,686.03**	**2**	**5.31%**
ALENDRONATE PRODUCTS						
ALENDRONATE SOL 70MG/75ML	10	1	$2,109.93	$210.99	10	0.30%
BINOSTO TAB 70MG	1	1	$298.82	$298.82	1	0.04%
SUBTOTAL	**11**	**2**	**$2,408.75**	**$218.98**	**5.5**	**0.34%**
SPECIAL PA SUBTOTAL	**228**	**89**	**$658,276.44**	**$2,887.18**	**2.56**	**93.00%**
TOTAL	**3,511**	**1,132***	**$707,838.00**	**$201.61**	**3.1**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PA = prior authorization; SOL = solution; TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims (All Plans)

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PROLIA/XGEVA (J0897)	452	172	$1,339,812.77	$2,964.19	2.63
ZOLEDRONIC ACID (J3489)	444	232	$15,904.34	$35.82	1.91
EVENITY (J3111)	127	29	$312,373.22	$2,459.63	4.38
JUBBONTI/WYOST (Q5136)	11	7	$24,136.21	$2,194.20	1.57
TOTAL	**1,034**	**435**	**$1,692,226.54**	**$1,636.58**	**2.38**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 10/2026. Last accessed 10/28/2026.

[2] Biocon. Biocon Biologics Receives U.S. Food and Drug Administration Approval for Bosaya and Aukelso, Denosumab Biosimilars. https://www.biocon.com/biocon-biologics-receives-u-s-food-and-drug-administration-approval-for-bosaya-and-aukelso-denosumab-biosimilars/. Issued 09/17/2025. Last accessed 10/28/2026.

[3] Hikma. Hikma and Richter Receive FDA Approval for Denosumab Biosimilars Enoby (Denosumab-qbde) and Xtrenbo (denosumab-qbde) Referencing Prolia and Xgeva Respectively. https://www.hikma.com/news/hikma-and-richter-receive-fda-approval-for-denosumab-biosimilars-enobytm-denosumab-qbde-and-xtrenbotm-denosumab-qbde-referencing-prolia-and-xgeva-respectively/. Issued 09/29/2025. Last accessed 10/28/2026.

[4]Accord Biopharma. Accord BioPharma, Inc. Announces FDA Approval of Denosumab Biosimilars Osvyrti (Denosumab-desu) and Jubereq (Denosumab-desu). Issued 11/20/2025. Last accessed 10/28/2026.



Appendix R

Fiscal Year 2026 Annual Review of Ophthalmic Anti-Inflammatory Products and 30-Day Notice to Prior Authorize Byqlovi (Clobetasol 0.05% Suspension)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone 0.1% sus (Maxidex)	fluorometholone 0.25% sus (FML Forte)
dexamethasone sodium phosphate 0.1% sol	loteprednol 0.5% sus (Lotemax)
difluprednate 0.05% emu (Durezol) – **Brand Preferred**	loteprednol 1% sus (Inveltys)
fluorometholone 0.1% sus (Flarex)	loteprednol 0.38% gel (Lotemax SM)
fluorometholone 0.1% sus (FML Liquifilm)	prednisolone acetate 1% sus (Pred Forte)
loteprednol 0.5% gel, oint (Lotemax) – **Brand Preferred**	
prednisolone acetate 1% sus (Omnipred)	
prednisolone acetate 0.12% sus (Pred Mild)	
prednisolone sodium phosphate 1% sol	

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)
emu = emulsion; oint = ointment; sol = solution; sus = suspension

Ophthalmic Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic corticosteroids (from different product lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower-tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic corticosteroids lack.

Dextenza (Dexamethasone Ophthalmic Insert) Approval Criteria [Ocular Inflammation and Pain following Ophthalmic Surgery Diagnosis]:

1. An FDA approved indication of the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric members; and
2. Dextenza must be prescribed by and administered immediately following ophthalmic surgery by an ophthalmologist, or a physician experienced in intracanalicular administration; and
3. Date of ophthalmic surgery must be provided; and
4. A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used

following ophthalmic surgery are not appropriate for the member must be provided; and
5. A quantity limit of 1 insert per eye every 30 days will apply.

Dextenza (Dexamethasone Ophthalmic Insert) Approval Criteria [Ocular Itching Associated with Allergic Conjunctivitis Diagnosis]:

1. An FDA approved indication of the treatment of ocular itching associated with allergic conjunctivitis; and
2. Member must be 2 years of age or older; and
3. Dextenza must be prescribed by and administered by an ophthalmologist, or a physician experienced in intracanalicular administration; and
4. For pediatric members, the prescriber must attest the member does not require sedation; and
5. A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used for allergic conjunctivitis are not appropriate for the member must be provided; and
6. A quantity limit of 1 insert per eye every 30 days will apply.

Iluvien (Fluocinolone Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure; or
    b. Treatment of chronic non-infectious uveitis affecting the posterior segment of the eye; and
2. Iluvien must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Iluvien in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A quantity limit of 1 implant per eye every 36 months will apply.

Ozurdex (Dexamethasone Intravitreal Implant) Approval Criteria:

1. An FDA approved indication for 1 of the following:
    a. Treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); or
    b. Treatment of non-infectious uveitis affecting the posterior segment of the eye; or
    c. Treatment of diabetic macular edema; and
2. Ozurdex must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and

4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Ozurdex in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A quantity limit of 1 implant per eye every 3 months will apply.

Retisert (Fluocinolone Intravitreal Implant) Approval Criteria

1. An FDA approved diagnosis of chronic non-infectious posterior uveitis; and
2. Retisert must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Retisert in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A patient-specific, clinically significant reason why the member requires Retisert in place of Ozurdex (dexamethasone intravitreal implant) must be provided; and
7. A quantity limit of 1 implant per eye every 30 months will apply.

Xipere (Triamcinolone Acetonide Injection) Approval Criteria:

1. An FDA approved indication for the treatment of macular edema associated with non-infectious uveitis; and
2. Member must be 18 years of age or older; and
3. Xipere must be administered by an ophthalmologist; and
4. Prescriber must confirm that the member does not have an active ocular or periocular infection; and
5. Prescriber must confirm member does not have untreated ocular hypertension or uncontrolled glaucoma; and
6. A patient-specific, clinically significant reason why the member cannot use corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
7. A patient-specific, clinically significant reason the member cannot use Triesence (triamcinolone acetonide injection) must be provided; and
8. Initial authorization will be for 12 weeks, with an additional dose approved at or after 12 weeks if the prescriber documents improvement from baseline in visual acuity.

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
Tier-1	**Tier-2**
diclofenac 0.1% sol (Voltaren)	bromfenac 0.09% sol (Bromday)
flurbiprofen 0.03% sol[Δ] (Ocufen)	bromfenac 0.075% sol (BromSite)
ketorolac 0.5% sol (Acular)	bromfenac 0.07% sol (Prolensa)
	ketorolac 0.4% sol (Acular LS)
	ketorolac 0.45% sol (Acuvail)
	nepafenac 0.1% sus (Nevanac)
	nepafenac 0.3% sus (Ilevro)

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).
sol = solution; sus = suspension
[Δ]Not a required Tier-1 trial; does not have to be attempted for approval of a Tier-2 medication.

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic NSAIDs (from different medication lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic NSAIDs lack.

Utilization of Ophthalmic Anti-Inflammatory Products: Fiscal Year 2026

Comparison of Fiscal Years: Ophthalmic Corticosteroids Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	2,335	3,277	$173,909.05	$53.07	$2.24	20,580	77,485
Aetna	1,309	1,729	$99,872.62	$57.76	$3.17	10,322	31,526
Humana	1,408	1,925	$104,717.91	$54.40	$2.69	11,746	38,862
OCH	1,428	1,968	$105,566.36	$53.64	$2.68	11,731	39,460
2025 Total	**6,342**	**8,899**	**$484,065.94**	**$54.40**	**$2.58**	**54,379**	**187,333**
Fiscal Year 2026							
FFS	2,348	3,344	$169,376.16	$50.65	$2.07	21,319	81,716
Aetna	1,388	1,807	$93,727.57	$51.87	$2.93	10,661	32,023
Humana	1,524	2,180	$104,822.02	$48.08	$2.26	12,783	46,398
OCH	1,611	2,145	$107,211.29	$49.98	$2.40	12,621	44,655
2026 Total	**6,733**	**9,476**	**$475,137.04**	**$50.14**	**$2.32**	**57,382**	**204,792**
% Change	**6.20%**	**6.50%**	**-1.80%**	**-7.80%**	**-10.10%**	**5.50%**	**9.30%**
Change	**391**	**577**	**-$8,928.90**	**-$4.26**	**-$0.26**	**3,003**	**17,459**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Ophthalmic Corticosteroids Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	4	7	$16,781.56	$2,397.37	1.75
Aetna	1	2	$2,878.26	$1,439.13	2
Humana	5	8	$5,756.52	$719.57	1.6
OCH	1	1	$2,878.68	$2,878.68	1
2025 Total	**11**	**18**	**$28,295.02**	**$1,571.95**	**1.64**
Fiscal Year 2026					
FFS	3	5	$8,601.53	$1,720.31	1.67
Aetna	0	0	$0.00	$0.00	0
Humana	2	3	$2,221.06	$740.35	1.5
OCH	1	1	$213.25	$213.25	1
2026 Total	**6**	**9**	**$11,035.84**	**$1,226.20**	**1.5**
% Change	**-45.45%**	**-50.00%**	**-61.00%**	**-21.99%**	**-8.54%**
Change	**-5**	**-9**	**-$17,259.18**	**-$345.75**	**-0.14**

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 = OK Complete Health
Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

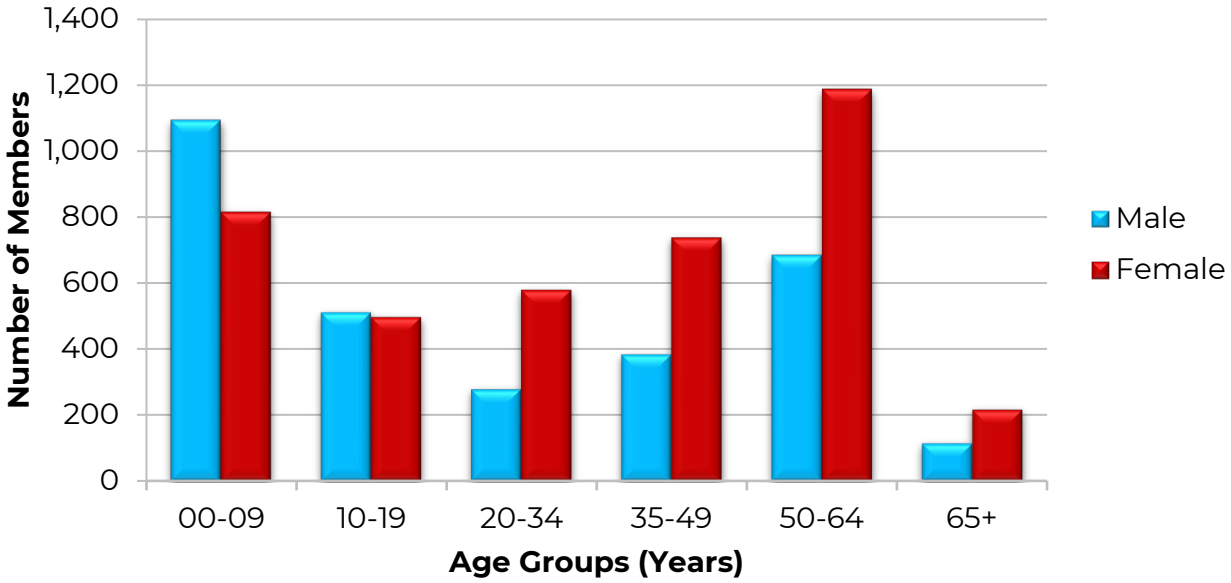
Comparison of Fiscal Years: Ophthalmic NSAIDs Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	646	865	$15,333.48	$17.73	$0.71	4,850	21,730
Aetna	233	323	$6,279.49	$19.44	$0.90	1,753	6,961
Humana	333	495	$12,708.19	$25.67	$1.07	2,761	11,842
OCH	268	370	$9,577.01	$25.88	$1.08	2,092	8,895
2025 Total	**1,457**	**2,053**	**$43,898.17**	**$21.38**	**$0.89**	**11,456**	**49,428**
Fiscal Year 2026							
FFS	551	748	$16,070.01	$21.48	$0.82	4,215	19,518
Aetna	237	306	$5,894.41	$19.26	$0.82	1,700	7,212
Humana	368	542	$11,349.60	$20.94	$0.79	3,019	14,424
OCH	272	381	$8,237.21	$21.62	$0.82	2,129	9,989
2026 Total	**1,400**	**1,977**	**$41,551.23**	**$21.02**	**$0.81**	**11,062**	**51,143**
% Change	**-3.90%**	**-3.70%**	**-5.30%**	**-1.70%**	**-9.00%**	**-3.40%**	**3.50%**
Change	**-57**	**-76**	**-$2,346.94**	**-$0.36**	**-$0.08**	**-394**	**1,715**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

- Aggregate drug rebates collected during fiscal year 2026 for the ophthalmic anti-inflammatory products totaled $147,570.54.[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 Ophthalmic Anti-Inflammatory Products (All Plans)



Top Prescriber Specialties of Ophthalmic Anti-Inflammatory Products by Number of Claims (All Plans)

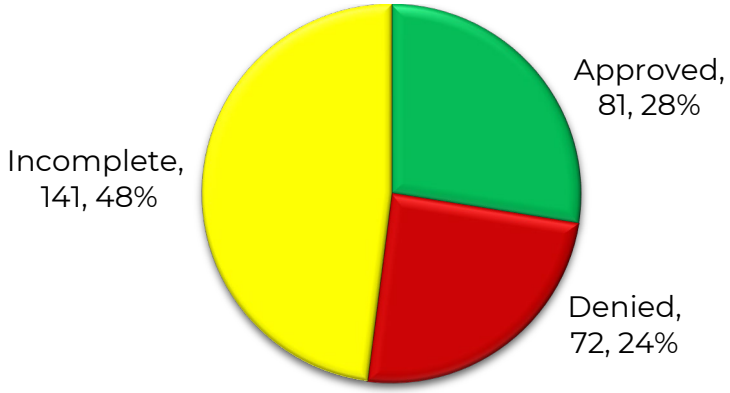


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Prior Authorization of Ophthalmic Anti-Inflammatory Products

There were 294 prior authorization requests submitted for ophthalmic anti-inflammatory products during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	37	32%	72	62%	8	7%	**117**
Aetna	2	4%	27	59%	17	37%	**46**
Humana	6	11%	23	40%	28	49%	**57**
OCH	36	49%	19	26%	19	26%	**74**
Total	**81**	**28%**	**141**	**48%**	**72**	**24%**	**294**

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

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

Anticipated Patent Expiration(s):

- Nevanac (nepafenac 0.1% ophthalmic suspension): January 2027
- Acular LS (ketorolac 0.4% ophthalmic solution): November 2027
- Iluvien (fluocinolone intravitreal implant): November 2028
- BromSite (bromfenac 0.075% ophthalmic solution): March 2029
- Acuvail (ketorolac 0.45% ophthalmic solution): August 2029
- Ilevro (nepafenac 0.3% ophthalmic suspension): March 2032
- Inveltys (loteprednol 1% ophthalmic suspension): May 2033
- Prolensa (bromfenac 0.07% ophthalmic solution): November 2033
- Byqlovi (clobetasol 0.05% suspension): May 2036
- Lotemax SM (loteprednol 0.38% ophthalmic gel): December 2036
- Xipere (triamcinolone acetonide injectable suspension): April 2040
- Dextenza (dexamethasone ophthalmic insert): April 2041

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

- **March 2024:** The FDA approved Byqlovi (clobetasol 0.05% suspension) for the treatment of post-operative inflammation and pain following ocular surgery. In June 2025, Harrow, a pharmaceutical company, acquired the rights to Byqlovi from Formosa Pharmaceuticals. The National Drug Code (NDC) Directory indicates a start marketing date of January 25, 2026 for Byqlovi to Harrow.

Pipeline:

- **OCS-01:** OCS-01 is a high concentration dexamethasone product that is being studied for diabetic macular edema (DME). OCS-01 uses a proprietary OPTIREACH technology that improves the solubility of lipophilic drugs; therefore, increasing the time on the surface of the eye. In May 2026, Oculis, the makers of OCS-01, announced the results of the Phase 3 DIAMOND-1 and DIAMOND-2 trials that studied OCS-01 in DME. The primary endpoint of mean change in best corrected visual acuity (BCVA) from baseline to week 52 in both Phase 3 trials was not met; therefore, Oculis does not plan to pursue FDA approval for OCS-01 in DME at this time.

Byqlovi (Clobetasol 0.05% Suspension) Product Summary[6]

Therapeutic Class: Corticosteroid

Indication(s): Treatment of post-operative inflammation and pain following ocular surgery

How Supplied: Ophthalmic suspension containing clobetasol propionate 0.05% (0.5mg/mL)

Dosing and Administration: Patients should instill 1 drop of Byqlovi into the affected eye twice daily, beginning the day after surgery and continuing through the first 2 weeks of the post-operative period.

Efficacy: The efficacy of Byqlovi was evaluated in 2 multi-center, randomized, double-masked, vehicle-controlled trials in patients after cataract surgery.

- Key Inclusion Criteria:
  - Patients had ≥10 cells in the anterior chamber after cataract surgery
- Intervention: Randomized to receive 1 drop of Byqlovi or vehicle control twice daily for 14 days, beginning the day after surgery.
- Primary Outcome: The co-primary efficacy endpoints in both trials were the proportion of patients with Anterior Chamber Cell (ACC) count = 0 (ACC grade = 0) at post-operative day (POD) 8 maintained through POD15, and the proportion of patients with Ocular Pain Grade = 0 at POD4 maintained through POD15.

- Results: In the intent-to-treat analysis, both co-primary efficacy endpoints were statistically significantly better in Byqlovi-treated patients compared to vehicle control-treated patients (P<0.01).
  - Study 1:
    - The percent of patients with ACC grade = 0 at POD8 was 32.6% in the Byqlovi-treated group versus 11.7% in the vehicle control group and at POD15 was 58.6% in the Byqlovi-treated group versus 15.7% in the vehicle control group.
    - The percent of patients with Ocular Pain Grade = 0 at POD4 was 77.3% in the Byqlovi-treated group versus 43.7% in the vehicle control group, at POD8 was 82.3% in the Byqlovi-treated group versus 42.6% in the vehicle control group, and at POD15 was 90.6% in the Byqlovi-treated group versus 42.1% in the vehicle control group.
  - Study 2:
    - The percent of patients with ACC grade = 0 at POD8 was 29.7% in the Byqlovi-treated group versus 13.0% in the vehicle control group and at POD15 was 57.8% in the Byqlovi-treated group versus 18.9% in the vehicle control group.
    - The percent of patients with Ocular Pain Grade = 0 at POD4 was 85.4% in the Byqlovi-treated group versus 51.4% in the vehicle control group, at POD8 was 87.0% in the Byqlovi-treated group versus 46.5% in the vehicle control group, and at POD15 was 86.5% in the Byqlovi-treated group versus 49.7% in the vehicle control group.

Cost Comparison:

Product	Cost Per mL	Cost Per Bottle*
Byqlovi (clobetasol 0.05% ophthalmic suspension)	**$108.57**	**$380.00**
difluprednate 0.05% ophthalmic emulsion (generic)	$8.62	$43.10
dexamethasone sodium phosphate 0.1% solution (generic)	$8.31	$41.55
prednisolone 1% suspension (generic)	$4.61	$23.05

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 bottle is based on a 3.5mL bottle for Byqlovi and a 5mL bottle for the other products.

Recommendations

The College of Pharmacy recommends the following changes to the Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Product Based Prior Authorization (PBPA) category based on net cost (changes noted in red in the following Tier chart):

1. Moving bromfenac 0.07% sol (Prolensa) from Tier-2 to Tier-1 and designating it as brand preferred.

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
Tier-1	**Tier-2**
bromfenac 0.07% sol (Prolensa) – Brand Preferred	bromfenac 0.09% sol (Bromday)
diclofenac 0.1% sol (Voltaren)	bromfenac 0.075% sol (BromSite)
flurbiprofen 0.03% sol[Δ] (Ocufen)	~~**bromfenac 0.07% sol (Prolensa**~~)
ketorolac 0.5% sol (Acular)	ketorolac 0.4% sol (Acular LS)
	ketorolac 0.45% sol (Acuvail)
	nepafenac 0.1% sus (Nevanac)
	nepafenac 0.3% sus (Ilevro)

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).
sol = solution; sus = suspension
[Δ]Not a required Tier-1 trial; does not have to be attempted for approval of a Tier-2 medication.

The College of Pharmacy also recommends the following changes to the Ophthalmic Corticosteroids PBPA category based on net costs (changes noted in red in the following Tier chart):

1. The prior authorization of Byqlovi (clobetasol 0.05% suspension) with placement into Tier-2; and
2. Moving fluorometholone 0.1% sus (Flarex) from Tier-1 to Tier-2; and
3. Moving fluorometholone 0.25% sus (FML Forte) from Tier-2 to Tier-1; and
4. Removing the brand preferred status for Lotemax (loteprednol) gel and moving it from Tier-1 to Tier-2.

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone 0.1% sus (Maxidex)	**clobetasol 0.05% sus (Byqlovi)**
dexamethasone sodium phosphate 0.1% sol	**fluorometholone 0.1% sus (Flarex)**
difluprednate 0.05% emu (Durezol) **– Brand Preferred**	~~**fluorometholone 0.25% sus (FML Forte)**~~
~~**fluorometholone 0.1% sus (Flarex)**~~	loteprednol 0.5% **gel,** sus (Lotemax)
fluorometholone 0.25% sus (FML Forte)	loteprednol 1% sus (Inveltys)
fluorometholone 0.1% sus (FML Liquifilm)	loteprednol 0.38% gel (Lotemax SM)
loteprednol 0.5% ~~**gel,**~~ oint (Lotemax) – **Brand Preferred**	prednisolone acetate 1% sus (Pred Forte)
prednisolone acetate 1% sus (Omnipred)	
prednisolone acetate 0.12% sus (Pred Mild)	
prednisolone sodium phosphate 1% sol	

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)
emu = emulsion; oint = ointment; sol = solution; sus = suspension

Lastly, the College of Pharmacy recommends updating the Retisert (fluocinolone intravitreal implant) approval criteria based on net cost (changes shown in red):

Retisert (Fluocinolone Intravitreal Implant) Approval Criteria

1. An FDA approved diagnosis of chronic non-infectious posterior uveitis; and
2. Retisert must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Retisert in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A patient-specific, clinically significant reason why the member requires Retisert in place of Ozurdex (dexamethasone intravitreal implant) and Iluvien (fluocinolone intravitreal implant) must be provided; and
7. A quantity limit of 1 implant per eye every 30 months will apply.

Utilization Details of Ophthalmic Corticosteroids: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
PREDNISOLONE PRODUCTS						
PREDNISOLONE SUS 1% OP	5,410	3,535	$186,001.91	$34.38	1.53	39.15%
PRED SOD PHO SOL 1% OP	25	22	$1,465.19	$58.61	1.14	0.31%
PRED MILD SUS 0.12% OP	20	14	$3,763.81	$188.19	1.43	0.79%
SUBTOTAL	**5,455**	**3,571**	**$191,230.91**	**$35.06**	**1.53**	**40.25%**
DEXAMETHASONE PRODUCTS						
DEXAMETH PHO SOL 0.1% OP	2,913	2,503	$157,282.72	$53.99	1.16	33.10%
MAXIDEX SUS 0.1% OP	264	250	$22,536.93	$85.37	1.06	4.74%
SUBTOTAL	**3,177**	**2,753**	**$179,819.65**	**$56.60**	**1.15**	**37.85%**
FLUOROMETHOLONE PRODUCTS						
FLUOROMETHOLONE SUS 0.1% OP	504	381	$34,919.97	$69.29	1.32	7.35%
FLAREX SUS 0.1% OP	23	17	$3,252.46	$141.41	1.35	0.68%
FML LIQUIFLM SUS 0.1% OP	1	1	$172.43	$172.43	1	0.04%
SUBTOTAL	**528**	**399**	**$38,344.86**	**$72.62**	**1.32**	**8.07%**
DIFLUPREDONATE PRODUCTS						
DUREZOL EMU 0.05%	154	85	$34,660.67	$225.07	1.81	7.29%
DIFLUPREDNATE EMU 0.05%	36	21	$2,139.85	$59.44	1.71	0.45%
SUBTOTAL	**190**	**106**	**$36,800.52**	**$193.69**	**1.79**	**7.75%**
LOTEPREDNOL PRODUCTS						
LOTEMAX GEL 0.5%	43	29	$10,885.53	$253.15	1.48	2.29%
LOTEMAX OIN 0.5%	22	14	$8,390.08	$381.37	1.57	1.77%
LOTEPREDNOL GEL 0.5% OP	17	6	$2,841.58	$167.15	2.83	0.60%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**82**	**49**	**$22,117.19**	**$269.72**	**1.67**	**4.65%**
TIER-1 SUBTOTAL	**9,432**	**6,878**	**$468,313.13**	**$49.65**	**1.37**	**98.56%**
TIER-2 UTILIZATION						
LOTEPREDNOL PRODUCTS						
LOTEPREDNOL SUS 0.5%	31	29	$2,861.52	$92.31	1.07	0.60%
LOTEMAX SUS 0.5%	6	6	$2,235.53	$372.59	1	0.47%
LOTEMAX SM GEL 0.38%	6	4	$1,554.46	$259.08	1.5	0.33%
SUBTOTAL	**43**	**39**	**$6,651.51**	**$154.69**	**1.1**	**1.40%**
FLUOROMETHOLONE PRODUCTS						
FML FORTE SUS 0.25% OP	1	1	$172.40	$172.40	1	0.04%
SUBTOTAL	1	1	$172.40	$172.40	1	0.04%
TIER-2 SUBTOTAL	**44**	**40**	**$6,823.91**	**$155.09**	**1.1**	**1.44%**
TOTAL	**9,476**	**6,733***	**$475,137.04**	**$50.14**	**1.41**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DEXAMETH = dexamethasone; EMU = emulsion; FML = fluorometholone; OIN = ointment; OP = ophthalmic; PHO = phosphate; PRED = prednisolone; SOD = sodium; SOL = solution; SUS = suspension
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OZURDEX (J7312)	6	4	$10,033.31	$1,672.22	1.5
DEXTENZA (J1096)	3	2	$1,002.53	$334.18	1.5
TOTAL	**9**	**6**	**$11,035.84**	**$1,226.20**	**1.5**

*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Utilization Details of Ophthalmic NSAIDs: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
KETOROLAC SOL 0.5% OP	1,847	1,312	$36,651.25	$19.84	1.41	88.21%
DICLOFENAC SOL 0.1% OP	82	61	$1,573.02	$19.18	1.34	3.79%
FLURBIPROFEN SOL 0.03% OP	21	11	$758.37	$36.11	1.91	1.83%
TIER-1 SUBTOTAL	**1,950**	**1,384**	**$38,982.64**	**$19.99**	**1.41**	**93.82%**
TIER-2 UTILIZATION						
KETOROLAC SOL 0.4% OP	13	13	$892.93	$68.69	1	2.15%
BROMFENAC DRO 0.07% OP	9	8	$475.41	$52.82	1.13	1.14%
BROMFENAC DRO 0.09% OP	2	2	$91.89	$45.95	1	0.22%
ILEVRO DRO 0.3% OP	2	1	$749.81	$374.91	2	1.80%
PROLENSA DRO 0.07% OP	1	1	$358.55	$358.55	1	0.86%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 SUBTOTAL	**27**	**25**	**$2,568.59**	**$95.13**	**1.08**	**6.18%**
TOTAL	**1,977**	**1,400***	**$41,551.23**	**$21.02**	**1.41**	**100%**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
DRO = drops; OP = ophthalmic; SOL = solution
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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[3] U.S. FDA. National Drug Code (NDC) Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm. Last accessed 10/14/2026.
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[6] Byqlovi (Clobetasol Propionate Ophthalmic Suspension) Prescribing Information. Eyenovia, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218158s001lbl.pdf. Last revised 04/2025. Last accessed 10/14/2026.

Appendix S

Fiscal Year 2026 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Beclomethasone Dipropionate HFA, Exdensur (Depemokimab-ulaa) and Trimbow (Beclomethasone/ Formoterol/Glycopyrrolate)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (Qvar RediHaler)	budesonide/formoterol (Symbicort Aerosphere)
budesonide suspension (Pulmicort Respules)[α]	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)[€] – **Brand Preferred**	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.
[α]An age restriction of 0 to 8 years of age will apply for Pulmicort Respules. Members older than 8 years of age will require a patient-specific, clinically significant reason why the member requires the respule formulation and cannot use a Tier-1 hand-actuated device.
[β]Does not include Breyna; authorization of Breyna requires a reason why the member cannot use the brand formulation (Symbicort).
[€]Does not include Wixela; authorization of Wixela requires a reason why the member cannot use the brand formulation (Advair).
[¥]Asmanex 110mcg is only covered for members 4-11 years of age based on FDA recommended dosing.
[◊]Includes all strengths other than Dulera 50mcg/5mcg.

Inhaled Corticosteroids (ICS) and Combination Products Tier-1 Approval Criteria:

1. Tier-1 products indicated for the member's age are covered with no prior authorization required; or

2. Approval of Tier-1 products may be considered for members younger than the FDA approved age range if prescribed by a pulmonologist, immunologist, or an allergist (or a mid-level practitioner supervised by a pulmonologist, immunologist, or an allergist).

AirDuo RespiClick (Fluticasone Propionate/Salmeterol) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at or above the minimum age indicated; and
3. Failure of Advair, Dulera, and Symbicort or a reason why Advair, Dulera, and Symbicort are not appropriate for the member must be provided; and
4. Member must have used an inhaled corticosteroid for at least 1 month immediately prior; and
5. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or
6. A clinical situation warranting initiation with combination therapy due to severity of asthma.

Alvesco (Ciclesonide) and Fluticasone Propionate (Generic Flovent) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. A trial of all available Tier-1 inhaled corticosteroids appropriate to the members' age or a patient-specific, clinically significant reason why they are not appropriate for the member must be provided.

Breo Ellipta (Fluticasone Furoate/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) or chronic bronchitis and/or emphysema associated with COPD; and
    a. For a diagnosis of COPD or chronic bronchitis and/or emphysema associated with COPD, trials of Advair and Symbicort, consisting of at least 30 days each within the last 90 days that did not adequately control COPD symptoms; or
2. An FDA approved diagnosis of asthma in members 5 years of age and older; and
    a. For a diagnosis of asthma, trials of Advair, Dulera, and Symbicort consisting of at least 30 days each within the last 120 days that did not adequately control asthma symptoms; and
3. Requests for generic fluticasone furoate/vilanterol will require a patient-specific, clinically significant reason why brand name Breo Ellipta cannot be used.

Breyna (Budesonide/Formoterol Fumarate) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand name Symbicort must be provided (brand formulation is preferred and does not require prior authorization).

Dulera (Mometasone Furoate/Formoterol) 50mcg/5mcg Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be between 5 and 11 years of age; and
3. Failure of Advair and Symbicort or a reason why Advair and Symbicort are not appropriate for the member must be provided; and
4. Member must have used an inhaled corticosteroid (ICS) for at least 1 month immediately prior; and
5. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or
6. A clinical situation warranting initiation with combination therapy due to severity of asthma.

Wixela Inhub (Fluticasone/Salmeterol Inhalation Powder) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand formulation (Advair Diskus) must be provided.

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
Long-Acting Muscarinic Antagonists (LAMA)	
tiotropium inhalation powder (Spiriva HandiHaler) – **Brand Preferred**	aclidinium inhalation powder (Tudorza PressAir)
tiotropium soft mist inhaler (Spiriva Respimat)	revefenacin inhalation solution (Yupelri)
umeclidinium inhalation powder (Incruse Ellipta)– **Brand Preferred**	

*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).

Long-Acting Beta$_2$ Agonist (LABA) and Long-Acting Muscarinic Antagonist (LAMA) Tier-2 Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD), chronic bronchitis, or emphysema; and
2. Member must be 18 years of age or older; and
3. A 4-week trial of at least 1 LABA and a 4-week trial of 1 LAMA within the past 90 days; or
4. A documented adverse effect, drug interaction, or contraindication to all available Tier-1 products; or
5. A clinical exception may apply for members who are unable to effectively use hand-actuated devices, such as Spiriva HandiHaler, or who are stable on nebulized therapy.

Umeclidinium/Vilanterol (Unbranded Anoro Ellipta), 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 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.

Breztri Aerosphere (Budesonide/Glycopyrrolate/Formoterol) and Trelegy Ellipta (Fluticasone Furoate/Umeclidinium/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. A 4-week trial of at least 1 long-acting beta$_2$ agonist (LABA) and a 4-week trial of 1 long-acting muscarinic antagonist (LAMA) within the past 90 days used concomitantly with an inhaled corticosteroid (ICS); and
4. For Breztri Aerosphere, the following additional criteria will apply:
    a. A patient-specific, clinically significant reason why the member requires the triple combination therapy in place of the individual components or use of a LABA/ICS combination with a LAMA must be provided; and
    b. A patient-specific, clinically significant reason why the member cannot use Trelegy Ellipta (fluticasone furoate/umeclidinium/ vilanterol) must be provided.

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 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.

Current Prior Authorization Criteria: Asthma-Indicated Monoclonal Antibodies

Cinqair (Reslizumab Injection) 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. 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 [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 6 months 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 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'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
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. 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
7. Initial approvals will be for the duration of 16 weeks. 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 [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 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 ≥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 [long-acting beta$_2$ agonist/long-acting muscarinic agonist/inhaled

corticosteroid (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. 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 [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 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 [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. 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
8. 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 [Eosinophilic Esophagitis (EoE) Diagnosis]:

1. An FDA approved diagnosis of 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 year 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 of the following therapies (or have a contraindication or documented intolerance):
    a. One high-dose proton pump inhibitor; 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.

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. 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 Injection) 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.
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.

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; and
12. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

Nucala (Mepolizumab 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 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; and
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 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. 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.

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 dose must be an FDA approved regimen per package labeling; and
8. For authorization 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 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 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; and
10. 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 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 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. For authorization 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
6. For authorization of the 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 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; and

7. 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
8. 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
9. 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
10. 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
11. 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 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 dose must be an FDA approved regimen per package labeling; and

9. For authorization 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 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 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; and
11. 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 dose must be an FDA approved regimen per package labeling; and
10. For authorization 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 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 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; and
12. 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.

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

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and

5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. For authorization of Tezspire in a health care facility, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or
7. For authorization of Tezspire prefilled 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. 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 prefilled syringe) per 28 days will apply.

Tezspire (Tezepelumab-ekko 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. 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 prefilled 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 prefilled syringe) per 28 days will apply.

Utilization of Asthma and COPD Maintenance Medications: Fiscal Year 2026

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 2025							
FFS	16,229	51,793	$14,978,660.09	$289.20	$8.46	1,510,292	1,769,667
Aetna	8,638	26,685	$6,985,642.99	$261.78	$7.77	712,147	899,376
Humana	9,557	31,393	$8,687,762.75	$276.74	$8.14	851,324	1,067,007
OCH	9,873	28,543	$7,811,679.54	$273.68	$7.69	787,221	1,015,238
2025 Total	**40,724**	**138,414**	**$38,463,745.37**	**$277.89**	**$8.10**	**3,860,984**	**4,751,288**
Fiscal Year 2026							
FFS	15,310	49,803	$14,564,261.29	$292.44	$8.58	1,531,628	1,698,403
Aetna	8,178	24,814	$6,845,050.21	$275.85	$8.11	690,408	843,881
Humana	9,217	30,985	$9,057,300.92	$292.31	$8.48	894,086	1,068,405
OCH	9,138	26,526	$7,596,967.10	$286.40	$7.69	787,280	988,231
2026 Total	**38,350**	**132,128**	**$38,063,579.52**	**$288.08**	**$8.28**	**3,903,401**	**4,598,920**
% Change	**-5.80%**	**-4.50%**	**-1.00%**	**3.70%**	**2.20%**	**1.10%**	**-3.20%**
Change	**-2,374**	**-6,286**	**-$400,165.85**	**$10.19**	**$0.18**	**42,417**	**-152,368**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

- Aggregate drug rebates collected during fiscal year 2026 for the asthma and COPD maintenance medications totaled $25,807,916.85.[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.

Comparison of Fiscal Years: Asthma-Indicated Monoclonal Antibodies: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	720	3,771	$14,713,340.09	$3,901.71	$121.57	13,351	121,024
Aetna	465	2,515	$9,724,575.79	$3,866.63	$123.82	8,634	78,536
Humana	517	3,007	$11,727,591.75	$3,900.10	$128.06	10,356	91,580
OCH	496	2,423	$9,533,476.08	$3,934.58	$115.83	8,225	82,308
2025 Total	**1,957**	**11,716**	**$45,698,983.71**	**$3,900.56**	**$122.37**	**40,566**	**373,448**
Fiscal Year 2026							
FFS	798	4,138	$17,131,736.46	$4,140.10	$128.23	14,621	133,602
Aetna	553	2,888	$11,675,806.12	$4,042.87	$122.05	9,860	95,666
Humana	613	3,480	$14,374,159.09	$4,130.51	$132.62	11,820	108,384
OCH	626	3,292	$13,420,539.96	$4,076.71	$119.27	11,170	112,518
2026 Total	**2,354**	**13,798**	**$56,602,241.63**	**$4,102.21**	**$125.74**	**47,470**	**450,170**
% Change	**20.30%**	**17.80%**	**23.90%**	**5.20%**	**2.80%**	**17.00%**	**20.50%**
Change	**397**	**2,082**	**$10,903,257.92**	**$201.65**	**$3.37**	**6,904**	**76,722**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Utilization data includes all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

[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.

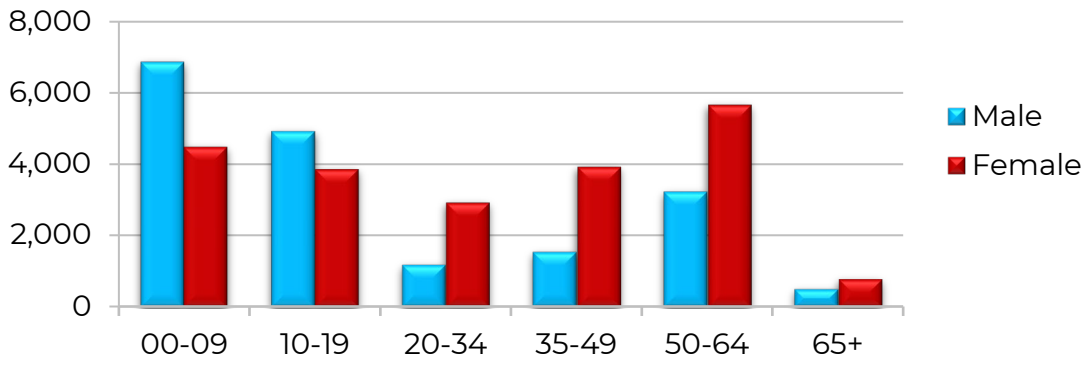
Comparison of Fiscal Years: Asthma-Indicated Monoclonal Antibodies: Medical Claims (All Plans)

Plan Type	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	32	265	$650,474.55	$2,454.62	8.28
Aetna	23	92	$236,569.50	$2,571.41	4
Humana	51	237	$451,828.42	$1,906.45	4.65
OCH	27	105	$196,518.75	$1,871.61	3.89
2025 Total	**128**	**699**	**$1,535,391.22**	**$2,196.55**	**5.46**
Fiscal Year 2026					
FFS	32	261	$770,675.23	$2,952.78	8.16
Aetna	29	130	$367,320.46	$2,825.54	4.48
Humana	52	308	$696,040.29	$2,259.87	5.92
OCH	25	140	$312,577.16	$2,232.69	5.6
2026 Total	**134**	**839**	**$2,146,613.14**	**$2,558.54**	**6.26**
% Change	**4.69%**	**20.03%**	**39.81%**	**16.48%**	**14.65%**
Change	**6**	**140**	**$611,221.92**	**$361.98**	**0.8**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Utilization data includes all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

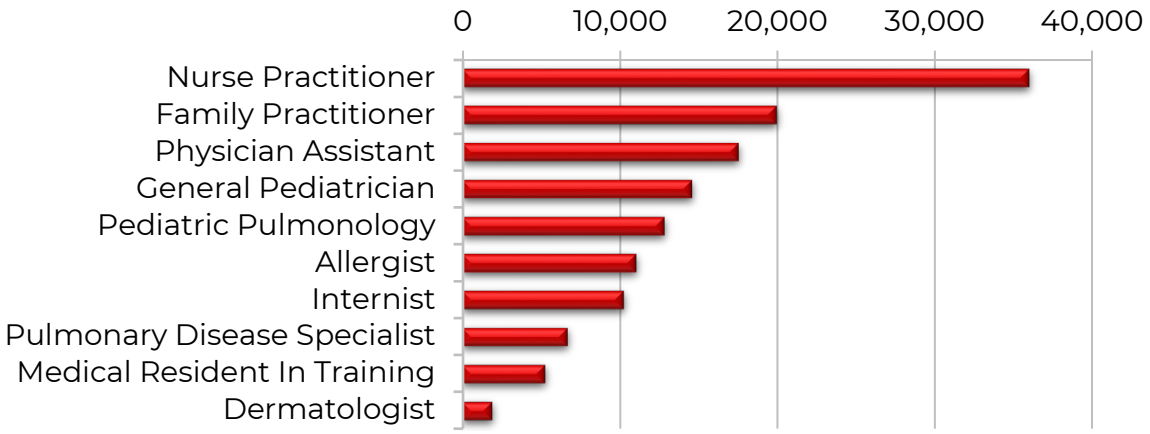
- Aggregate drug rebates collected during fiscal year 2026 for the asthma-indicated monoclonal antibodies totaled $16,776,134.18.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Asthma and COPD Maintenance 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.

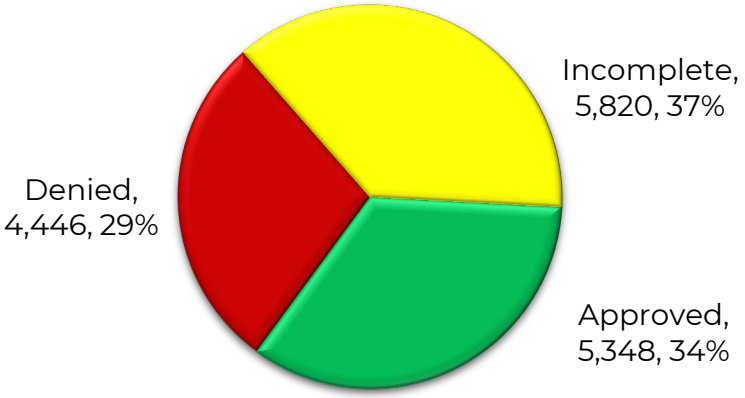
Top Prescriber Specialties of Asthma and COPD Maintenance Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Asthma and COPD Maintenance Medications

There were 15,614 prior authorization requests submitted for asthma and COPD maintenance medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	2,244	27%	4,547	56%	1,382	17%	**8,173**
Aetna	843	37%	431	19%	981	44%	**2,255**
Humana	960	51%	219	12%	695	37%	**1,874**
OCH	1301	39%	623	19%	1388	42%	**3,312**
Total	**5,348**	**34%**	**5,820**	**37%**	**4,446**	**29%**	**15,614**

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]

Anticipated Patent Expiration(s):

- Striverdi Respimat (olodaterol inhalation spray): January 2027
- Incruse Ellipta (umeclidinium inhalation powder): December 2027
- Duaklir Pressair (aclidinium/formoterol inhalation powder): March 2029
- Tudorza Pressair (aclidinium inhalation powder): March 2029
- Stiolto Respimat (tiotropium/olodaterol inhalation spray): October 2030
- Anoro Ellipta (umeclidinium/vilanterol inhalation powder): November 2030
- Bevespi Aerosphere (glycopyrrolate/formoterol inhalation aerosol): March 2031
- Breo Ellipta (fluticasone furoate/vilanterol inhalation powder): April 2031
- Spiriva Respimat (tiotropium soft mist inhaler): April 2031
- Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol inhalation powder): April 2031
- Trimbow (beclomethasone/formoterol fumarate/glycopyrrolate): December 2034
- Breztri Aerosphere (budesonide/glycopyrrolate/formoterol aerosol): October 2038
- AirDuo RespiClick (fluticasone propionate/salmeterol inhalation powder): February 2040
- Qvar RediHaler (beclomethasone inhalation aerosol): August 2041
- Ohtuvayre (ensifentrine inhalation suspension): June 2044

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

- **December 2025:** The FDA approved Exdensur (depemokimab-ulaa) as an add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in patients 12 years of age or older. Exdensur is the first and only biologic for patients with severe eosinophilic asthma that is dosed twice yearly.
- **February 2026:** The FDA approved Dupixent (dupilumab) for the treatment of patients 6 years of age and older with allergic fungal rhinosinusitis (AFRS) with a history of sino-nasal surgery. AFRS is an uncommon type of chronic sinus inflammation caused by an allergic reaction to fungi growing in the sinuses, with production of thick, sticky mucus often described as resembling peanut butter. AFRS affects up to 8% of people with chronic sinus inflammation and nasal polyps, and is more common in warm, humid areas where fungi thrive. If left untreated, AFRS can cause serious problems, including expansion of the sinuses, erosion of surrounding bone (occurs in approximately 90% of patients), and invasion of the eye area or brain, leading to facial deformities, vision problems, and nerve damage. Dupixent is the first FDA approved therapy for AFRS.

- **April 2026:** The FDA approved Dupixent (dupilumab) for an age expansion for the treatment of chronic spontaneous urticaria (CSU) in patients 2 years of age or older. Previously, Dupixent was approved for CSU in patients 12 years of age or older.
- **April 2026:** The FDA approved Breztri Aerosphere (budesonide/ glycopyrrolate/formoterol fumarate) for the maintenance treatment of asthma in patients 12 years of age or older. In addition to the new indication, a new strength of Breztri Aerosphere was also approved in a 160mcg/18mcg/4.8mcg strength. Previously, Breztri Aerosphere was only approved for COPD in adults in a 160mcg/9mcg/4.8mcg strength.
- **May 2026:** The FDA approved Fasenra (benralizumab) for the treatment of patients 12 years of age or older with hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause. The approval of Fasenra for HES was based on a randomized, double-blind, placebo-controlled trial in patients 12 years of age and older who had signs or symptoms of an HES flare or who had experienced at least 2 HES flares within the past 12 months. Patients were randomized to receive Fasenra or placebo while continuing their stable HES therapy. The trial demonstrated that treatment with Fasenra delayed the time to first HES flare and resulted in a 65% reduction in the risk of first flare vs. placebo [hazard ratio: 0.35; 95% confidence interval (CI): 0.18, 0.69; P=0.0024]. Additionally, treatment with Fasenra resulted in 52% relative reduction in the proportion of patients who experienced an HES flare and significantly reduced the number of HES flares observed during the treatment period.
- **May 2026:** The FDA approved Trimbow (beclomethasone/formoterol fumarate/glycopyrrolate) for the maintenance treatment of asthma in patients 18 years of age or older. The cost of Trimbow is not yet available.

News:

- **April 2026:** A generic version of Qvar HFA (beclomethasone dipropionate) was launched.
- **October 2026:** Omlyclo (omalizumab-igec) was launched on the market after its FDA approval in March 2025. Omlyclo is an interchangeable biosimilar to Xolair (omalizumab) and is approved for all of the same indications.

Guideline Update(s):

- **Global Initiative for Asthma (GINA) Guideline Update:** GINA has released its annual guideline update for 2026. Some notable updates include:
    - Updated flowcharts are provided for the assessment, treatment, and follow-up of patients presenting for management of an

exacerbation or acute asthma. This update includes more conservative dosing of short-acting beta$_2$ agonists (SABAs) during acute exacerbations and the inclusion of inhaled corticosteroid (ICS)-formoterol as an alternative option to inhaled SABAs for patients 6 years of age or older experiencing a mild exacerbation.
    - The Step 1 treatment options for patients 6-11 years of age have been updated based on data from the CARE trial in patients 5-15 years of age who were on a SABA alone showing that low-dose budesonide-formoterol used as needed for symptom relief reduced the risk of moderate-to-severe exacerbations compared to a SABA alone. Step 1 now lists the recommended treatment as using anti-inflammatory reliever (AIR) therapy only with as-needed low-dose ICS-formoterol or as-needed low-dose ICS+SABA as a combination inhaler or separate inhalers.
    - Asthma treatment in adults and adolescents reconfirms that Track 1 with ICS-formoterol AIR therapy remains the preferred treatment option if available because it substantially reduces the risk of severe exacerbations, systemic corticosteroid exposure, and need for urgent care compared with SABA-based regimens. Additionally, Track 2 was updated to state that if ICS-formoterol is not available, AIR therapy can be delivered with as-needed low-dose combination ICS-SABA. If combination ICS-SABA is not available, a patient can use low-dose ICS whenever they take their SABA.
    - Options for the treatment of severe asthma with biologic medications have been updated to include new treatment options including depemokimab-ulaa and the biosimilar omalizumab-igec.
- **Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guideline Update:** The GOLD guidelines have been updated for 2026. Some notable updates include:
    - The criteria defining GOLD A, B, and E categories have been updated based on evidence from observational studies showing that even 1 moderate or severe exacerbation prior to initiating maintenance pharmacological therapy increases the risk of subsequent events. The threshold of 1 moderate exacerbation should now be used to consider treatment escalation, with the aim of achieving a low disease activity characterized by no exacerbations.
    - The treatment algorithms have been updated to further clarify and emphasize the distinction between initial versus follow-up treatment. Additionally, mepolizumab is now listed as a biologic therapy option for patients treated with a long-acting beta$_2$ agonist (LABA)/long-acting muscarinic agonist (LAMA)/ICS who still have exacerbations and have eosinophils ≥300 cells/mcL.

- **International Guideline for Urticaria Update:** The *International Guideline for the Definition, Classification, Diagnosis, and Management of Urticaria* was updated in February 2026. Some notable updates include:
    - Patients should be assessed for disease activity, impact, and control at all visits using validated Patient-Reported Outcome Measures (PROMs) such as the urticaria activity score (UAS), angioedema activity score (AAS), chronic urticaria quality of life questionnaire (CU-Q2oL), angioedema quality of life questionnaire (AE-QoL), urticaria control test (UCT), and angioedema control test (AECT).
        - The UCT was developed and validated to determine the level of disease control in all forms of chronic urticaria (CSU and CIndU). It is a simple 4-item tool with a clearly defined cut off for patients with "well-controlled" vs. "poorly controlled" disease, and it is thus suited for the management of patients in routine clinical practice.
    - Treatment should follow the basic principles of treating as much as needed and as little as possible, taking into consideration that the activity of the disease may vary. This implies stepping up or stepping down in the treatment algorithm according to the course of disease. It is important to highlight that patients need good counseling regarding continuous treatment and using PROMs, especially about using the UAS.
    - First line treatment for all types of urticaria continues to be a second-generation H1 antihistamine and then dosing up to 4-fold in patients with chronic urticaria unresponsive to a standard-dosed second-generation H1 antihistamine as second-line treatment before other treatments are considered.
    - For patients who are unresponsive to high doses of second-generation H1 antihistamines, the following are recommended: omalizumab (strong recommendation), dupilumab (conditional recommendation), or remibrutinib (conditional recommendation).

Pipeline:

- **Tezspire (Tezepelumab-ekko):** Tezepelumab-ekko is a monoclonal antibody that inhibits thymic stromal lymphopoietin (TSLP) and is currently FDA approved for the treatment of severe asthma and the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP). Tezepelumab-ekko is currently being studied for the treatment of eosinophilic esophagitis (EoE) in patients 12 years of age or older. Results from the Phase 3 CROSSING trial showed that tezepelumab-ekko demonstrated statistically significant and clinically meaningful improvements in the co-primary endpoints of histologic remission and the frequency and severity of dysphagia despite continued treatment

with background medications. Treatment with tezepelumab-ekko showed that histological remission was achieved in 64.8% of patients on the 210mg dose and 68.9% of patients on the 420mg dose versus 3.5% of patients on placebo. Tezepelumab-ekko was granted Orphan Drug designation for EoE in 2021 and is also currently in Phase 3 trials for COPD.

- **Tozorakimab:** Tozorakimab is an investigational monoclonal antibody that binds to interleukin-33 (IL-33) being studied for the treatment of adults with symptomatic COPD and a history of ≥2 moderate or ≥1 severe COPD exacerbation. Results from the OBERON and TITANIA Phase 3 trials showed that tozorakimab demonstrated a reduction in moderate and severe COPD exacerbations in the primary population of former smokers by 29% (OBERON) and 34% (TITANIA), and in the overall population of current and former smokers by 30% (OBERON) and 29% (TITANIA) compared with placebo while on inhaled standard of care therapy. The FDA has accepted a Biologics License application (BLA) under Priority Review for tozorakimab for COPD and a Prescription Drug User Fee Act (PDUFA) target date is anticipated in the first quarter of 2027.

Exdensur (Depemokimab-ulaa) Product Summary[15]

Therapeutic Class: Interleukin-5 (IL-5) antagonist

Indication(s): Add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients 12 years of age and older

- **Limitation(s) of Use:** Not for relief of acute bronchospasm or status asthmaticus

How Supplied: 100mg/mL solution in a single-dose prefilled pen or prefilled syringe

Dosing and Administration:

- The recommended dose is 100mg once every 6 months administered by subcutaneous (sub-Q) injection.
- Exdensur should be administered by a health care provider.

Efficacy: Exdensur was studied in 2 replicate, randomized, double-blind, parallel-group, placebo-controlled, multicenter clinical trials, SWIFT-1 and SWIFT-2.

- Key Inclusion Criteria:
  - ≥12 years of age with eosinophilic asthma (blood eosinophils ≥150 cells/mcL at screening or ≥300cells/mcL in prior year)

    - ≥2 asthma exacerbations requiring systemic corticosteroids in prior year despite medium- to high-dose ICS plus ≥1 controller with or without maintenance oral corticosteroids
- Key Exclusion Criteria:
    - Received monoclonal antibodies targeting IL-5 within 12 months prior to visit 1 or have a previous documented failure with anti-IL-5 therapy
    - Received Xolair or Dupixent within 130 days prior to visit 1
- Intervention(s): Patients were randomized to receive Exdensur 100mg once every 6 months for a total of 2 doses in addition to background asthma therapy or placebo
- Primary Endpoint(s): Annualized rate of clinically significant exacerbations over 52 weeks
- Results:
    - SWIFT-1: The annualized rate of clinically significant asthma exacerbations was 0.46 in the Exdensur group vs. 1.11 in the placebo group (rate ratio: 0.42; 95% CI: 0.30, 0.59; P<0.001).
    - SWIFT-2: The annualized rate of clinically significant asthma exacerbations was 0.56 in the Exdensur group vs. 1.08 in the placebo group (rate ratio: 0.52; 95% CI: 0.36, 0.73; P<0.001).

Cost: The Wholesale Acquisition Cost (WAC) of Exdensur is $26,000 per dose resulting in an estimated cost of $52,000 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Exdensur (depemokimab-ulaa) with the following criteria (shown in red):

Exdensur (Depemokimab-ulaa 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 12 years of age or older; and
3. Member must have a blood eosinophil count of ≥150cells/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. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Dupixent (dupilumab), Fasenra (benralizumab), and Nucala (mepolizumab) must be provided; and
8. Exdensur must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Exdensur will be administered; and
9. Exdensur 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 1 year. 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 prefilled pen or syringe per 180 days will apply.

Additionally, the College of Pharmacy recommends the following changes to the Dupixent (dupilumab) approval criteria based on the new FDA approved indication for AFRS and age expansion for the treatment of CSU (changes shown in red):

Dupixent (Dupilumab Injection) Approval Criteria [Allergic Fungal Rhinosinusitis (AFRS) Diagnosis]:

1. An FDA approved diagnosis of AFRS defined as:
    a. Evidence of sinus opacification; and
    b. Evidence of nasal polyposis; and
    c. IgE mediated inflammatory response to fungus or sensitization to fungus; and
    d. Eosinophilic mucus; and
    e. Characteristic CT signs of AFRS (i.e., hyperdensities, bone erosion of sinus, bony demineralization); and
2. Member must be 6 years of age or older; and
3. Member has required prior sino-nasal surgery; and
4. Member does not have fungal invasive sinusitis; and
5. Member must have a documented trial with an intranasal or systemic corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and

6. 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 be an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent; 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; 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; and
10. A quantity limit of 2 syringes every 28 days will apply.

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

1. An FDA approved diagnosis of CSU; and
2. Member must be ~~12~~ 2 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. 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
8. 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.

Next, the College of Pharmacy recommends the following changes to the Fasenra (benralizumab) approval criteria based on the new FDA approved indication for HES (changes shown in red):

Fasenra (Benralizumab Injection) Approval Criteria [Hypereosinophilic Syndrome (HES) Diagnosis]:

1. An FDA approved diagnosis of HES 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 Fasenra; and
5. A 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. Fasenra 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 Fasenra prefilled syringe, 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 Fasenra prefilled autoinjector pen, 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
10. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 28 days will apply.
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 Fasenra as demonstrated by fewer HES flares from baseline or by a decrease in daily OCS dosing from baseline. Subsequent approvals will be for 1 year.

Next, the College of Pharmacy recommends the prior authorization of Trimbow (beclomethasone/formoterol fumarate/glycopyrrolate) with criteria similar to Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) and Breztri Aerosphere (budesonide/glycopyrrolate/formoterol) and recommends updating the Breztri Aerosphere approval criteria based on the new FDA approved indication for asthma (changes shown in red):

Breztri Aerosphere (Budesonide/Glycopyrrolate/Formoterol), ~~and~~ Trelegy Ellipta (Fluticasone Furoate/Umeclidinium/Vilanterol), and Trimbow (Beclomethasone/Formoterol Fumarate/Glycopyrrolate) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; ~~and~~ or
   a. For Breztri Aerosphere, for a diagnosis of asthma, member must be 12 years of age or older; and
3. A 4-week trial of at least 1 long-acting beta$_2$ agonist (LABA) and a 4-week trial of 1 long-acting muscarinic antagonist (LAMA) within the past 90 days used concomitantly with an inhaled corticosteroid (ICS); and
4. For Breztri Aerosphere and Trimbow, the following additional criteria will apply:
   a. A patient-specific, clinically significant reason why the member requires the triple combination therapy in place of the individual components or use of a LABA/ICS combination with a LAMA must be provided; and
   b. For adults, a patient-specific, clinically significant reason why the member cannot use Trelegy Ellipta (fluticasone furoate/ umeclidinium/vilanterol) must be provided.

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. Prior authorization of beclomethasone dipropionate (generic Qvar HFA) and placement into Tier-2 with the following additional criteria:

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (Qvar RediHaler)	**beclomethasone diproprionate (Qvar HFA)**
budesonide suspension (Pulmicort Respules)[α]	budesonide/formoterol (Symbicort Aerosphere)
budesonide/formoterol (Symbicort)[β] – **Brand Preferred**	ciclesonide (Alvesco)
fluticasone furoate (Arnuity Ellipta) – **Brand Preferred**	fluticasone propionate (Flovent)

fluticasone propionate/salmeterol (Advair)[€] – **Brand Preferred**	fluticasone furoate/vilanterol (Breo Ellipta) – **Brand Preferred**
mometasone furoate (Asmanex)	fluticasone propionate/salmeterol (AirDuo RespiClick)
mometasone furoate/formoterol (Dulera)[◊]	mometasone furoate/formoterol 50mcg/5mcg (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.
[α]An age restriction of 0 to 8 years of age will apply for Pulmicort Respules. Members older than 8 years of age will require a patient-specific, clinically significant reason why the member requires the respule formulation and cannot use a Tier-1 hand-actuated device.
[β]Does not include Breyna; authorization of Breyna requires a reason why the member cannot use the brand formulation (Symbicort).
[€]Does not include Wixela; authorization of Wixela requires a reason why the member cannot use the brand formulation (Advair).
[¥] Asmanex 110mcg is only covered for members 4-11 years of age based on FDA recommended dosing.
[◊]Includes all strengths other than Dulera 50mcg/5mcg.

Alvesco (Ciclesonide), Beclomethasone Dipropionate (generic Qvar HFA), and Fluticasone Propionate (generic Flovent) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. A trial of all available Tier-1 inhaled corticosteroids appropriate to the members' age or a patient-specific, clinically significant reason why they are not appropriate for the member must be provided.

Utilization Details of Asthma and COPD Maintenance Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ICS/LABA COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
SYMBICORT AER 160/4.5MCG	19,926	6,672	$5,481,327.32	$275.08	2.99	14.40%
SYMBICORT AER 80/4.5MCG	12,344	5,051	$2,889,984.00	$234.12	2.44	7.59%
FLUTIC/SALME AER 250/50MCG	9,737	3,651	$1,012,219.71	$103.96	2.67	2.66%
FLUTIC/SALME AER 115/21MCG	6,696	2,569	$1,958,489.68	$292.49	2.61	5.15%
DULERA AER 200/5MCG	3,891	1,154	$1,471,113.45	$378.08	3.37	3.86%
FLUTIC/SALME AER 100/50MCG	3,589	1,496	$322,186.16	$89.77	2.4	0.85%
FLUTIC/SALME AER 500/50MCG	3,281	1,104	$477,123.66	$145.42	2.97	1.25%
ADVAIR HFA AER 115/21MCG	3,117	1,152	$1,040,437.65	$333.79	2.71	2.73%
DULERA AER 100/5MCG	2,395	889	$902,586.14	$376.86	2.69	2.37%
WIXELA INHUB AER 250/50MCG	2,269	1,010	$293,840.96	$129.50	2.25	0.77%
FLUTIC/SALME AER 45/21MCG	2,149	816	$469,797.51	$218.61	2.63	1.23%
FLUTIC/SALME AER 230/21MCG	1,944	705	$745,080.56	$383.27	2.76	1.96%
WIXELA INHUB AER 100/50	975	477	$104,624.20	$107.31	2.04	0.27%
ADVAIR HFA AER 45/21MCG	821	330	$208,862.57	$254.40	2.49	0.55%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
WIXELA INHUB AER 500/50MCG	712	286	$115,101.24	$161.66	2.49	0.30%
ADVAIR DISKUS AER 250/50MCG	712	295	$179,759.49	$252.47	2.41	0.47%
ADVAIR HFA AER 230/21MCG	650	254	$301,507.77	$463.86	2.56	0.79%
BREYNA AER 160/4.5MCG	340	212	$70,246.65	$206.61	1.6	0.18%
BUDES/FORMOT AER 160/4.5MCG	312	204	$71,400.06	$228.85	1.53	0.19%
BUDES/FORMOT AER 80/4.5MCG	267	188	$52,107.74	$195.16	1.42	0.14%
ADVAIR DISKUS AER 500/50MCG	254	90	$90,433.57	$356.04	2.82	0.24%
BREYNA AER 80/4.5MCG	240	171	$51,016.58	$212.57	1.4	0.13%
ADVAIR DISKUS AER 100/50MCG	195	77	$33,263.64	$170.58	2.53	0.09%
FLUTIC/SALME INH 55/14MCG	11	5	$1,299.56	$118.14	2.2	0.00%
FLUTIC/SALME INH 232/14MCG	7	4	$819.10	$117.01	1.75	0.00%
FLUTIC/SALME INH 113/14MCG	7	4	$755.09	$107.87	1.75	0.00%
SUBTOTAL	**76,841**	**28,866**	**$18,345,384.06**	**$238.74**	**2.66**	**48.20%**
TIER-2 UTILIZATION						
BREO ELLIPTA INH 100-25MCG	217	80	$86,366.19	$398.00	2.71	0.23%
BREO ELLIPTA INH 200-25MCG	193	73	$75,547.43	$391.44	2.64	0.20%
FLUTIC/VILAN INH 200-25MCG	37	17	$8,950.96	$241.92	2.18	0.02%
FLUTIC/VILAN INH 100-25MCG	11	9	$2,676.60	$243.33	1.22	0.01%
DULERA AER 50-5MCG	8	5	$2,717.04	$339.63	1.6	0.01%
BREO ELLIPTA INH 50-25MCG	6	5	$2,400.96	$400.16	1.2	0.01%
AIRDUO RESPICLICK INH 55-14MCG	4	1	$1,654.04	$413.51	4	0.00%
SUBTOTAL	**476**	**190**	**$180,313.22**	**$378.81**	**2.51**	**0.47%**
ICS/LABA TOTAL	**77,317**	**29,056**	**$18,525,697.28**	**$239.61**	**2.66**	**48.67%**
INDIVIDIUAL COMPONENT ICS PRODUCTS						
TIER-1 UTILIZATION						
ASMANEX HFA AER 100MCG	3,851	2,157	$421,654.29	$109.49	1.79	1.11%
BUDESONIDE SUS 0.5MG/2ML	3,290	1,523	$260,165.38	$79.08	2.16	0.68%
QVAR REDIHALER AER 40MCG	2,755	1,430	$617,405.05	$224.10	1.93	1.62%
BUDESONIDE SUS 0.25MG/2ML	2,382	1,421	$179,253.91	$75.25	1.68	0.47%
ASMANEX HFA AER 50MCG	2,346	1,237	$234,699.96	$100.04	1.9	0.62%
QVAR REDIHALER AER 80MCG	1,421	746	$420,370.61	$295.83	1.9	1.10%
ASMANEX HFA AER 200MCG	791	410	$100,334.82	$126.85	1.93	0.26%
PULMICORT INH 90MCG	719	383	$163,055.85	$226.78	1.88	0.43%
ARNUITY ELLIPTA INH 100MCG	566	214	$118,527.80	$209.41	2.64	0.31%
BUDESONIDE SUS 1MG/2ML	505	173	$186,717.32	$369.74	2.92	0.49%
PULMICORT INH 180MCG	425	256	$118,266.62	$278.27	1.66	0.31%
ASMANEX 30 AER 110MCG	190	92	$19,219.38	$101.15	2.07	0.05%
ARNUITY ELLIPTA INH 50MCG	173	59	$35,750.04	$206.65	2.93	0.09%
ASMANEX 60 AER 220MCG	144	72	$24,595.96	$170.81	2	0.06%
ARNUITY ELLIPTA INH 200MCG	119	45	$32,130.90	$270.01	2.64	0.08%
ASMANEX 120 AER 220MCG	93	57	$17,625.72	$189.52	1.63	0.05%
ASMANEX 30 AER 220MCG	90	39	$12,956.47	$143.96	2.31	0.03%
FLUTICASONE FUR INH 100MCG	28	17	$3,937.53	$140.63	1.65	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FLUTICASONE FUR INH 50MCG	3	3	$440.79	$146.93	1	0.00%
ASMANEX 14 AER 220MCG	2	1	$96.78	$48.39	2	0.00%
SUBTOTAL	**19,893**	**10,355**	**$2,967,205.18**	**$149.16**	**1.92**	**7.80%**
TIER-2 UTILIZATION						
FLUTICASONE HFA AER 110MCG	3,861	1,788	$762,297.25	$197.44	2.16	2.00%
FLUTICASONE HFA AER 44MCG	1,628	800	$228,599.84	$140.42	2.04	0.60%
FLUTICASONE HFA AER 220MCG	359	137	$104,655.32	$291.52	2.62	0.27%
FLUTICASONE DISKUS AER 100MCG	118	38	$19,003.88	$161.05	3.11	0.05%
FLUTICASONE DISKUS AER 50MCG	73	23	$10,941.44	$149.88	3.17	0.03%
FLUTICASONE DISKUS AER 250MCG	48	13	$10,529.22	$219.36	3.69	0.03%
ALVESCO AER 80MCG	23	12	$6,292.66	$273.59	1.92	0.02%
ALVESCO AER 160MCG	12	3	$3,096.36	$258.03	4	0.01%
SUBTOTAL	**6,122**	**2,814**	**$1,145,415.97**	**$187.10**	**2.18**	**3.01%**
ICS TOTAL	**26,015**	**13,149**	**$4,112,621.15**	**$158.09**	**1.98**	**10.80%**
INDIVIDIUAL COMPONENT LAMA PRODUCTS						
TIER-1 UTILIZATION						
SPIRIVA RESPIMAT AER 2.5MCG	9,052	2,431	$4,637,791.91	$512.35	3.72	12.18%
SPIRIVA RESPIMAT AER 1.25MCG	5,285	1,420	$2,693,734.57	$509.69	3.72	7.08%
SPIRIVA CAP HANDIHALER 18MCG	4,112	1,332	$1,905,247.50	$463.34	3.09	5.01%
INCRUSE ELLIPTA INH 62.5MCG	1,005	297	$348,973.20	$347.24	3.38	0.92%
TIOTROPIUM BROM CAP 18MCG	46	30	$23,017.18	$500.37	1.53	0.06%
UMECLIDINIUM ELLIPTA INH 62.5MCG	8	8	$1,900.70	$237.59	1	0.00%
SUBTOTAL	**19,508**	**5,518**	**$9,610,665.06**	**$492.65**	**3.54**	**25.25%**
TIER-2 UTILIZATION						
YUPELRI NEB 175MCG/3ML	111	33	$170,506.20	$1,536.09	3.36	0.45%
TUDORZA PRESSAIR AER 400MCG/ACT	56	12	$24,136.42	$431.01	4.67	0.06%
SUBTOTAL	**167**	**45**	**$194,642.62**	**$1,165.52**	**3.71**	**0.51%**
LAMA TOTAL	**19,675**	**5,563**	**$9,805,307.68**	**$498.36**	**3.54**	**25.76%**
LABA/LAMA/ICS COMBINATION PRODUCTS						
TRELEGY AER 200/62.5/25MCG	2,622	624	$1,760,692.06	$671.51	4.2	4.63%
TRELEGY AER 100/62.5/25MCG	2,376	650	$1,594,342.19	$671.02	3.66	4.19%
BREZTRI AEROSPHERE 160/9/4.8MCG	1,802	486	$1,184,053.83	$657.08	3.71	3.11%
LABA/LAMA/ICS TOTAL	**6,800**	**1760**	**$4,539,088.08**	**$667.51**	**3.86**	**11.93%**
LABA/LAMA COMBINATION PRODUCTS						
ANORO ELLIPTA AER 62.5/25MCG	550	227	$262,555.31	$477.37	2.42	0.69%
STIOLTO AER 2.5/2.5MCG	255	80	$120,390.38	$472.12	3.19	0.32%
UMECLID/VILA INH 62.5/25MCG	79	31	$24,182.94	$306.11	2.55	0.06%
BEVESPI AER 9/4.8MCG	2	1	$874.29	$437.15	2	0.00%
LABA/LAMA TOTAL	**886**	**339**	**$408,002.92**	**$460.50**	**2.61**	**1.07%**
INDIVIDUAL COMPONENT LABA PRODUCTS						
TIER-1 UTILIZATION						
SEREVENT DISKUS AER 50MCG	572	208	$278,456.76	$486.81	2.75	0.73%
STRIVERDI AER 2.5MCG	15	9	$4,071.85	$271.46	1.67	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**587**	**217**	**$282,528.61**	**$481.31**	**2.71**	**0.74%**
TIER-2 UTILIZATION						
ARFORMOTEROL NEB 15MCG/2ML	133	32	$11,607.34	$87.27	4.16	0.03%
FORMOTEROL NEB 20MCG/2ML	91	22	$23,281.10	$255.84	4.14	0.06%
SUBTOTAL	**224**	**54**	**$34,888.44**	**$155.75**	**4.15**	**0.09%**
LABA TOTAL	**811**	**271**	**$317,417.05**	**$391.39**	**2.99**	**0.83%**
PDE4 INHIBITOR PRODUCTS						
ROFLUMILAST TAB 500MCG	411	96	$8,164.60	$19.87	4.28	0.02%
ROFLUMILAST TAB 250MCG	98	25	$6,863.96	$70.04	3.92	0.02%
PDE4 INHIBITOR TOTAL	**509**	**121**	**$15,028.56**	**$29.53**	**4.21**	**0.04%**
PDE3/PDE4 INHIBITOR PRODUCTS						
OHTUVAYRE SUS 3MG/2.5ML	115	34	$340,416.80	$2,960.15	3.38	0.89%
PDE3/PDE4 INHIBITOR TOTAL	**115**	**34**	**$340,416.80**	**$2,960.15**	**3.38**	**0.89%**
TOTAL	**132,128**	**38,350***	**$38,063,579.52**	**$288.08**	**3.45**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; AER = aerosol; BROM = bromide; BUDES = budesonide; CAP = capsule; FLUTIC = fluticasone; FORMOT = formoterol; FUR = furoate; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; INH = inhaler; LABA = long-acting beta$_2$ agonist; LAMA = long-acting muscarinic antagonist; NEB = nebulizer; PDE4 = phosphodiesterase-4; SALME = salmeterol; SOL = solution; SPR = spray; SUS = suspension; TAB = tablet; UMECLID = umeclidinium; VILAN = vilanterol
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Utilization Details of Asthma-Indicated Monoclonal Antibodies: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DUPILUMAB PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	6,869	1,245	$28,890,963.98	$4,205.99	5.52	51.04%
DUPIXENT INJ 300MG/2ML SYR	1,696	339	$7,181,920.77	$4,234.62	5	12.69%
DUPIXENT INJ 200MG/1.14ML PEN	1,618	305	$6,395,746.79	$3,952.87	5.3	11.30%
DUPIXENT INJ 200MG/1.14ML SYR	1,316	280	$5,201,860.44	$3,952.78	4.7	9.19%
SUBTOTAL	**11,499**	**2,169**	**$47,670,491.98**	**$4,145.62**	**5.3**	**84.22%**
OMALIZUMAB PRODUCTS						
XOLAIR INJ 150MG/ML SYR	308	39	$743,477.34	$2,413.89	7.9	1.31%
XOLAIR INJ 300MG/2ML PEN	278	50	$1,238,695.50	$4,455.74	5.56	2.19%
XOLAIR INJ 300MG/2ML SYR	159	26	$586,411.29	$3,688.12	6.12	1.04%
XOLAIR INJ 75MG/0.5ML SYR	127	18	$134,347.17	$1,057.85	7.06	0.24%
XOLAIR INJ 150MG/ML PEN	80	17	$118,224.66	$1,477.81	4.71	0.21%
XOLAIR INJ 75MG/0.5ML PEN	78	15	$81,579.87	$1,045.90	5.2	0.14%
XOLAIR SOL 150MG	21	5	$99,943.44	$4,759.21	4.2	0.18%
SUBTOTAL	**1,051**	**170**	**$3,002,679.27**	**$2,856.97**	**6.18**	**5.30%**
TEZEPELUMAB-EKKO PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TEZSPIRE INJ 210MG/1.91ML PEN	362	65	$1,740,341.84	$4,807.57	5.57	3.07%
TEZSPIRE SOL 210MG/1.91ML SYR	80	12	$359,540.50	$4,494.26	6.67	0.64%
SUBTOTAL	**442**	**77**	**$2,099,882.34**	**$4,750.87**	**5.74**	**3.71%**
MEPOLIZUMAB PRODUCTS						
NUCALA INJ 100MG/ML PEN	344	67	$1,398,478.90	$4,065.35	5.13	2.47%
NUCALA INJ 40MG/0.4ML SYR	49	6	$77,125.38	$1,573.99	8.17	0.14%
NUCALA INJ 100MG/ML SYR	32	5	$126,183.48	$3,943.23	6.4	0.22%
NUCALA INJ 100MG	16	3	$58,206.54	$3,637.91	5.33	0.10%
SUBTOTAL	**441**	**81**	**$1,659,994.30**	**$3,764.16**	**5.44**	**2.93%**
BENRALIZUMAB PRODUCTS						
FASENRA INJ 30MG/ML PEN	289	74	$1,717,138.40	$5,941.66	3.91	3.03%
FASENRA INJ 30MG/ML SYR	76	15	$452,055.34	$5,948.10	5.07	0.80%
SUBTOTAL	**365**	**89**	**$2,169,193.74**	**$5,943.00**	**4.1**	**3.83%**
TOTAL	**13,798**	**2,354***	**$56,602,241.63**	**$4,102.21**	**5.86**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution; SYR = syringe
Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Please note: Utilization data includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OMALIZUMAB (J2357)	537	74	$1,119,662.46	$2,085.03	7.26
TEZEPELUMAB-EKKO INJ (J2356)	143	27	$435,409.62	$3,044.82	5.3
BENRALIZUMAB INJ (J0517)	86	23	$376,554.63	$4,378.54	3.74
MEPOLIZUMAB INJ (J2812)	73	11	$214,986.43	$2,945.02	6.64
TOTAL	**839**	**134**	**$2,146,613.14**	**$2,558.54**	**6.26**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Please note: Utilization data includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

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Appendix T

Fiscal Year 2026 Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications (Non-Oncology) and 30-Day Notice to Prior Authorize Vobrig (Leuprolide)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

Utilization data and approval criteria for GnRH medications indicated for oncology diagnoses can be found in the June 2026 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the genitourinary and gynecologic cancer medications.

Central Precocious Puberty (CPP) Medications		
Tier-1	**Tier-2**	**Tier-3**
leuprolide (Fensolvi)		histrelin (Supprelin LA)
leuprolide (Lupron Depot-Ped)*		leuprolide (Lupron Depot-Ped) 45mg
nafarelin (Synarel)		
triptorelin (Triptodur)		

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).
*All strengths except 45mg.

Central Precocious Puberty (CPP) Medications Tier-3 Approval Criteria:

1. An FDA approved indication of CPP confirmed by submitting the following:
    a. Documentation of onset of symptoms prior to 8 years of age in females and 9 years of age in males; and
    b. Documentation that bone age is advanced 1 year beyond the chronological age; and
    c. Lab assessment:
        i. Documentation of abnormal basal gonadotropin levels; or
        ii. Documentation of pubertal response to a gonadotropin-releasing hormone analog stimulation test; and
2. Approvals may be granted with documentation of failed trials of lower tiered products or an FDA approved indication not covered by a lower tiered product.

Myfembree (Relugolix/Estradiol/Norethindrone) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women; or

   b. Moderate-to-severe pain associated with endometriosis in premenopausal women; and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to therapy including:
   a. Osteoporosis; and
   b. Pregnancy; and
      i. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
      ii. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment and for at least 1 week after discontinuing treatment; and
   c. Hepatic impairment or disease; and
   d. Undiagnosed abnormal uterine bleeding; and
   e. High risk of arterial, venous thrombotic, or thromboembolic disease, including uncontrolled hypertension; and
   f. Current or history of breast cancer or other hormonally-sensitive malignancies; and
   g. Known hypersensitivity to ingredients in Myfembree; and
4. Must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of uterine leiomyomas (fibroids) or endometriosis; and
5. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs; and
6. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives; and
7. A quantity limit of 28 tablets per 28 days will apply; and
8. Lifetime approval duration will be limited to a maximum of 24 months. For members previously approved for Oriahnn or Orilissa, a combined cumulative maximum treatment duration of 24 months will apply.

Oriahnn (Elagolix/Estradiol/Norethindrone and Elagolix) Approval Criteria:

1. An FDA approved diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women; and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to therapy including:
   a. Osteoporosis; and
   b. Pregnancy; and
      i. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
      ii. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment and for at least 1 week after discontinuing treatment; and

c. Hepatic impairment or disease; and
d. Undiagnosed abnormal uterine bleeding; and
e. High risk of arterial, venous thrombotic, or thromboembolic disease, including uncontrolled hypertension; and
f. Current or history of breast cancer or other hormonally-sensitive malignancies; and
g. Known hypersensitivity to ingredients in Oriahnn; and
h. Prescriber must verify the member will not use Oriahnn concomitantly with an organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); and

4. Must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of uterine leiomyomas (fibroids); and
5. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs; and
6. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives; and
7. A quantity limit of 56 tablets per 28 days will apply; and
8. Lifetime approval duration will be limited to a maximum of 24 months. For members previously approved for Myfembree, a combined cumulative maximum treatment duration of 24 months will apply.

Orilissa (Elagolix) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe pain associated with endometriosis; and
2. Member must be 18 years of age or older; and
3. Member must not have known osteoporosis; and
4. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
5. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment with Orilissa and for at least 1 week after discontinuing treatment; and
6. Member must not have severe hepatic impairment (Child-Pugh C); and
7. Member must not be taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); and
8. Orilissa must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of endometriosis; and
9. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs must be provided; and

10. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives must be provided; and
11. Dosing and lifetime approval duration will be limited based on the following:
    a. Coexisting condition of moderate hepatic impairment (Child-Pugh B):
        i. 150mg once daily for a maximum of 6 months; or
    b. Normal liver function or mild hepatic impairment (Child-Pugh A):
        i. 150mg once daily for a maximum of 24 months; or
        ii. 200mg twice daily for a maximum of 6 months.

Utilization of GnRH Medications (Non-Oncology): Fiscal Year 2026

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 2025							
FFS	88	205	$1,812,554.34	$8,841.73	$111.01	3,930	16,328
Aetna	48	116	$672,924.23	$5,801.07	$100.35	3,217	6,706
Humana	58	152	$645,887.88	$4,249.26	$88.34	3,765	7,311
OCH	63	153	$1,224,600.65	$8,003.93	$113.73	3,177	10,768
2025 Total	**243**	**626**	**$4,355,967.10**	**$6,958.41**	**$105.95**	**14,089**	**41,113**
Fiscal Year 2026							
FFS	61	146	$1,575,993.76	$10,794.48	$120.67	2,036	13,060
Aetna	62	136	$765,705.01	$5,630.18	$110.27	3,283	6,944
Humana	61	175	$699,895.62	$3,999.40	$93.77	4,601	7,464
OCH	49	102	$904,145.87	$8,864.18	$123.15	2,239	7,342
2026 Total	**225**	**559**	**$3,945,740.26**	**$7,058.57**	**$113.35**	**12,159**	**34,810**
% Change	**-7.40%**	**-10.70%**	**-9.40%**	**1.40%**	**7.00%**	**-13.70%**	**-15.30%**
Change	**-18**	**-67**	**-$410,226.84**	**$100.16**	**$7.40**	**-1,930**	**-6,303**

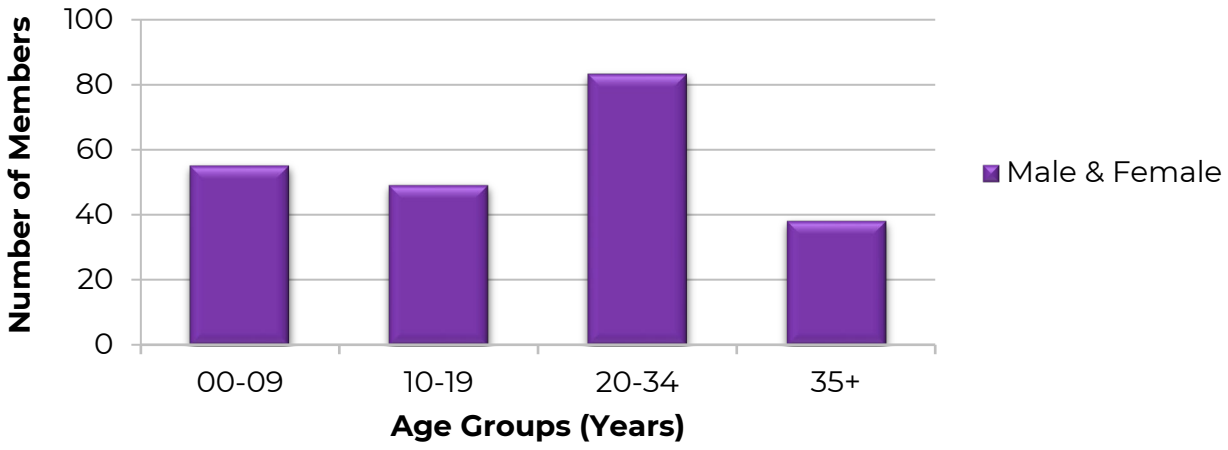
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Medical Claims (All Plans)

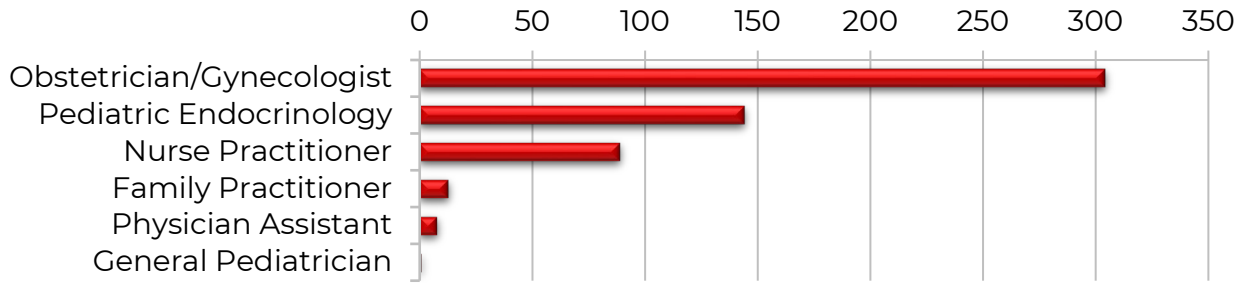
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	107	287	$332,319.64	$1,157.91	2.68
Aetna	29	64	$55,005.14	$859.46	2.21
Humana	60	152	$154,616.25	$1,017.21	2.53
OCH	52	104	$82,830.08	$796.44	2
2025 Total	**231**	**607**	**$624,771.11**	**$1,029.28**	**2.63**
Fiscal Year 2026					
FFS	110	283	$358,679.03	$1,267.42	2.57
Aetna	38	97	$123,130.34	$1,269.38	2.55
Humana	60	142	$138,442.09	$974.94	2.37
OCH	48	104	$183,646.84	$1,765.84	2.17
2026 Total	**232**	**626**	**$803,898.30**	**$1,284.18**	**2.7**
% Change	**0.43%**	**3.13%**	**28.67%**	**24.76%**	**2.66%**
Change	**1**	**19**	**$179,127.19**	**$254.90**	**0.07**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Please note: This utilization data includes GnRH medications used for all indications. The codes J9217 and J1950 may be used for leuprolide depot formulations indicated for multiple indications, including oncology indications.

Demographics of Members Utilizing GnRH Medications (Non-Oncology): Pharmacy Claims (All Plans)



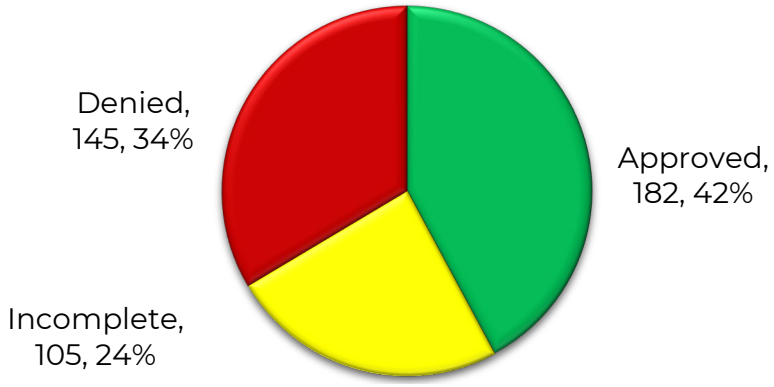
Top Prescriber Specialties of GnRH Medications (Non-Oncology) by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of GnRH Medications (Non-Oncology)

There were 432 prior authorization requests submitted for non-oncology GnRH medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	65	41%	80	50%	15	9%	**160**
Aetna	46	58%	3	4%	31	39%	**80**
Humana	42	47%	7	8%	41	46%	**90**
OCH	29	28%	15	15%	58	57%	**102**
Total	**182**	**42%**	**105**	**24%**	**145**	**34%**	**432**

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

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Triptodur (triptorelin injection): June 2029
- Lupron Depot-Ped (leuprolide 45mg injection): February 2031

- Oriahnn (elagolix/estradiol/norethindrone and elagolix capsule): August 2040
- Orilissa (elagolix tablet): August 2040
- Fensolvi (leuprolide acetate injection): December 2041
- Myfembree (relugolix/estradiol/norethindrone tablet): November 2042

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

- **August 2026:** The FDA approved Vobrig (leuprolide) for the treatment of central precocious puberty (CPP) in pediatric patients.

Vobrig (Leuprolide) Product Summary[3]

Therapeutic Class: GnRH agonist

Indication(s): Treatment of CPP in pediatric patients

How Supplied: 28mg/2.8mL (10mg/mL) single-patient-use prefilled pen

Dosing and Administration:

- The recommended starting dosage is weight-based and administered as a subcutaneous (sub-Q) injection once daily into the abdomen or front of the middle thighs.

Weight	Once Daily Starting Dosage
Less than or equal to 16kg	0.8mg
Greater than 16kg up to 24kg	1.2mg
Greater than 24kg up to 32kg	1.6mg
Greater than 32kg up to 40kg	2.0mg
Greater than 40kg up to 48kg	2.4mg
Greater than 48kg	2.8mg

- Vobrig delivers doses ranging from 0.8mg to 2mg in increments of 0.4mg. Two injections are required for doses above 2mg.
- The daily dose may be increased in 0.4mg increments, if necessary, based on clinical response.

Cost: Cost information for Vobrig is not yet available.

Recommendations

The College of Pharmacy recommends the following additions and changes to the CPP Medications Product Based Prior Authorization (PBPA) Tier chart which will be implemented on 01/01/2027 (changes shown in red in the following Tier chart and additional criteria):

1. Prior authorization of Vobrig (leuprolide) and placement into Tier-3; and
2. Moving Triptodur (triptorelin) and Lupron Depot-Ped (leuprolide) strengths for 3-month administration from Tier-1 to Tier-2 based on net cost; and

3. Moving Supprelin LA (histrelin) from Tier-3 to Tier-2 based on net cost; and
4. Adding initial approval criteria for all CPP medications for clarity; and
5. Adding new Tier-2 approval criteria; and
6. Updating the Tier-3 criteria for clarity and based on clinical practice.

Central Precocious Puberty (CPP) Medications		
Tier-1	**Tier-2**	**Tier-3**
leuprolide (Fensolvi)	**histrelin (Supprelin LA)**	~~**histrelin (Supprelin LA)**~~
leuprolide (Lupron Depot-Ped)*** 7.5mg, 11.25mg, or 15mg for 1-month administration**	**leuprolide (Lupron Depot-Ped) 11.25mg or 30mg for 3-month administration**	leuprolide (Lupron Depot-Ped) 45mg **for 6-month administration**
nafarelin (Synarel)	**triptorelin (Triptodur)**	**leuprolide (Vobrig)**
~~**triptorelin (Triptodur)**~~		

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).
~~*All strengths except 45mg.~~

Initial Approval Criteria for All Central Precocious Puberty (CPP) Medications:

1. An FDA approved indication of CPP confirmed by submitting the following:
   a. Documentation of onset of symptoms prior to 8 years of age in females and 9 years of age in males; and
   b. Lab assessment:
      i. Documentation of abnormal basal gonadotropin levels; or
      ii. Documentation of pubertal response to a gonadotropin-releasing hormone analog stimulation test.

Central Precocious Puberty (CPP) Medications Tier-2 Approval Criteria:

1. An FDA approved indication of CPP confirmed by submitting the following:
   a. Documentation of onset of symptoms prior to 8 years of age in females and 9 years of age in males; and
   b. Lab assessment:
      i. Documentation of abnormal basal gonadotropin levels; or
      ii. Documentation of pubertal response to a gonadotropin-releasing hormone analog stimulation test; and
2. A failed trial of at least 1 Tier-1 CPP medication, used compliantly.

Central Precocious Puberty (CPP) Medications Tier-3 Approval Criteria:

1. An FDA approved indication of CPP confirmed by submitting the following:
   a. Documentation of onset of symptoms prior to 8 years of age in females and 9 years of age in males; and

~~b. Documentation that bone age is advanced 1 year beyond the chronological age; and~~

c. Lab assessment:
   i. Documentation of abnormal basal gonadotropin levels; or
   ii. Documentation of pubertal response to a gonadotropin-releasing hormone analog stimulation test; and

~~2. Approvals may be granted with documentation of failed trials of lower tiered products or an FDA approved indication not covered by a lower tiered product.~~

3. A patient-specific, clinically significant reason why all lower-tiered products are not appropriate for the member must be provided.

Utilization Details of GnRH Medications (Non-Oncology): Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GONADOTROPIN-RELEASING HORMONE (GnRH) ANTAGONIST PRODUCTS						
ORILISSA TAB 150MG	192	62	$230,971.59	$1,202.98	3.1	5.85%
MYFEMBREE TAB 40-1-0.5MG	173	57	$217,868.60	$1,259.36	3.04	5.52%
ORILISSA TAB 200MG	24	11	$28,025.05	$1,167.71	2.18	0.71%
ORIAHNN CAP 300-1-0.5MG & 300MG	8	4	$9,506.01	$1,188.25	2	0.24%
SUBTOTAL	**397**	**131***	**$486,371.25**	**$1,225.12**	**3.03**	**12.33%**
GnRH AGONIST PRODUCTS						
TRIPTODUR SUS 22.5MG	91	57	$2,017,204.58	$22,167.08	1.6	51.12%
FENSOLVI INJ 45MG	33	22	$927,952.24	$28,119.76	1.5	23.52%
LUPRON DEP-PED INJ 3M 30MG	20	7	$238,906.58	$11,945.33	2.86	6.05%
LUPRON DEP-PED INJ 45MG	8	5	$214,553.33	$26,819.17	1.6	5.44%
LUPRON DEP-PED INJ 7.5MG	6	1	$13,502.32	$2,250.39	6	0.34%
LUPRON DEP-PED INJ 3M 11.25MG	4	3	$47,249.96	$11,812.49	1.33	1.20%
SUBTOTAL	**162**	**94***	**$3,459,369.01**	**$21,354.13**	**1.71**	**87.67%**
TOTAL	**559**	**225***	**$3,945,740.26**	**$7,058.57**	**2.48**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
3M = 3-month; CAP = capsule; DEP = depot; INJ = injection; PED = pediatric; SUS = suspension; TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Please note: This utilization data includes GnRH medications used for all indications.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9217 LEUPROLIDE DEPOT 7.5MG	303	130	$134,061.57	$442.45	2.33
J1950 LEUPROLIDE DEPOT 3.75MG	295	82	$644,389.03	$2,184.37	3.6
J3316 TRIPTORELIN 3.75MG (TRIPTODUR)	20	17	$6.05	$0.30	1.18
J1951 LEUPROLIDE DEPOT 0.25MG (FENSOLVI)	8	6	$25,441.65	$3,180.21	1.33
TOTAL	**626**	**232**	**$803,898.30**	**$1,284.18**	**2.7**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2026 = 07/01/2025 to 06/30/2026
Please note: This utilization data includes GnRH medications used for all indications. The codes J9217 and J1950 may be used for leuprolide depot formulations indicated for multiple indications, including oncology indications.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 10/2026. Last accessed 10/21/2026.
[2] Vobrig (Leuprolide) – New Drug Approval. *OptumRx*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval-vobrig-090126.pdf. Issued 08/26/2026. Last accessed 10/22/2026.
[3] Vobrig (Leuprolide) Prescribing Information. Sun Pharmaceutical Industries, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/213225Orig1s000lbl.pdf. Last revised 08/2026. Last accessed 10/22/2026.

Appendix U

Fiscal Year 2026 Annual Review of Brinsupri (Brensocatib)

Oklahoma Health Care Authority
November 2026

Current Prior Authorization Criteria

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.

Utilization of Brinsupri (Brensocatib): Fiscal Year 2026

Fiscal Year 2026 Utilization: Pharmacy Claims (All Plans)

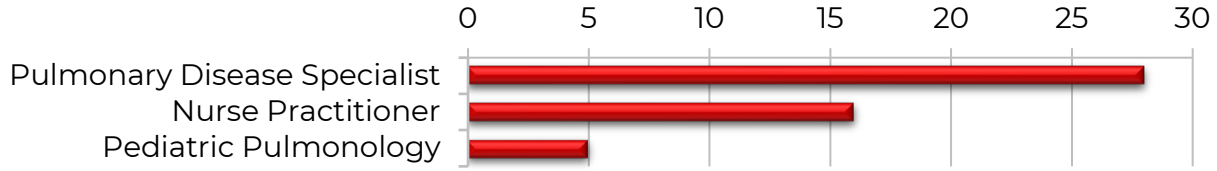
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2026							
FFS	6	28	$205,631.72	$7,343.99	$244.80	840	840
Aetna	1	2	$14,689.48	$7,344.74	$244.82	60	60
Humana	1	4	$29,378.96	$7,344.74	$244.82	120	120
OCH	4	15	$110,171.10	$7,344.74	$244.82	450	450
2026 Total	**11**	**49**	**$359,871.26**	**$7,344.31**	**$244.81**	**1,470**	**1,470**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; N/A = Not applicable; OCH = Oklahoma Complete Health
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Demographics of Members Utilizing Brinsupri (Brensocatib): Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing Brinsupri (brensocatib) during fiscal year 2026, detailed demographic information could not be provided.

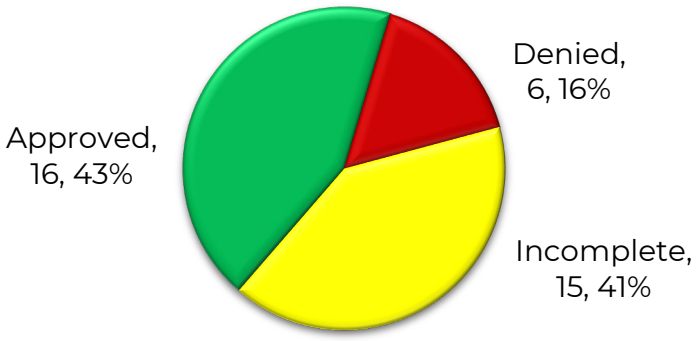
Top Prescriber Specialties of Brinsupri (Brensocatib) by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Brinsupri (Brensocatib)

There were 37 prior authorization requests submitted for Brinsupri (brensocatib) during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	12	41%	15	52%	2	7%	**29**
Aetna	2	100%	0	0%	0	0%	**2**
Humana	1	50%	0	0%	1	50%	**2**
OCH	1	25%	0	0%	3	75%	**4**
Total	**16**	**43%**	**15**	**41%**	**6**	**16%**	**37**

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

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Brinsupri (brensocatib tablets): February 2040

Guideline Update(s):

- **American College of Chest Physicians:** In June 2026, the American College of Chest Physicians published the *Management of Adult Bronchiectasis*, a clinical practice guideline for managing adults with non-cystic fibrosis bronchiectasis (NCFB). The guideline includes 13 evidence-based recommendations with some notable recommendations including:
  - For adults with frequent exacerbations, defined as ≥2 exacerbations per year, it is recommended patients receive long-term anti-inflammatory therapy including macrolide antibiotics or brensocatib therapy.
  - For the treatment of acute exacerbations, it is recommended that either longer-duration (≥10 days) or shorter-duration (<10 days) antibiotic therapy can be used dependent on clinical response.

Recommendations

The College of Pharmacy does not recommend any changes to the current Brinsupri (brensocatib) prior authorization criteria at this time.

Utilization Details of Brinsupri (Brensocatib): Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BRINSUPRI TAB 25MG	41	8	$301,116.84	$7,344.31	5.13	83.67%
BRINSUPRI TAB 10MG	8	4	$58,754.42	$7,344.30	2	16.33%
TOTAL	**49**	**11***	**$359,871.26**	**$7,344.31**	**4.45**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[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 10/2026. Last accessed 10/20/2026.
[2] Thomson R, Thornton C, Akasmit T, et al. Management of Adult Bronchiectasis. *CHEST* 2026; 170(4):1060-1073. doi: 10.1016/j.chest.2026.06.057.



Appendix V

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 2, 2026

FDA Provides Clarity to Support Cell and Gene Therapy Development and Quality

The FDA issued final guidance for manufacturers of cellular and gene therapy (CGT) products to implement a comprehensive, science- and risk-based plan for making sure their products meet potency standards. The guidance provides FDA's recommendations for a Potency Assurance Strategy, which guides manufacturers to test and verify — before a product reaches a patient — that every batch meets a defined standard of potency to do what the product is supposed to do therapeutically.

The Potency Assurance for Cellular and Gene Therapy Products final guidance replaces FDA's 2011 potency testing guidance for CGT products and applies to treatments for serious and often life-threatening conditions. By law, manufacturers are expected to verify that their products work as intended, from the time of approval through post-approval monitoring. This final guidance provides FDA's current thinking and recommendations on how manufacturers can meet that requirement.

The guidance provides flexible, risk-based recommendations for manufacturers on how to integrate potency considerations at every stage of development and commercialization — from early-phase investigational new drug (IND) submissions through biologics license application (BLA) approval and continued post-market verification. Key topics include controls for variability in raw materials, testing during manufacturing, and lab tests that confirm each batch is biologically active in a way that matches its intended therapeutic effect. The guidance also addresses specialized considerations for products with short shelf lives, viral vector gene therapies, and patient-specific therapies.

By giving manufacturers a clear, predictable roadmap, this guidance supports faster access to safe and effective therapies for patients who often have no other treatment options — many of whom receive products made individually for a single person. In doing so, it advances the FDA's public health pillars: protecting patients through rigorous quality standards, promoting innovation by providing regulatory clarity, and reinforcing the integrity of the supply chain for some of the most complex medical products in existence. The FDA will host a webinar on December 10, 2026, to help stakeholders understand and implement the guidance.

FDA NEWS RELEASE

For Immediate Release: October 30, 2026

FDA Approves First Plasmid DNA-based Immunotherapy for Adults with Recurrent Respiratory Papillomatosis

The FDA granted accelerated approval for Voceryq (doruxapapogene ralaplasmid and lalikinogene sifuplasmid-gxfd) for treatment of adults with recurrent respiratory papillomatosis (RRP), a rare disease caused by human papillomavirus (HPV) that leads to the formation of small, wart-like growths in the patient's airways. This approval, the first for a plasmid DNA-based immunotherapy in the U.S., offers patients a new therapeutic option that targets the root cause of RRP and has been shown to reduce the burden of surgical intervention, representing an important step forward for a patient population with limited treatment options.

The agency based this accelerated approval on clinical trial data showing Voceryq helps reduce the frequency of surgical procedures required to remove growths in adult patients with RRP — an intermediate clinical endpoint reasonably likely to predict clinical benefit. The accelerated approval pathway allows the FDA to approve drugs or biologics for serious or life-threatening conditions based on an effect on a surrogate or intermediate clinical endpoint reasonably likely to predict clinical benefit. The manufacturer must conduct post-approval clinical trials to verify and describe Voceryq's clinical benefit.

RRP is a rare, chronic disease in which wart-like growths caused by HPV types 6 and/or 11 form in the airways, most often around the larynx, particularly the vocal cords. These growths, called papillomas, can cause symptoms like hoarseness, chronic cough, and voice changes, and in severe cases can spread to other parts of the respiratory tract, causing difficulty breathing. While surgery can remove the papillomas, there is no cure, and the virus persists in the tissue even after the growths are removed, so patients often need repeated procedures over many years. In some cases, RRP carries a risk of becoming cancerous over time.

Voceryq is a recombinant plasmid DNA-based immunotherapy that delivers two plasmids into the body's cells, one of which contains the genetic instructions for specific HPV proteins and the other an immune response-enhancing molecule called IL-12. The therapy is designed to stimulate the immune system to respond to and attack cells infected by the specific types of HPV that cause RRP (types 6 and 11). Voceryq is administered via intramuscular (IM) injection using the CELLECTRA 5PSP Device, which delivers the dose and facilitates electroporation, a technique which uses brief electrical pulses to temporarily and reversibly create pores in the cell membranes to enable the delivery of Voceryq into the body's cells.

The safety and effectiveness of Voceryq was evaluated in an open-label multicenter clinical trial in 32 adults diagnosed with RRP. Eligible patients had 2 or more surgeries to remove laryngotracheal papillomas in the 12

months prior to Voceryq treatment, including a scheduled surgery at trial entry. There were 7 out of 26 patients (27%) who had at least three baseline surgeries who did not require any surgery intervention during the first year after treatment.

The most commonly reported adverse reactions to Voceryq were injection site reactions, headache, fatigue, hypertension, nausea, and dizziness. Adverse effects associated with the electroporation technique may include brief muscle contractions or tetany, temporary bleeding at the administration site, anxiety, vasovagal reactions including lightheadedness and dizziness, transient changes in creatine phosphokinase, erythema (skin redness) at the injection site, and pain at the injection site.

The FDA granted Voceryq Breakthrough and Orphan Drug designations. The FDA granted accelerated approval of Voceryq to Inovio Pharmaceuticals, Inc.

FDA NEWS RELEASE

For Immediate Release: October 20, 2026

FDA Approves First-of-Its-Kind Chronic Hepatitis B Treatment

The FDA approved Hibsago (bepirovirsen) injection, in combination with existing antiviral therapy, to treat chronic hepatitis B virus (HBV) infection in certain adults without cirrhosis. Hibsago is the first FDA-approved antisense oligonucleotide to treat chronic hepatitis B. Hibsago is approved for certain adults without cirrhosis who have been taking HBV antiviral therapy for at least 6 months, have suppressed levels of HBV in their blood and have hepatitis B surface antigen (HBsAg) levels of 3,000 IU/mL or less, as determined by an FDA-authorized test.

Chronic hepatitis B is a long-term liver infection caused by HBV. Over time, the infection can lead to serious liver disease, including cirrhosis, and increase the risk of liver cancer. Hibsago works by targeting the genetic instructions the virus uses to make copies of itself and viral proteins, helping reduce the amount of virus and HBsAg in the body.

The FDA also authorized the Roche Elecsys HBsAg II quant II RxDx assay as a companion diagnostic device to aid in the selection of patients with chronic HBV infection for treatment with antiviral therapy in accordance with the FDA approved drug labeling and to assist in monitoring patients throughout the course of treatment.

Researchers studied Hibsago in 2 clinical trials that compared it with a placebo. Hibsago is injected under the skin for up to 24 weeks. Patients take it alongside their existing hepatitis B medicine and continue that medicine for at least 24 weeks after their last Hibsago injection. Some patients may then be able to stop their existing medicine if they meet certain health and lab test requirements.

Across the 2 trials, 24% of patients who received Hibsago met the requirements to stop their existing medicine, compared with none who

received placebo. After 24 weeks without hepatitis B treatment, 19% of patients who received Hibsago still had the virus under control, and a protein that signals hepatitis B infection (HBsAg) could not be detected in their blood.

Hibsago has a boxed warning for serious liver reactions as well as low platelet counts, which can increase the risk of potentially life-threatening bleeding. Hibsago also has warnings for worsening kidney function, serious inflammatory adverse reactions like vasculitis, and serious risks if the injection is not administered properly. Patients need regular blood tests and follow up with their healthcare provider before and during treatment to monitor these risks. The most common side effects, excluding laboratory abnormalities, are injection site reactions, fever, fatigue and headache.

The FDA granted Hibsago Fast Track and Breakthrough Therapy designations as well as Priority Review. The approval was granted to GSK plc.

FDA NEWS RELEASE

For Immediate Release: October 20, 2026

FDA Issues Final Guidance on Prescription Drug Apps and Software

The FDA released final guidance establishing a clear framework for how drug companies can develop, distribute, and label apps used alongside their prescription medicines. The guidance ends longstanding uncertainty by providing recommendations about when app content is subject to FDA submission requirements, when an app should be mentioned on a drug's official label, and what companies should submit to the agency.

The guidance addresses 3 key questions for industry: when app content is treated as FDA-required labeling versus promotional labeling, when an app should be referenced in a drug's official prescribing information, and what companies should submit to FDA when they distribute app content to users.

The guidance identifies 2 categories of companion software. The first addresses apps connected to a medical device (such as an app paired with an asthma inhaler) and generally should be described on the drug's official prescribing label, given the central role the software plays in how the medicine is used. The second category is standalone apps (such as symptom trackers, dose reminders, or health coaching tools) and these should appear on the prescribing label if the company can show the app is essential for safe and effective use or can demonstrate a meaningful clinical benefit. In most cases, content displayed on a companion app will be treated as promotional material, consistent with how the FDA handles other drug advertising.

This guidance also reflects the FDA's ongoing commitment to modernizing its regulatory framework to keep pace with rapidly evolving digital health technologies. By providing clear, practical recommendations for both drug-connected software and standalone software, the agency aims to reduce unnecessary uncertainty for developers and manufacturers while preserving the safety and effectiveness standards that patients and

healthcare providers rely on. The final guidance is available online at: https://www.federalregister.gov/public-inspection/2026-21516/guidance-regulatory-considerations-for-prescription-drug-use-related-software.

FDA NEWS RELEASE

For Immediate Release: October 20, 2026

FDA Approves Once-Weekly Generic Hormone Therapy Patch for Women

The FDA approved the first generic of Climara Pro (estradiol and levonorgestrel transdermal system, 0.045mg/0.015mg per day), a transdermal hormone therapy patch applied once weekly for women with an intact uterus. The approval aligns with FDA's Public Health Pillar: Increasing Access to Affordable Medicines & Medical Products.

The generic estradiol and levonorgestrel transdermal system is therapeutically equivalent to Climara Pro, which is indicated for use in women with an intact uterus for the treatment of moderate to severe vasomotor symptoms due to menopause and for prevention of postmenopausal osteoporosis.

Climara Pro and the generic estradiol and levonorgestrel transdermal system contain both estrogen and progestogen in a single patch; this differs from estrogen-only patches commonly used in menopause treatment. Climara Pro and the generic estradiol and levonorgestrel transdermal system are specifically approved for women with an intact uterus, as the progestogen component is included to reduce the risk of endometrial hyperplasia that can occur with estrogen use alone.

Climara Pro and the generic estradiol and levonorgestrel transdermal system are contraindicated in patients with undiagnosed abnormal genital bleeding, breast cancer or a history of breast cancer, estrogen-dependent neoplasia, active deep vein thrombosis (DVT), pulmonary embolism (PE) or a history of these conditions, active arterial thromboembolic disease or a history of these conditions, known anaphylactic reaction or angioedema or hypersensitivity to estradiol and levonorgestrel, hepatic impairment or disease; and protein C, protein S, or antithrombin deficiency, or other thrombophilic disorders.

The most common adverse reactions (≥5%) are: application site reaction, vaginal bleeding, breast pain, upper respiratory infection, back pain, depression, pain, headache and flu syndrome.

In the U.S., 90% of prescriptions filled are for generic drugs. Increasing the availability of generic drugs helps to create competition in the marketplace, which then helps to make treatment more affordable and increases access to healthcare for more patients. Learn more about the FDA Drug Competition Action Plan.

Climara Pro is a registered trademark of Bayer. The FDA approved Zydus Pharmaceuticals (USA) Inc.'s estradiol and levonorgestrel transdermal

system. Please contact the manufacturer for information about the product availability.

FDA NEWS RELEASE

For Immediate Release: October 19, 2026

FDA Approves Immunotherapy That May Allow Certain Patients with Rectal Cancer to Avoid Chemotherapy, Radiation and Surgery

The FDA granted accelerated approval for a new use of the immunotherapy Jemperli (dostarlimab-gxly) that may allow some patients with locally advanced rectal cancer to avoid common treatments that can have a lasting impact on their daily life.

Patients with locally advanced rectal cancer often receive chemotherapy and radiation prior to surgery, which can affect bowel, urinary, and sexual function, as well as fertility. Surgery also carries risks of serious, sometimes life-threatening complications, including poor healing and leaks where the bowel is reconnected, and in some patients, permanent colostomy.

The approval is for Jemperli used alone in adults with previously untreated stage II or stage III locally advanced rectal cancer. At these stages, the cancer has grown into nearby tissue or reached nearby lymph nodes but has not spread to distant organs. To be eligible, patients' tumors must be mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H), as determined by an FDA-authorized test. Published estimates suggest that approximately 3% of locally advanced rectal cancers are dMMR or MSI-H.

Both terms describe a defect in the way cancer cells correct errors when copying their DNA. Normally, a built-in repair system catches and fixes these mistakes. When the system does not work properly, errors accumulate and create proteins the immune system can recognize, making these tumors particularly vulnerable to immunotherapy.

Jemperli works by blocking a signal that cancer cells use to shield themselves from the immune system. Specifically, it targets a protein called programmed cell death protein 1 (PD-1) on immune cells.

The FDA based its decision on interim results from AZUR-1 (NCT05723562), a Phase 2 study, evaluating Jemperli alone in 154 patients with previously untreated dMMR or MSI-H locally advanced rectal cancer. In the study, patients received up to 9 doses of Jemperli, given every 3 weeks over 6 months. After a median follow-up of more than 2 years, almost 75% of patients had not needed surgery, radiotherapy or chemotherapy. Longer follow-up is needed to understand the duration of response and how often the cancer returns.

An earlier study at Memorial Sloan Kettering Cancer Center (NCT04165772) evaluated Jemperli alone in 50 patients with previously untreated dMMR or MSI-H locally advanced rectal cancer. None of the patients had detectable signs of cancer after Jemperli treatment, and 93% of

patients maintained that cancer-free status for at least 12 months. Of the 27 patients followed for at least 3 years, only one had their cancer return, and it recurred in the same area.

Jemperli can cause the immune system to attack healthy organs and tissues. These reactions can be severe or fatal. The most common side effects, reported in at least 15% of patients treated for this type of rectal cancer, were fatigue, rash, diarrhea and itching.

The FDA granted Priority Review to the application and Breakthrough Therapy designation to Jemperli for the treatment of dMMR or MSI-H locally advanced rectal cancer. This action marks the 11th approval of a drug reviewed under the Commissioner's National Priority Voucher pilot program, which aims to help accelerate the review of therapies that address national public health priorities. Because this is an accelerated approval based on interim trial results, the sponsor must continue following patients to show these responses create lasting clinical benefit. The approval was granted to GlaxoSmithKline.

FDA NEWS RELEASE

For Immediate Release: October 14, 2026

FDA Approves First Treatment for Certain People With BCG-Unresponsive Bladder Cancer

The FDA expanded the approved use of Anktiva (nogapendekin alfa inbakicept-pmln), given with Bacillus Calmette-Guérin (BCG), to include adults with high-grade papillary-only bladder cancer that has not spread into the bladder muscle and has not responded to BCG treatment. Anktiva is the first FDA-approved treatment specifically for patients with BCG-unresponsive, high-grade papillary-only disease.

The approval marks a new FDA approach to evaluating treatments for BCG-unresponsive, non-muscle invasive bladder cancer (NMIBC). The agency based its decision on evidence supporting an earlier approval of Anktiva for adults with another form of NMIBC, carcinoma in situ (CIS), with or without papillary tumors, and scientific similarities between CIS and high-grade papillary-only disease.

NMIBC is bladder cancer that has not grown into the bladder's muscle layer and can include CIS and papillary tumors. CIS forms flat patches along the bladder's lining, while papillary tumors grow from the lining into the bladder as small, finger-like projections. CIS is always high-grade, while papillary tumors can be low-grade or high-grade. High-grade cancers are more likely to grow and spread than low-grade cancers.

Treatment for high-risk NMIBC often starts with BCG, which activates the immune system inside the bladder to fight cancer. Sometimes, however, the cancer persists or returns. Adding Anktiva gives the immune system another way to fight the cancer, and the combination can help some people whose cancer was not controlled by BCG alone.

Anktiva's CIS approval was supported by a trial (NCT03022825) that evaluated the treatment's effectiveness in 77 adults, some of whom also had papillary tumors. 62% achieved a complete response, meaning no high-grade cancer was detected during follow-up assessments, and of those, 58% maintained that response for at least 12 months and 40% for at least 24 months.

The FDA considered these results alongside clinical and laboratory evidence showing that CIS and high-grade papillary tumors share important features. They often occur together, can be difficult to distinguish under a microscope, and carry a high risk of returning or progressing when BCG treatment no longer works. These similarities supported applying the evidence of Anktiva's effectiveness in people with CIS to those with high-grade papillary-only disease.

To help developers apply this approach, the FDA is working toward finalizing its draft guidance, "Bacillus Calmette-Guérin-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment." The guidance is intended to include discussion of using evidence from studies in patients with CIS to support approval of treatments for BCG-unresponsive, high-grade papillary-only NMIBC.

Anktiva is given with BCG directly into the bladder through a catheter. It is given once a week for 6 weeks, with additional treatment based on how the cancer responds. Treatment may continue for up to 37 months. It should be stopped if the cancer persists after a second 6-week course, returns or progresses, or side effects become unacceptable.

The most common side effects and laboratory abnormalities included painful or frequent urination, an urgent need to urinate, blood in the urine, urinary tract infections, muscle or joint pain, chills, fever, and increased blood levels of creatinine and potassium. Anktiva's prescribing information warns that delaying surgery to remove all or part of the bladder can allow the cancer to spread to other parts of the body, which can be fatal. The approval was granted to Altor BioScience, LLC.

FDA NEWS RELEASE

For Immediate Release: October 14, 2026

FDA Launches the Rare Disease Framework Initiative to Develop a Holistic, Fit-For-Purpose Framework for Rare Disease Drug Development

The FDA announced the Rare Disease Framework Initiative to reimagine the development of drugs and biologics for rare diseases. As outlined in a new white paper, the Initiative will develop an optimized, fit-for-purpose framework that reflects the realities of rare disease drug development by considering the nuances of each disease, patient needs, product type and the evidence that can be realistically generated in small patient populations.

To solicit feedback on the Rare Disease Framework Initiative from patients and disease advocates, industry, and others, the FDA will host an October 28 meeting at the FDA's White Oak campus. The meeting will be facilitated by the Reagan-Udall Foundation for the FDA.

The FDA has long used regulatory flexibility and developed targeted programs to support innovation in the development of drugs and biologics for rare diseases. These efforts have led to meaningful advances for patients and families. Nevertheless, with only 5% or so of rare conditions having an FDA-approved treatment, the FDA agrees with patients, drug developers, and providers that more must be done to speed the development of safe and effective treatments for rare diseases. In developing the framework, the FDA is committed to the following: providing greater clarity, consistency, and predictability in regulatory decision-making through tailored guidance and transparent communication, embedding the patient's voice both early, and at clearly defined milestones, in the drug development and review process, further leveraging external expertise to support customization of regulatory review, building shared resources, robust training, and institutional knowledge on rare disease drug development and review, applying risk-based approaches, particularly to chemistry, manufacturing, and controls review and pre-approval inspections, and championing the use of cutting-edge science, novel methods and innovative statistical approaches in rare disease drug development.

The Initiative is led by the FDA's Rare Disease Innovation Hub, partnering with the Office of the Commissioner, the Center for Biologics Evaluation and Research, and the Center for Drug Evaluation and Research.

Further opportunities to provide input will follow the public meeting, including sector-specific roundtables, Requests for Information, and internal FDA feedback sessions. This feedback will inform the detailed development of a new framework, which might include potential new or revised guidance, revisions to regulations, staff training, and organizational changes.

Current Drug Shortages Index (as of October 28, 2026):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

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***
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***
Furosemide Oral Solution	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***

Ifosfamide Injection	***Currently in Shortage***
Isocarboxazid Tablet	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Pentostatin 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***
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 Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***