OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
November 12, 2025
4:00pm

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

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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, 2025

DATE: November 5, 2025

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

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

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Enclosed are the following items related to the 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 DUR Board Meeting Dates – Appendix B

Update on the Medication Coverage Authorization Unit – Appendix C

Hepatitis C Program Update – Appendix D

Action Item – Vote to Prior Authorize Eliquis® (Apixaban) Tablet for Oral Suspension and Eliquis® Sprinkle (Apixaban) Capsule for Oral Suspension and Update the Approval Criteria for the Anticoagulants and Platelet Aggregation Inhibitors – Appendix E

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

Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Boruzu® (Bortezomib) and Lynozyfic™ (Linvoseltamab-gcpt) – Appendix G

Annual Review of Bone Density Regulators and 30-Day Notice to Prior Authorize Bildyos® (Denosumab-nxxp), Bilprevda® (Denosumab-nxxp), Bomyntra® (Denosumab-bnht), Conexxence® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), and Stoboclo® (Denosumab-bmwo) – Appendix H

30-Day Notice to Prior Authorize Forzinity™ (Elamipretide) – Appendix I

Annual Review of Amino Acid Disorder Medications and 30-Day Notice to Prior Authorize Harliku™ (Nitisinone), Orfadin® (Nitisone), Nityr® (Nitisinone), and Sephience™ (Sepiapterin) – Appendix J

30-Day Notice to Prior Authorize Brinsupri™ (Brensocatib) – Appendix K

Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Anzupgo® (Delgocitinib 2% Cream) – Appendix L

Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Omlyclo® (Omalizumab-igec) – Appendix M

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

30-Day Notice to Prior Authorize Rhapsido® (Remibrutinib) – Appendix O

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

Future Business

Action Item – Nomination and Approval of DUR Board Officers

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – November 12, 2025 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

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

Public Comment for Meeting:

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

Items to be presented by Dr. Haymore, Chairman:

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

Items to be presented by Dr. Haymore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. October 8, 2025 DUR Board Meeting Minutes
   B. October 8, 2025 DUR Board Recommendations Memorandum
   C. Correspondence

Items to be presented by Dr. Haymore, Chairman:

4. **Action Item – Approval of 2026 DUR Board Meeting Dates – See Appendix B**
   A. 2026 DUR Board Meeting Dates

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

5. **Update on Medication Coverage Authorization Unit – See Appendix C**
   A. Pharmacy Help Desk Activity for October 2025
   B. Medication Coverage Activity for October 2025

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

6. **Hepatitis C Program Update – See Appendix D**
   A. Background
   B. Results of Claims Analysis
   C. Conclusions

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

7. **Action Item – Vote to Prior Authorize Eliquis® (Apixaban) Tablet for Oral Suspension and Eliquis® Sprinkle (Apixaban) Capsule for Oral Suspension and Update the Approval Criteria for the Anticoagulants and Platelet Aggregation Inhibitors – See Appendix E**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Avtozma® (Tocilizumab-anoh), Imuldosa® (Ustekinumab-srlf), Otezla XR™ [Apremilast Extended-Release (ER)], Starjemza™ (Ustekinumab-hmny), Steqeyma® (Ustekinumab-stba), and Yesintek™ (Ustekinumab-kfce) and Update the Approval Criteria for the Targeted Immunomodulator Agents – See Appendix F**
   A. Market News and Updates
   B. Cost Comparison: Currently Available Subcutaneous (Sub-Q) Ustekinumab Products
   C. College of Pharmacy Recommendations

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

9. **Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Boruzu® (Bortezomib) and Lynozyfic™ (Linvoseltamab-gcpt) – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Multiple Myeloma Medications
   C. Prior Authorization of Multiple Myeloma Medications
   D. Market News and Updates
   E. Lynozyfic™ (Linvoseltamab-gcpt) Product Summary
   F. Cost Comparison: Bortezomib Products
   G. College of Pharmacy Recommendations
   H. Utilization Details of Multiple Myeloma Medications

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

10. **Annual Review of Bone Density Regulators and 30-Day Notice to Prior Authorize Bildyos® (Denosumab-nxxp), Bilprevda® (Denosumab-nxxp), Bomyntra® (Denosumab-bnht), Conexxence® (Denosumab-bnht), Osenvelt® (Denosumab-bmwo), and Stoboclo® (Denosumab-bmwo) – See Appendix H**
    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. Wilson, Dr. Haymore, Chairman:

11. **30-Day Notice to Prior Authorize Forzinity™ (Elamipretide) – See Appendix I**
    A. Introduction
    B. Forzinity™ (Elamipretide) Product Summary
    C. College of Pharmacy Recommendations

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

12. **Annual Review of Amino Acid Disorder Medications and 30-Day Notice to Prior Authorize Harliku™ (Nitisinone), Orfadin® (Nitisone), Nityr® (Nitisinone), and Sephience™ (Sepiapterin) – See Appendix J**
    A. Current Prior Authorization Criteria
    B. Utilization of Amino Acid Disorder Medications
    C. Prior Authorization of Amino Acid Disorder Medications
    D. Market News and Updates
    E. Product Summaries
    F. Cost Comparison: Phenylketonuria (PKU) Products
    G. College of Pharmacy Recommendations
    H. Utilization Details of Amino Acid Disorder Medications

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

13. **30-Day Notice to Prior Authorize Brinsupri™ (Brensocatib) – See Appendix K**
    A. Introduction
    B. Brinsupri™ (Brensocatib) Product Summary
    C. College of Pharmacy Recommendations

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

14. **Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Anzupgo® (Delgocitinib 2% Cream) – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of AD Medications
    C. Prior Authorization of AD Medications
    D. Market News and Updates
    E. Anzupgo® (Delgocitinib 2% Cream) Product Summary
    F. Cost Comparisons
    G. College of Pharmacy Recommendations
    H. Utilization Details of AD Medications

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

15. **Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Omlyclo® (Omalizumab-igec) – See Appendix M**
    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. College of Pharmacy Recommendations
F. Utilization Details of Asthma and COPD Maintenance Medications

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

16. 60-Day Notice to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the Hereditary Angioedema (HAE) Medications – See Appendix N

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

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

17. 30-Day Notice to Prior Authorize Rhapsido® (Remibrutinib) – See Appendix O

A. Introduction
B. Rhapsido® (Remibrutinib) Product Summary
C. College of Pharmacy Recommendations

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

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

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

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

A. Antidepressants
B. Complement Inhibitors and Miscellaneous Immunomodulatory Agents
C. Immune Globulin Intravenous and Subcutaneous Products
D. Lysosomal Storage Disease Medications
E. Skin Cancer Medications
F. Thrombocytopenia Medications

*Future product and class reviews subject to change.

Items to be presented by Dr. Haymore, Chairman:

20. Action Item – Nomination and Approval of DUR Board Officers

A. Nominations and Approval of DUR Board Chair and Vice Chair

21. Action Item – Adjournment

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

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING OCTOBER 8, 2025

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

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Clay Bullard; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Travis Dennis, J.D.; Deputy General Counsel		X
Christina Foss, Chief of Staff; State Medicaid Director		X
Gentry Kincade, J.D.; Deputy General Counsel		X
Gwendolyn Maxey, J.D.; Deputy General Counsel	X	

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

OTHERS PRESENT:	
Bryan Steffan, Boehringer	Matthew Nguyen, AbbVie
Eardie Curry, Genentech	Deidra Williams, Humana
Mark Kaiser, Otsuka	David Prather, Novo Nordisk
Kenneth Berry, Alkermes	Lee Stout, Chiesi
Irene Chung, Aetna	Jenna Doerr, Artia Solutions
Marc Parker, VS Health Group	Adriana Sanchez, Bridge Bio
Jay Milton, Bayer	Melissa Abbott, Galderma
Mike Thiem, Incyte	Jennifer Lauper, Bristol Myers Squibb
Michael Sullivan, Amgen	Lisa Dunn, Amgen
Valerie Willard, Glaukos	Pam Storey, PTC Therapeutics
Alexander Kaiser, Bristol Myers Squibb	Andy Berg, Concis Labs
Melanie Kitto, BioCryst	Laura Cordell, Sanofi
Brent Fushimi, UCB	Lynn Kaye, Indivior
Kristen Winters, Centene	Jim Semans, SK Life Science
Michael J Pericozzi, Sanofi	Scott Burns, Johnson & Johnson
Amy Breen, Teva	Todd Ness, AbbVie
Kim Greenberg, Acadia	John SUelzer, LEO Pharma
Richard McCue, Glaukos	David Miley, Teva

PRESENT FOR PUBLIC COMMENT:	
Matthew Nguyen, AbbVie	

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

1A: ROLL CALL

Dr. Patatanian 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. 19 MATTHEW NGUYEN

ACTION: NONE REQUIRED

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

3A: SEPTEMBER 10, 2025 DUR MINUTES

Materials included in agenda packet; presented by Dr. Haymore

Dr. Patatanian 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 SEPTEMBER 2025

4B: MEDICATION COVERAGE ACTIVITY FOR SEPTEMBER 2025
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 SUMMARIES
5C: PIPELINE TABLE
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE ATTRUBY™ (ACORAMIDIS) AND UPDATE THE APPROVAL CRITERIA FOR THE AMYLOIDOSIS MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: ATTRUBY™ (ACORAMIDIS) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Patatanian moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ALYFTREK® (VANZACAFTOR/TEZACAFTOR/ DEUTIVACAFTOR) AND UPDATE THE APPROVAL CRITERIA FOR THE CYSTIC FIBROSIS (CF) MEDICATIONS
7A: MARKET NEWS AND UPDATES
7B: ALYFTREK® (VANZACAFTOR/TEZACAFTOR/DEUTIVACAFTOR) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Weakley
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE ENCELTO™ (REVAKINAGENE TARORETCEL-LWEY)
8A: ENCELTO™ (REVAKINAGENE TARORETCEL-LWEY) PRODUCT SUMMARY
8B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Weakley moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE FOSRENOL® (LANTHANUM CARBONATE) 750MG AND 1,000MG ORAL POWDER PACKET AND UPDATE THE APPROVAL CRITERIA FOR THE HYPERPHOSPHATEMIA MEDICATIONS
9A: COST COMPARISON: LANTHANUM CARBONATE PRODUCTS
9B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Mr. Foster moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE PHOTREXA®/PHOTREXA® VISCOUS (RIBOFLAVIN 5'-PHOSPHATE)
10A: PHOTREXA®/PHOTREXA® VISCOUS (RIBOFLAVIN 5'-PHOSPHATE) PRODUCT SUMMARY
10B: COLLEGE OF PHARMACY RECOMMENDATIONS

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

<u>AGENDA ITEM NO. 11:</u> VOTE TO PRIOR AUTHORIZE DATROWAY® (DATOPOTAMAB DERUXTECAN-DLNK) AND ITOVEBI™ (INAVOLISIB) AND UPDATE THE APPROVAL CRITERIA FOR THE BREAST CANCER MEDICATIONS
11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COST COMPARISON: TRASTUZUMAB PRODUCTS
11D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Blaiss moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF MYELOPROLIFERATIVE NEOPLASM (MPN) MEDICATIONS
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF MPN MEDICATIONS
12C: PRIOR AUTHORIZATION OF MPN MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF MPN MEDICATIONS
Non-presentation item; materials included in agenda packet by Dr. Sinko
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF *CLOSTRIDIOIDES DIFFICILE* (*C. DIFFICILE*) MEDICATIONS
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF *C. DIFFICILE* MEDICATIONS
13C: PRIOR AUTHORIZATION OF *C. DIFFICILE* MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF *C. DIFFICILE* MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF ALLERGEN IMMUNOTHERAPIES
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ALLERGEN IMMUNOTHERAPIES
14C: PRIOR AUTHORIZATION OF ALLERGEN IMMUNOTHERAPIES
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS
14F: UTILIZATION DETAILS OF ALLERGEN IMMUNOTHERAPIES
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Blaiss moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF CUSHING'S SYNDROME MEDICATIONS
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF CUSHING'S SYNDROME MEDICATIONS

15C: PRIOR AUTHORIZATION OF CUSHING'S SYNDROME MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF CUSHING'S SYNDROME MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Blaiss moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: ANNUAL REVIEW OF OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
16C: PRIOR AUTHORIZATION OF OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS
16F: UTILIZATION DETAILS OF OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
Materials included in agenda packet; presented by Dr. Moss
Mr. Foster moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 17: ANNUAL REVIEW OF HYPEROXALURIA MEDICATIONS
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF HYPEROXALURIA MEDICATIONS
17C: PRIOR AUTHORIZATION OF HYPEROXALURIA MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Blaiss moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

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

AGENDA ITEM NO. 19: ANNUAL REVIEW OF TARGETED IMMUNOMODULATOR AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AVTOZMA® (TOCILIZUMAB-ANOH), IMULDOSA® (USTEKINUMAB-SRLF), OTEZLA XR™ [APREMILAST EXTENDED-RELEASE (ER)], STARJEMZA™ (USTEKINUMAB-HMNY), STEQEYMA® (USTEKINUMAB-STBA), AND YESINTEK™ (USTEKINUMAB-KFCE)
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF TARGETED IMMUNOMODULATOR AGENTS
19C: PRIOR AUTHORIZATION OF TARGETED IMMUNOMODULATOR AGENTS
19D: MARKET NEWS AND UPDATES
19E: COST COMPARISON

19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF TARGETED IMMUNOMODULATOR AGENTS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 20: ANNUAL REVIEW OF HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS AND 60-DAY NOTICE TO PRIOR AUTHORIZE ANDEMBRY® (GARADACIMAB-GXII), DAWNZERA™ (DONIDALORSEN), AND EKTERLY® (SEBETRALSTAT) AND CREATE A PRODUCT BASED PRIOR AUTHORIZATION (PBPA) CATEGORY FOR THE HAE MEDICATIONS
20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF HAE MEDICATIONS
20C: PRIOR AUTHORIZATION OF HAE MEDICATIONS
20D: MARKET NEWS AND UPDATES
20E: PRODUCT SUMMARIES
20F: COST COMPARISON: HAE PROPHYLAXIS PRODUCTS
20G: COLLEGE OF PHARMACY RECOMMENDATIONS
20H: UTILIZATION DETAILS OF HAE MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 21: ANNUAL REVIEW OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ELIQUIS® (APIXABAN) TABLET FOR ORAL SUSPENSION AND ELIQUIS® SPRINKLE (APIXABAN) CAPSULE FOR ORAL SUSPENSION
21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: UTILIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
21C: PRIOR AUTHORIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
21D: MARKET NEWS AND UPDATES
21E: COLLEGE OF PHARMACY RECOMMENDATIONS
21F: UTILIZATION DETAILS OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 22: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 23: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
23A: AMINO ACID DISORDER MEDICATIONS
23B: ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
23C: ATOPIC DERMATITIS MEDICATIONS
23D: BRINSUPRI™ (BRENSOCATIB)
23E: BUTALBITAL MEDICATIONS
23F: MULTIPLE MYELOMA MEDICATIONS
23G: OSTEOPOROSIS MEDICATIONS AND DENOSUMAB PRODUCTS
*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. 24: ADJOURNMENT

The meeting was adjourned at 5:15pm.

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

Memorandum

Date: October 10, 2025

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

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

Subject: DUR Board Recommendations from Packet Meeting on October 8, 2025

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 Attruby™ (Acoramidis) and Update the Approval Criteria for the Amyloidosis Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Attruby™ (acoramidis) with the following criteria (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), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (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.

The College of Pharmacy also recommends updating the approval criteria for Amvuttra® (vutrisiran) based on the new FDA approved indication and the FDA approval of Attruby™ (acoramidis) (changes shown in red):

Amvuttra® (Vutrisiran) Approval Criteria:

1. An FDA approved indication ~~for~~ of 1 of the following:
   a. The treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; ~~and~~ 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; ~~and~~ 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. 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
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Amvuttra® will not be approved for concomitant use with Attruby™ (acoramidis), Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
9. 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
10. A quantity limit of 0.5mL per 90 days will apply; 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.

Lastly, the College of Pharmacy recommends updating the Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), Vyndamax® (tafamidis), and Wainua® (eplontersen) approval criteria based on the FDA approval of Attruby™ (acoramidis) (changes shown in red):

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; and
2. Diagnosis confirmed by 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. 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
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. 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
9. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby™ (acoramidis), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua® (eplontersen); and
10. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
11. 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.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of the polyneuropathy of 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. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Tegsedi® 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
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and

7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. 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 Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby™ (acoramidis), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua® (eplontersen); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® 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
13. A quantity limit of 4 syringes per 28 days will apply.

Vyndamax® (Tafamidis) and Vyndaqel® (Tafamidis Meglumine) 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 have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® or Vyndaqel® 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. Vyndamax® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby™ (acoramidis), Onpattro® (patisiran), or Tegsedi® (inotersen), or Wainua® (eplontersen); and
9. 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
10. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

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. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. 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
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. 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
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Wainua® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby™ (acoramidis), Onpattro® (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
9. 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
10. A quantity limit of 0.8mL per 28 days will apply.

Recommendation 4: Vote to Prior Authorize Alyftrek® (Vanzacaftor/ Tezacaftor/Deutivacaftor) and Update the Approval Criteria for the Cystic Fibrosis (CF) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor) with the following criteria (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 *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; 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 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 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
7. Prescriber must verify that the member does not have severe hepatic impairment; 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 strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Alyftrek®; and
10. 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
11. 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
12. 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

13. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) approval criteria based on the new FDA approved label expansion, clinical practice, and to be consistent with the other CF transmembrane conductance regulator (CFTR) modulator therapies (changes shown in red):

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

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 *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; 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 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 verify that ALT, AST, and bilirubin will be assessed prior to initiating Trikafta, every 3 months during the first year of treatment, and annually thereafter; and~~
7. 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

8. Prescriber must verify that the member does not have severe hepatic impairment; 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 Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and
11. 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
12. 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
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) or Symdeko® (tezacaftor/ivacaftor and ivacaftor); and
15. Subsequent approvals will be for the duration of 1 year.

Finally, the College of Pharmacy recommends updating the Kalydeco® (ivacaftor) approval criteria to be consistent with the FDA approved label, clinical practice, and the other CFTR modulator therapies and recommends updating the Orkambi® (lumacaftor/ivacaftor) and Symdeko® (tezacaftor/ivacaftor and ivacaftor) approval criteria to be consistent with clinical practice and the other CFTR modulator therapies (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 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
6. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
7. Member must not be taking any of the following medications concomitantly with Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
8. 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
9. 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
10. 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
11. 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
12. 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
13. 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. 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
7. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
8. Members must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. 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
10. 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
11. 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
12. 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
13. 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 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
7. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
8. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
10. 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
11. 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
12. Subsequent approvals will be for the duration of 1 year.

Recommendation 5: Vote to Prior Authorize Encelto™ (Revakinagene Taroretcel-lwey)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Encelto™ (revakinagene taroretcel-lwey) with the following criteria:

Encelto™ (Revakinagene Taroretcel-lwey) Approval Criteria:

1. An FDA approved diagnosis of idiopathic macular telangiectasia (MacTel) type 2; and
2. The diagnosis must be supported by evidence of fluorescein leakage and at least 1 of the following other features typical of MacTel Type 2:
   a. Hyperpigmentation that is outside of a 500-micron radius from the center of the fovea; or
   b. Retinal opacification; or
   c. Crystalline deposits; or
   d. Right-angle vessels; or
   e. Inner/outer lamellar cavities; and
3. Member must be 18 years of age or older; and
4. Encelto™ must be prescribed and administered by a qualified ophthalmologist under aseptic conditions; and
5. Member must have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00mm^2 measured by spectral domain-optical coherence tomography (SD-OCT); and
6. Member must have a best corrected visual acuity (BCVA) of 20/80 or better; and
7. Member must not have neovascular MacTel type 2: and
8. Member must not have ocular or periocular infections; and
9. Member must not have known hypersensitivity to Endothelial Serum Free Media (Endo-SFM); and
10. If the member is taking an antithrombotic medication (i.e., oral anticoagulants, aspirin, and nonsteroidal anti-inflammatory drugs) they have been counseled to temporarily discontinue therapy with their antithrombotic medication prior to Encelto™ implantation due to the risk of vitreous hemorrhage; and
11. Prescriber must verify the member will be monitored for vision loss, infectious endophthalmitis, retinal tear and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related complications, and delayed dark adaptation after Encelto™ implantation and treated, if appropriate; and
12. A quantity limit of 1 implant per eye per lifetime will apply.

Recommendation 6: Vote to Prior Authorize Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet and Update the Approval Criteria for the Hyperphosphatemia Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Fosrenol® (lanthanum carbonate) 750mg and 1,000mg Oral Powder Packet based on net costs with the following criteria (shown in red):

Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the chewable tablet formulation must be provided.

The College of Pharmacy also recommends designating Auryxia® as brand preferred and updating the approval criteria based on net costs (changes shown in red):

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; ~~and~~ or
   ~~a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use all phosphate binders available without prior authorization must be provided; and~~
   ~~b. A patient-specific, clinically significant reason why the member cannot use Velphoro® (sucroferric oxyhydroxide) must be provided; or~~
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
   a. Documented lab results verifying IDA; and
   b. Documented intolerance or inadequate response to prior treatment with oral iron; and
3. Auryxia® is brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Lastly, the College of Pharmacy recommends updating the lanthanum carbonate (generic Fosrenol®) approval criteria and removing the brand preferred status of Fosrenol® (lanthanum carbonate) 1,000mg chewable tablet based on net costs (changes shown in red):

Lanthanum Carbonate (Generic Fosrenol®) 500mg and 750mg Chewable Tablet Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; and
3. Fosrenol® 500mg and 750mg chewable tablet are brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Generic calcium acetate containing products, brand name Fosrenol® (lanthanum carbonate 500mg~~,~~ and 750mg~~, and 1,000mg~~ chewable tablet ~~and 750mg and 1,000mg oral powder packet~~), lanthanum carbonate (generic Fosrenol®) 1,000mg chewable tablet, PhosLo® (calcium acetate gel capsule), and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Recommendation 7: Vote to Prior Authorize Photrexa®/Photrexa® Viscous (Riboflavin 5'-Phosphate)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Photrexa®/Photrexa® Viscous (riboflavin 5'-phosphate) with the following criteria:

Photrexa®/Photrexa® Viscous (Riboflavin 5'-Phosphate) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Progressive keratoconus; or
   b. Corneal ectasia following refractive surgery; and
2. Must be prescribed by and administered by an optometrist or ophthalmologist trained in the corneal cross-linking procedure; and
3. Must be used in combination with the KXL® System in the corneal cross-linking procedure; and
4. Must be administered using the epithelial-off procedure as specified in the package labeling; and
5. A quantity limit of 1 kit (6mL) per eye will apply.

Recommendation 8: Vote to Prior Authorize Datroway® (Datopotamab Deruxtecan-dlnk) and Itovebi™ (Inavolisib) and Update the Approval Criteria for the Breast Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Datroway® (datopotamab deruxtecan-dlnk) and Itovebi™ (inavolisib) with the following criteria (shown in red):

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

1. Diagnosis of unresectable or metastatic breast cancer; and
2. Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative; and
3. Member has received prior endocrine-based therapy and chemotherapy; and
4. Used as a single agent.

Datroway® (Datopotamab Deruxtecan-dlnk) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Disease is epidermal growth factor receptor (EGFR)-mutated; and
3. Member has received prior EGFR-directed therapy and platinum-based chemotherapy; and
4. Used as a single agent.

Itovebi™ (Inavolisib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. PIK3CA-mutated; and
3. Used in combination with palbociclib and fulvestrant; and
4. Following recurrence on or after completing adjuvant endocrine therapy.

The College of Pharmacy also recommends updating the approval criteria for Enhertu® (fam-trastuzumab deruxtecan-nxki) and Ibrance® (palbociclib) based on recent FDA approvals with the following changes (shown in red):

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 disease, must meet the following:
        i. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and
        ii. Member has received ≥1 prior anti-HER2-based regimens; 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 advanced, metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. Used in combination with:
   a. An aromatase inhibitor in female members; or
   b. Fulvestrant in women with disease progression following endocrine therapy; or
   c. An aromatase inhibitor or fulvestrant in male patients; or
   d. Inavolisib and fulvestrant in patients with disease progression following endocrine therapy.

Next, the College of Pharmacy recommends updating the Trodelvy® (sacituzumab govitecan-hziy) approval criteria based on the withdrawal of the accelerated approval for metastatic urothelial cancer with the following changes (shown in red):

~~**Trodelvy® (Sacituzumab Govitecan-hziy) Approval Criteria [Urothelial Cancer Diagnosis]:**~~

~~1. Diagnosis of unresectable locally advanced or metastatic disease; and~~
~~2. Member must have previously received a platinum-containing chemotherapy; and~~
~~3. Member must have previously received either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.~~

Additionally, the College of Pharmacy recommends updating the Kadcyla® (ado-trastuzumab emtansine) and Nerlynx® (neratinib) approval criteria based on National Comprehensive Cancer Network (NCCN) recommendations (changes and new criteria noted in red):

Kadcyla® (Ado-Trastuzumab Emtansine) Approval Criteria [Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Previously received trastuzumab and a taxane, separately or in combination; and

4. Members should also have either:
    a. Received prior therapy for metastatic disease; or
    b. Developed disease recurrence during or within 6 months of completing adjuvant therapy; and
5. Used as a single agent; or
    a. If brain metastases are present, may be used in combination with neratinib.

Nerlynx® (Neratinib) Approval Criteria [Recurrent or Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Member must have human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
3. Used in combination with capecitabine; or
4. Used in combination with ado-trastuzumab emtansine, capecitabine, or paclitaxel if brain metastases are present.

Lastly, the College of Pharmacy recommends updating the approval criteria for the trastuzumab products based on net costs (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 Kanjinti®, Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Herceptin Hylecta™, Hercessi™, Herzuma®, or Ogivri®~~, or Ontruzant®~~) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (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 Kanjinti®, Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Hercessi™, Herzuma®, or Ogivri®~~, or Ontruzant®~~) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (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 Kanjinti®, Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Hercessi™, Herzuma®, or Ogivri®~~, or Ontruzant®~~) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (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.

Recommendation 9: Fiscal Year 2025 Annual Review of Myeloproliferative Neoplasm (MPN) Medications

NO ACTION REQUIRED.

Recommendation 10: Fiscal Year 2025 Annual Review of *Clostridioides difficile (C. difficile)* Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Rebyota® and Vowst® based on the discontinuation of Zinplava™ (changes shown in red):

Rebyota® (Fecal Microbiota, Live-jslm) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in members 18 years of age or older; and
2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days); and
5. The prescriber must verify that administration of Rebyota® will occur 24 to 72 hours following completion of antibiotic course for CDI treatment; and
6. Rebyota® must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and
7. ~~For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI upon presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and~~
8. The member must not be using Rebyota® in combination with Vowst® (fecal microbiota spores, live-brpk) ~~or Zinplava™ (bezlotoxumab)~~; and
9. Initial approvals will be for 1 treatment course. A second treatment course may be considered following a confirmed treatment failure within 8 weeks.

Vowst® (Fecal Microbiota Spores, Live-brpk) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in members 18 years of age or older; and
2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days) following 10 to 21 days of antibiotic therapy; and
5. The prescriber must verify that administration of Vowst® will occur 2 to 4 days following completion of antibiotic course for CDI treatment; and
6. The member must agree to bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst®; and
7. Vowst® must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with the expertise in the treatment of CDI; and

8. A patient specific, clinically specific reason (beyond convenience) why the member cannot use Rebyota® (fecal microbiota, live-jslm) must be provided; and
9. ~~For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI on presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and~~
10. The member must not be using Vowst® in combination with Rebyota® (fecal microbiota, live-jslm) ~~or Zinplava™ (bezlotoxumab)~~; and
11. A quantity limit of 12 capsules for 3 days for 1 treatment course will apply.

Recommendation 11: Fiscal Year 2025 Annual Review of Allergen Immunotherapies

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Odactra® (house dust mite allergen extract) based on the new FDA approved age expansion (changes shown in red):

Odactra® (House Dust Mite Allergen Extract) Approval Criteria:

1. Member must be ~~12~~ 5 to 65 years of age; and
2. Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or *in vitro* testing for immunoglobulin E (IgE) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each; and
6. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
7. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
8. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
9. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and

10. A quantity limit of 1 tablet daily will apply; and
11. Initial approvals will be for the duration of 6 months of therapy, at which time the prescriber must verify the member is responding well to Odactra® therapy. Additionally, compliance will be evaluated for continued approval.

Recommendation 12: Fiscal Year 2025 Annual Review of Cushing's Syndrome Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Isturisa® (osilodrostat) approval criteria based on the new FDA approved label expansion (changes shown in red):

Isturisa® (Osilodrostat) Approval Criteria:

1. An FDA approved indication for the treatment of endogenous hypercortisolemia in adult members with Cushing's syndrome ~~disease~~ for whom ~~pituitary or adrenal~~ surgery is not an option or has not been curative; and
2. Member must be 18 years of age or older; and
3. Prescriber must document that the member has had an inadequate response to ~~pituitary or adrenal~~ surgery or is not a candidate for ~~pituitary or adrenal~~ surgery; and
4. Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Isturisa®; and
5. Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline, 1 week after treatment initiation, and as clinically indicated thereafter; and
6. Prescriber must verify that dose titration will be followed according to package labeling; and
7. If the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or strong CYP3A4 and/or CYP2B6 inducers (e.g., carbamazepine, rifampin, phenobarbital), the prescriber must verify that the Isturisa® dose will be adjusted according to the package labeling; and
8. For female members, prescriber must verify that the member is not breastfeeding; and
9. Isturisa® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
10. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and
11. Initial authorizations will be for the duration of 3 months after which time, compliance and 24-hour urine free cortisol levels within the normal range (to demonstrate the effectiveness of this medication) will

be required for continued approval. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for ~~pituitary or adrenal~~ surgery.

Additionally, the College of Pharmacy recommends updating the Recorlev® (levoketoconazole) approval criteria to be consistent with the FDA approved label (changes shown in red):

Recorlev® (Levoketoconazole) Approval Criteria:

1. An FDA approved indication for the treatment of endogenous hypercortisolemia in adult members with Cushing's syndrome ~~disease~~ for whom ~~pituitary or adrenal~~ surgery is not an option or has not been curative; and
2. Member must be 18 years of age or older; and
3. Recorlev® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Prescriber must document that the member has had an inadequate response to ~~pituitary or adrenal~~ surgery or is not a candidate for ~~pituitary or adrenal~~ surgery; and
5. Prescriber agrees to obtain baseline liver test and electrocardiogram (ECG) prior to initiating treatment; and
6. Prescriber agrees to monitor liver enzymes and bilirubin weekly for at least 6 weeks after initiating treatment, every 2 weeks for the next 6 weeks, monthly for the next 3 months, and then as clinically indicated; and
7. Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Recorlev®; and
8. Member must not be taking medications that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes (e.g., dofetilide, dronedarone, methadone, quinidine, ranolazine); and
9. Member must not be taking medications that are sensitive substrates of CYP3A4 and/or P-gp (e.g., digoxin, lovastatin, simvastatin, tacrolimus, triazolam); and
10. If the member is taking medications that are strong CYP3A4 inhibitors (e.g., ritonavir, mifepristone) or strong CYP3A4 inducers (e.g., isoniazid, carbamazepine, rifampicin, phenytoin), the prescriber must verify the medication will be stopped 2 weeks before and during treatment with Recorlev® per package labeling; and
11. For female members, prescriber must verify that the member is not breastfeeding; and
12. A patient-specific, clinically significant reason why the member cannot use ketoconazole tablets and metyrapone capsules must be provided; and
13. Initial authorizations will be for the duration of 3 months. Continued authorization at that time will require the prescriber to provide a recent

24-hour urine free cortisol (UFC) level within the normal range to demonstrate the effectiveness of this medication, and compliance will also be checked at that time. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for ~~pituitary or adrenal~~ surgery.

Recommendation 13: Fiscal Year 2025 Annual Review of Ophthalmic Anti-Inflammatory Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Dextenza® approval criteria and creating new criteria based on the new FDA approved indication (changes shown in red):

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. ~~Prescriber must verify that Dextenza® will be placed by a physician immediately following ophthalmic surgery; and~~
4. Date of ophthalmic surgery must be provided; and
5. 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
6. 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.

The College of Pharmacy also recommends updating the Iluvein® (fluocinolone intravitreal implant) approval criteria based on the new FDA approved indication (changes shown in red):

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; ~~and~~ 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.

Additionally, the College of Pharmacy recommends updating the Oxervate® (cenegermin-bkbj) approval criteria based on clinical practice (changes shown in red):

Oxervate® (Cenegermin-bkbj) Approval Criteria:

1. An FDA approved diagnosis of neurotrophic keratitis; and
2. Oxervate® must be prescribed by~~, or in consultation with,~~ an optometrist or ophthalmologist; and
3. Prescriber must verify that the member has persistent epithelial defect (PED) (stage 2 disease) or corneal ulceration (stage 3 disease) of at least 2 weeks duration that is refractory to 1 or more conventional non-surgical treatments for neurotrophic keratitis; and
   a. Specific non-surgical treatments and dates of trials must be listed on the prior authorization request; and
4. Prescriber must verify that the member has evidence of decreased corneal sensitivity within the area of the PED or corneal ulcer and outside of the area of the defect in at least 1 corneal quadrant; and
5. Prescriber must verify the member has been counseled on the proper administration and storage of Oxervate®; and
6. Approvals will be for a maximum duration of 8 weeks of total therapy per eye; and
7. A quantity limit of 2 weekly kits per 14 days will apply. A quantity limit override will be approved for 4 weekly kits per 14 days with prescriber documentation of treatment in both eyes.

Lastly, the College of Pharmacy recommends moving Lotemax® (loteprednol) suspension to Tier-2 in the Ophthalmic Corticosteroids Product Based Prior Authorization (PBPA) category and removing the brand preferred status for

the suspension based on the discontinuation of brand name Lotemax® (loteprednol) suspension and due to net costs (changes shown in red):

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~~, sus~~ (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

Recommendation 14: Fiscal year 2025 Annual Review of Hyperoxaluria Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the updating the Rivfloza® (nedosiran) criteria based on the FDA approved age expansion (changes shown in red):

Rivfloza® (Nedosiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels. Diagnosis of PH1 must be confirmed by:
   a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene (results of genetic testing must be submitted); or
   b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and
2. Member must be ~~9~~ 2 years of age or older; and
3. Rivfloza® must be prescribed by a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1); and
4. Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2 prior to starting Rivfloza® and must agree to monitor renal function regularly during treatment; and
5. Prescriber must confirm the member has not undergone a liver or kidney transplant; and

6. Member must not have evidence of systemic oxalosis; and
7. Prescriber must verify that Rivfloza® will be administered by a health care professional or, if appropriate, the member or caregiver have been trained on the subcutaneous administration and proper storage of Rivfloza®; and
8. Rivfloza® will not be approved for concomitant use with Oxlumo® (lumasiran); and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion.

Recommendation 15: Fiscal Year 2025 Annual Review of Anemia Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Pyrukynd® (mitapivat) approval criteria based on the new FDA label update (changes shown in red):

Pyrukynd® (Mitapivat) Approval Criteria:

1. An FDA approved indication of hemolytic anemia in adults with pyruvate kinase (PK) deficiency confirmed by the following:
   a. Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, with at least 1 missense variant; and
      i. Hemoglobin (Hgb) ≤10g/dL; or
      ii. Member has received ≥6 red blood cell (RBC) transfusions in the past year; and
2. Pyrukynd® must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
3. Member must not have moderate or severe hepatic impairment; and
4. If Pyrukynd® is to be discontinued, prescriber must verify dose will be tapered gradually according to package labeling and member will be monitored for signs of acute hemolysis and worsening anemia; and
5. ~~Prescriber must agree to monitor Hgb levels and follow dose titration and maintenance according to package labeling; and~~
6. Prescriber must verify that all of the following will be completed as per package labeling:
   a. Hgb levels will be monitored and dose titration and maintenance dosing will be followed; and
   b. Liver function tests (LFTs) will be monitored prior to initiation, every month for the first 6 months, and as clinically indicated thereafter; and

c. If clinically significant increases in LFTs are observed or alanine aminotransferase is >5 times the upper limit of normal, Pyrukynd® treatment will be interrupted; and
d. Treatment will be discontinued if hepatic injury due to Pyrukynd® is suspected; and

7. Approvals will be for the duration of 6 months, after which time the prescriber must provide Hgb levels to support a dose increase or continuation of current dose; and
8. Pyrukynd® should be discontinued in members who do not show evidence of therapeutic benefit (i.e., Hgb increase of ≥1mg/dL from baseline, reduction in number of transfusions, improvement in hemolysis laboratory assessments) by week 24. Members will be granted short term approval to allow for gradual tapering per package labeling.

Recommendation 16: Fiscal Year 2025 Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Avtozma® (Tocilizumab-anoh), Imuldosa® (Ustekinumab-srlf), Otezla XR™ [Apremilast Extended-Release (ER)], Starjemza™ (Ustekinumab-hmny), Steqeyma® (Ustekinumab-stba), and Yesintek™ (Ustekinumab-kfce)

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

Recommendation 17: Fiscal Year 2025 Annual Review of Hereditary Angioedema (HAE) Medications and 60-Day Notice to Prior Authorize Andembry® (Garadacimab-gxii), Dawnzera™ (Donidalorsen), and Ekterly® (Sebetralstat) and Create a Product Based Prior Authorization (PBPA) Category for the HAE Medications

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

Recommendation 18: Fiscal Year 2025 Annual Review of Anticoagulants and Platelet Aggregation Inhibitors and 30-Day Notice to Prior Authorize Eliquis® (Apixaban) Tablet for Oral Suspension and Eliquis® Sprinkle (Apixaban) Capsule for Oral Suspension

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

Recommendation 19: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 20: Future Business

NO ACTION REQUIRED.

SSM Health Dermatology
9720 N. Broadway Extension
Oklahoma City, 0K 73114
phone: 405-280-SKIN (7546)
ssmhealth.com

September 16, 2025

To Whom It May Concern:

I am writing in support of making Skirizi (risankizumab-rzaa) as the drug of choice on Oklahoma Medicaid. Skirizi is a biologic medication that treats several autoimmune and inflammatory conditions by targeting the protein interleukin-23 (IL-23). It is approved for use in adults to manage moderate-to-severe forms of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. **I recommend this drug fully as I have seen firsthand not only the exceptional clinical efficacy but also the extraordinarily low side effect profile. Many of the other biologic choices render patients susceptible to infection and malignancy, increasing healthcare costs as well as morbidity and mortality.**

Please strongly consider the tremendous benefit to Oklahomans to have Skirizi as their first choice option as well as the cost savings for the state

Sincerely,

Renee H. Grau, MD
Medical Director, SSM Health Dermatology Center of Excellence
Associate Clinical Professor, University of Oklahoma Department of Dermatology

Appendix B

2026 Drug Utilization Review (DUR) Board Meeting Dates

Oklahoma Health Care Authority
November 2025

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

January 14, 2026

February 11, 2026

March 11, 2026

April 8, 2026

May 13, 2026

June 10, 2026

July 8, 2026

August 12, 2026

September 9, 2026

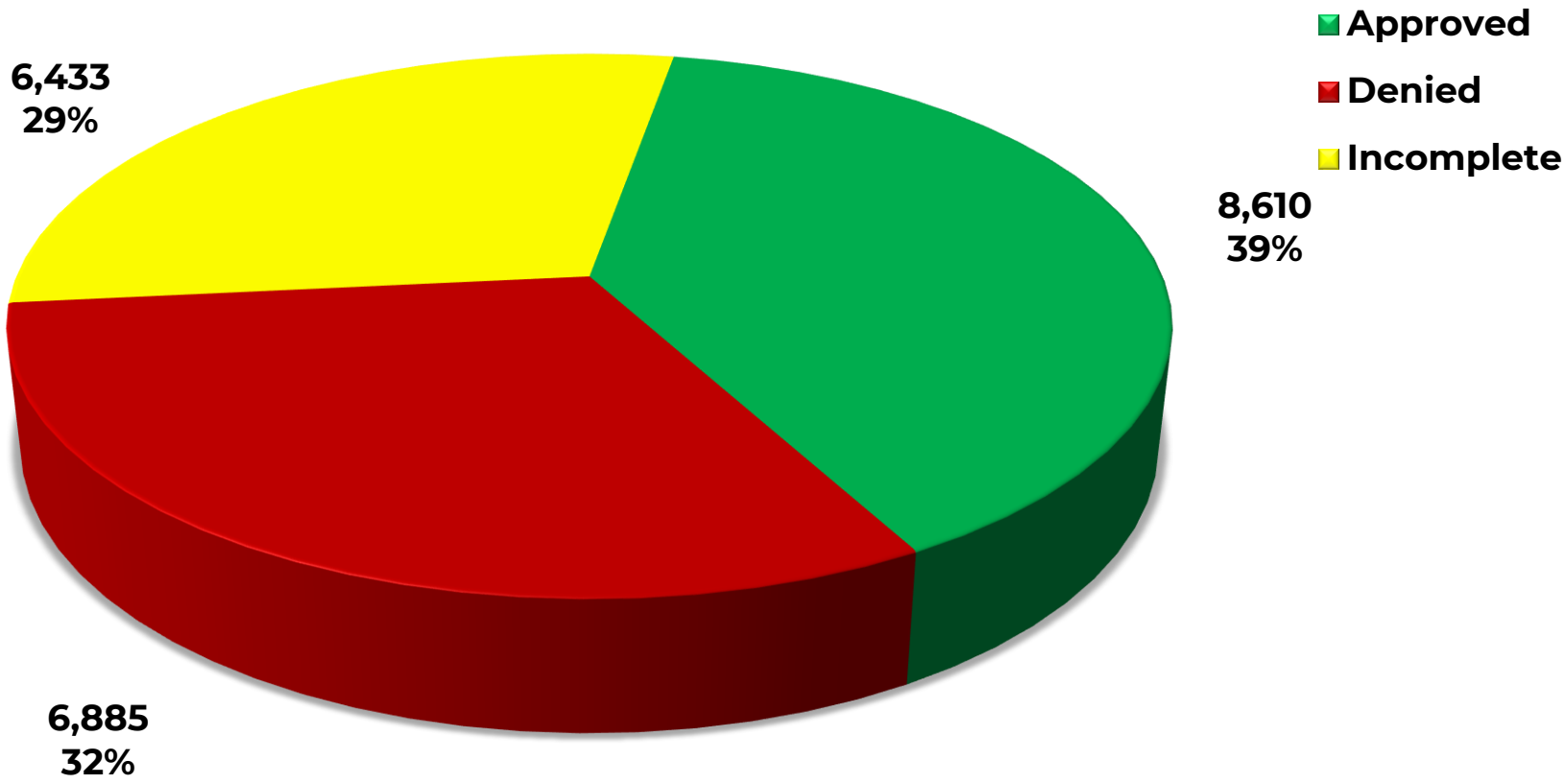
October 14, 2026

November 12, 2026*
*Scheduled for Thursday, November 12, 2026 due to the Veterans' Day holiday on Wednesday, November 11, 2026

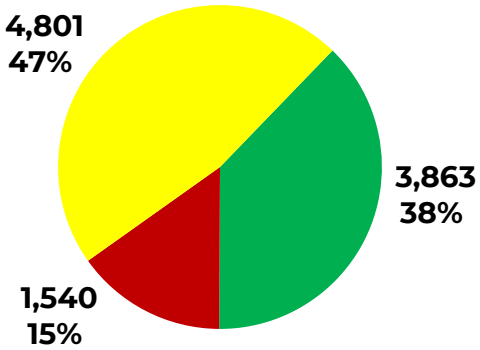
December 9, 2026

Appendix C

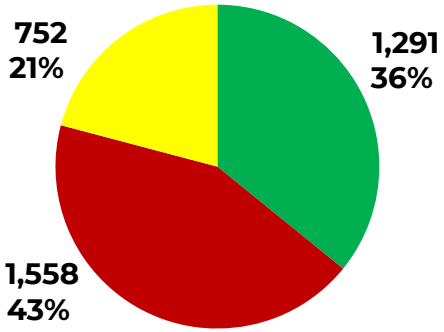
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: OCTOBER 2025



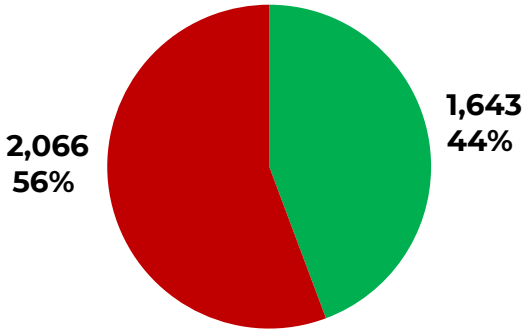
SoonerCare FFS



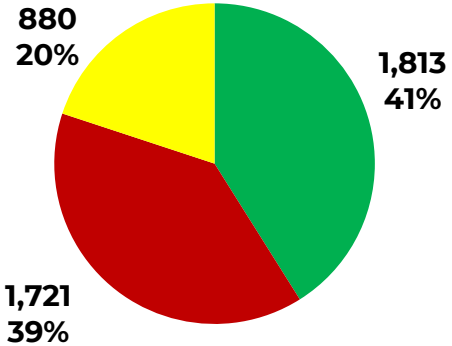
SoonerSelect Aetna



SoonerSelect Humana

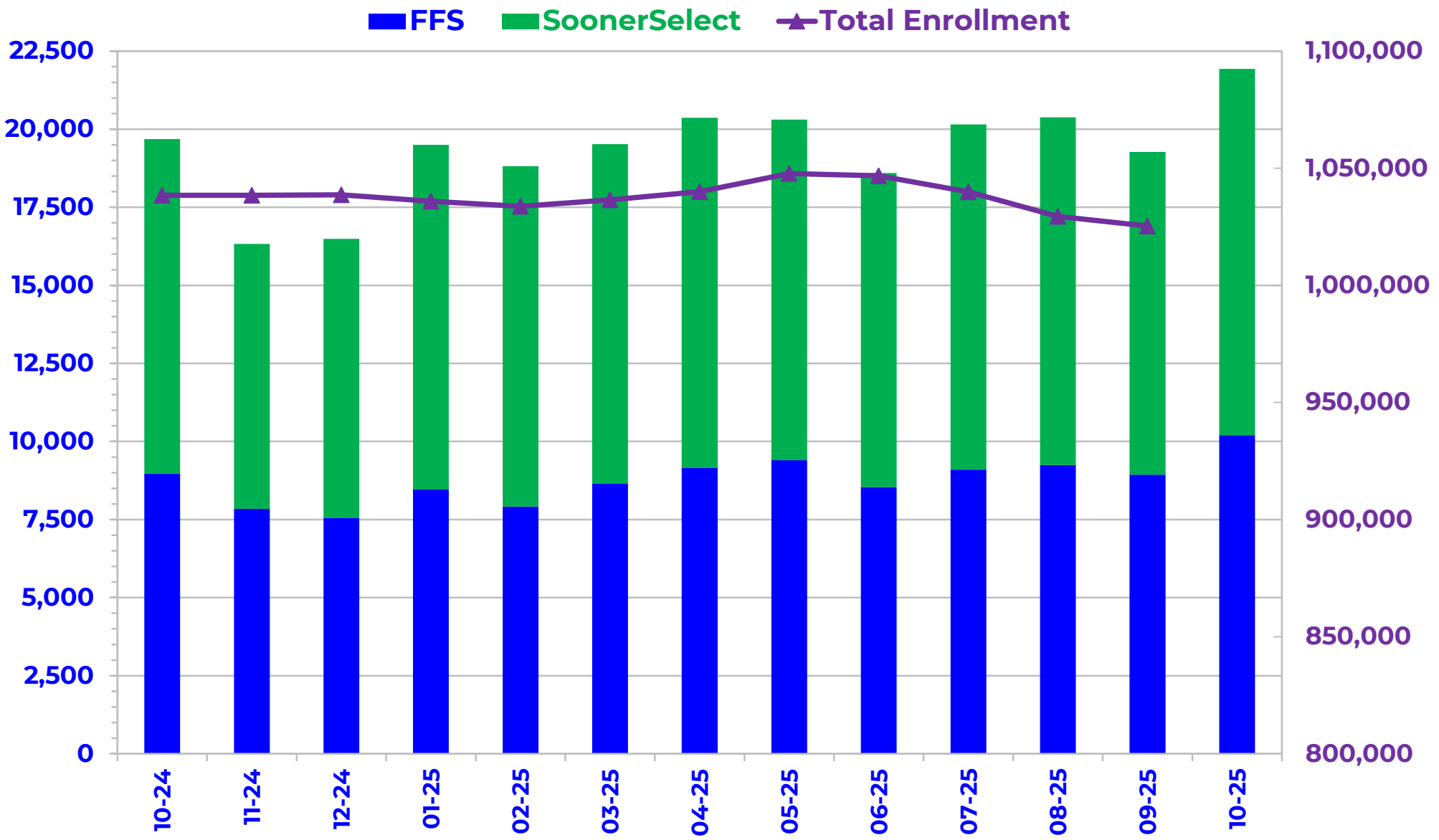


SoonerSelect OK Complete Health



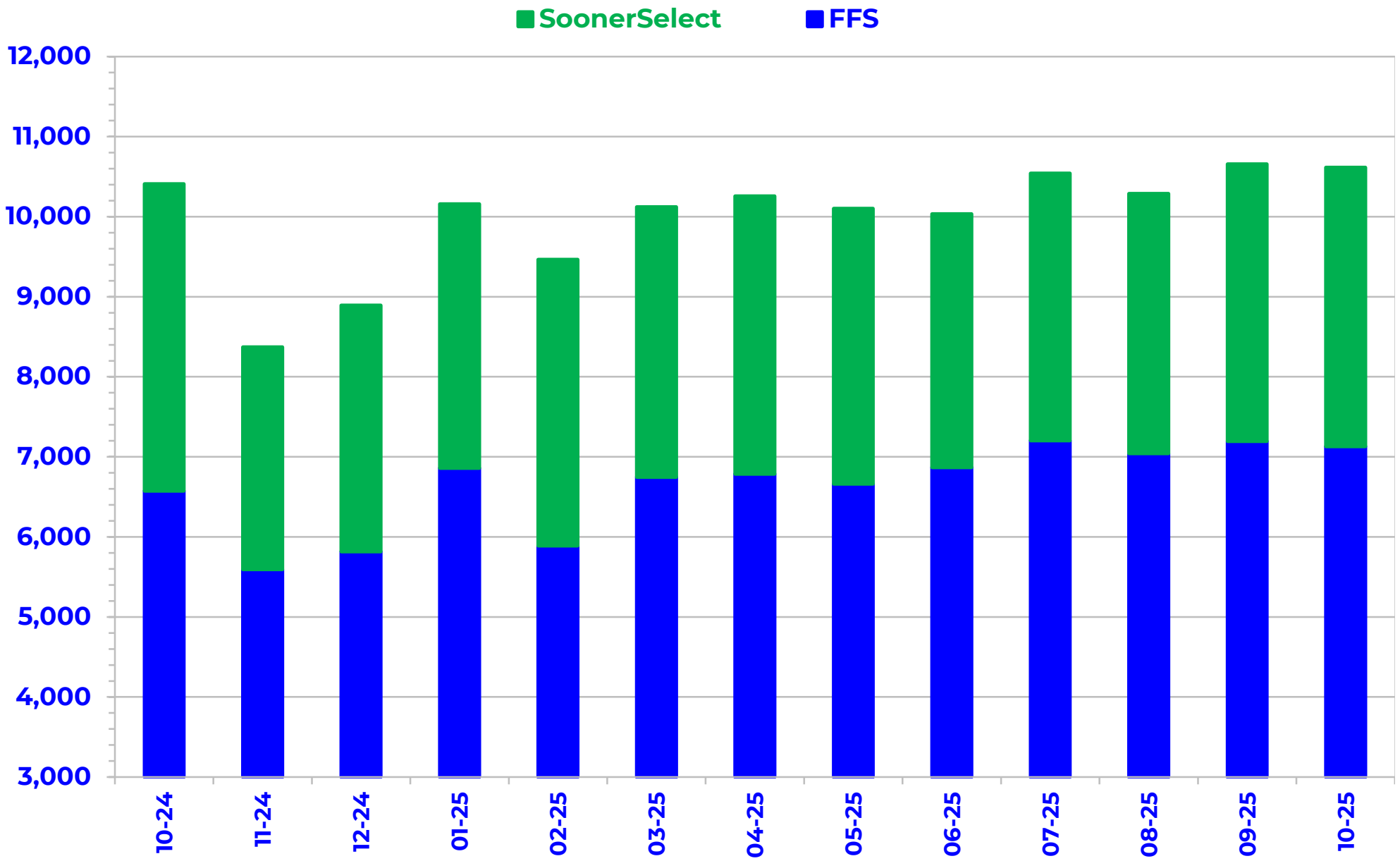
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: OCTOBER 2024 – OCTOBER 2025



SoonerCare FFS Prior Authorization Activity

10/1/2025 Through 10/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	966	452	74	440	352
Analgesics - Anti-Inflammatory	292	89	52	151	311
Analgesics - Nonnarcotic	13	0	1	12	0
Analgesics - Opioid	344	147	28	169	130
Androgens - Anabolic	94	21	13	60	359
Anorectal and Related Products	2	0	0	2	0
Anorexiants Non-Amphetamine	1	0	1	0	0
Anthelmintics	28	4	2	22	18
Anti-Infective Agents - Misc.	39	7	11	21	159
Anti-Obesity Agents	115	5	81	29	92
Antianxiety Agents	21	2	2	17	101
Antiasthmatic and Bronchodilator Agents	612	106	126	380	317
Antibiotics	25	6	3	16	79
Anticoagulants	12	2	1	9	360
Anticonvulsants	221	109	12	100	330
Antidepressants	234	70	25	139	288
Antidiabetics	1,508	478	257	773	354
Antidotes and Specific Antagonists	4	2	2	0	357
Antiemetics	12	2	0	10	212
Antifungals	4	2	0	2	47
Antihistamines	26	9	7	10	299
Antihyperlipidemics	56	15	14	27	331
Antihypertensives	10	2	2	6	360
Antimalarials	2	1	1	0	360
Antineoplastics and Adjunctive Therapies	182	121	2	59	178
Antiparkinson and Related Therapy Agents	11	4	3	4	207
Antipsychotics/Antimanic Agents	386	147	43	196	343
Antivirals	32	16	4	12	20
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	289	177	32	80	345
Beta Blockers	10	4	1	5	276
Calcium Channel Blockers	9	3	2	4	248
Cardiovascular Agents - Misc.	85	43	12	30	345
Chemicals	1	0	1	0	0
Contraceptives	35	16	4	15	350
Corticosteroids	13	2	3	8	191
Cough/Cold/Allergy	2	1	1	0	360
Dermatologicals	495	131	142	222	228
Diagnostic Products	68	30	3	35	129
Digestive Aids	6	5	0	1	358
Diuretics	12	5	0	7	359
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	6	1	1	4	361
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	235	122	29	84	238
Estrogens	7	2	0	5	360
Gastrointestinal Agents - Misc.	340	101	85	154	265
Genitourinary Agents - Misc.	4	2	0	2	360

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gout Agents	3	1	1	1	358
Hematological Agents - Misc.	30	17	3	10	299
Hematopoietic Agents	51	18	10	23	145
Histamine H3-Receptor Antagonist/Inverse Agonists	2	0	0	2	0
Hypnotics/Sedatives/Sleep Disorder Agents	72	4	16	52	222
Laxatives	18	8	2	8	234
Local Anesthetics - Parenteral	1	0	0	1	0
Medical Devices and Supplies	336	70	63	203	227
Migraine Products	499	110	124	265	250
Minerals and Electrolytes	6	1	0	5	350
Miscellaneous Therapeutic Classes	87	28	15	44	315
Mouth/Throat/Dental Agents	1	0	0	1	0
Multivitamins	5	4	0	1	359
Musculoskeletal Therapy Agents	22	4	4	14	276
Nasal Agents - Systemic and Topical	18	2	2	14	361
Neuromuscular Agents	78	41	12	25	354
Nutrients	2	1	0	1	359
Ophthalmic Agents	81	24	10	47	187
Other*	49	26	3	20	203
Otic Agents	33	9	2	22	17
Passive Immunizing and Treatment Agents	4	1	0	3	26
Progestins	4	1	1	2	360
Psychotherapeutic and Neurological Agents - Misc.	232	87	34	111	214
Respiratory Agents - Misc.	29	17	0	12	332
Stimulants - Misc.	308	127	20	161	354
Thyroid Agents	9	4	0	5	358
Ulcer Drugs/Antispasmodics/Anticholinergics	87	20	18	49	218
Urinary Antispasmodics	43	11	6	26	297
Vaginal and Related Products	7	0	3	4	0
Vasopressors	5	1	0	4	358
Vitamins	32	0	25	7	0
Total	**9,023**	**3,101**	**1,457**	**4,465**	
Overrides					
Brand	24	7	2	15	325
Compound	17	10	1	6	21
Diabetic Supplies	2	2	0	0	235
Dosage Change	191	171	1	19	19
High Dose	2	2	0	0	360
Ingredient Duplication	4	2	0	2	101
Lost/Broken Rx	50	46	1	3	17
MAT Override	17	9	0	8	69
NDC vs Age	172	105	27	40	285
NDC vs Sex	23	16	2	5	327
Nursing Home Issue	96	89	1	6	14
Opioid MME Limit	68	19	3	46	115
Opioid Quantity	30	12	5	13	164
Other	18	15	1	2	20
Quantity vs Days Supply	407	234	30	143	271
STBS/STBSM	15	4	6	5	67
Step Therapy Exception	6	1	2	3	358

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Stolen	3	3	0	0	16
Third Brand Request	36	15	1	20	16
Overrides Total	**1,181**	**762**	**83**	**336**	
Total Regular PAs + Overrides	**10,204**	**3,863**	**1,540**	**4,801**	

Denial Reasons	
Unable to verify required trials.	4,184
Does not meet established criteria.	1,587
Lack required information to process request.	647
Other PA Activity	
Duplicate Requests	1,199
Letters	45,034
No Process	0
Helpdesk Initiated Prior Authorizations	370
PAs Missing Information	372
Pharmacotherapy	122
Changes to Existing PAs	591

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

SoonerSelect Aetna Prior Authorization Activity

10/1/2025 Through 10/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	0	1	1	0
Alternative Medicines	1	0	1	0	0
Amphetamines	314	195	99	20	364
Analgesics - Anti-Inflammatory	107	75	19	13	312
Analgesics - Nonnarcotic	5	0	4	1	0
Analgesics - Opioid	133	58	42	33	165
Androgens - Anabolic	54	8	46	0	365
Anthelmintics	6	6	0	0	14
Antianxiety Agents	40	12	10	18	294
Antiasthmatic and Bronchodilator Agents	168	42	87	39	318
Antibiotics	13	1	5	7	7
Anticoagulants	8	2	2	4	106
Anticonvulsants	66	22	21	23	331
Antidepressants	240	66	94	80	307
Antidiabetics	545	140	308	97	313
Antiemetics	8	1	0	7	365
Antifungals	1	0	1	0	0
Antihistamines	26	2	20	4	242
Antihyperlipidemics	45	2	23	20	273
Antihypertensives	18	1	2	15	365
Anti-Infective Agents - Misc.	14	0	0	14	0
Antineoplastics and Adjunctive Therapies	31	14	1	16	306
Anti-Obesity Agents	84	6	75	3	230
Antiparkinson and Related Therapy Agents	5	0	1	4	0
Antipsychotics/Antimanic Agents	142	51	53	38	351
Antivirals	3	2	1	0	92
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	93	71	15	7	360
Beta Blockers	26	0	1	25	0
Calcium Channel Blockers	14	0	2	12	0
Cardiovascular Agents - Misc.	29	7	17	5	365
Contraceptives	16	2	12	2	365
Corticosteroids	10	4	3	3	281
Dermatologicals	306	135	127	44	213
Diagnostic Products	50	26	10	14	338
Dietary Products/Dietary Management Products	2	0	0	2	0
Digestive Aids	2	0	0	2	0
Diuretics	14	0	1	13	0
Endocrine and Metabolic Agents - Misc.	41	30	11	0	224
Estrogens	7	5	1	1	358
Gastrointestinal Agents - Misc.	104	33	47	24	196
Genitourinary Agents - Misc.	1	0	0	1	0
Gout Agents	4	1	0	3	365
Hematological Agents - Misc.	6	5	0	1	365

*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
Hematopoietic Agents	4	3	1	0	304
Hypnotics/Sedatives/Sleep Disorder Agents	28	4	13	11	243
Laxatives	3	1	1	1	15
Local Anesthetics - Parenteral	2	0	2	0	0
Medical Devices and Supplies	88	33	36	19	353
Migraine Products	261	82	159	20	202
Minerals and Electrolytes	10	2	2	6	180
Miscellaneous Therapeutic Classes	17	12	3	2	365
Multivitamins	1	1	0	0	365
Musculoskeletal Therapy Agents	46	4	15	27	209
Nasal Agents - Systemic and Topical	23	0	19	4	0
Neuromuscular Agents	5	3	1	1	182
Ophthalmic Agents	24	10	12	2	310
Other	6	1	3	2	180
Otic Agents	9	3	6	0	26
Passive Immunizing and Treatment Agents	1	0	0	1	0
Progestins	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	41	18	22	1	218
Stimulants - Misc.	100	66	27	7	352
Thyroid Agents	4	2	0	2	273
Ulcer Drugs/Antispasmodics/Anticholinergics	62	10	24	28	241
Urinary Antispasmodics	15	3	11	1	365
Vaccines	4	1	3	0	182
Vaginal and Related Products	1	0	0	1	0
Vitamins	41	6	35	0	304
****Total**	**3,601**	**1,291**	**1,558**	**752**	

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

Overrides					
Brand	1	1	0	0	365
Other	802	50	0	752	365
Quantity Level Limit	32	32	0	0	302
Overrides Total	**835**	**83**	**0**	**752**	

Denial Reason	
Benefit	89
Experimental/Investigational	154
Medical Necessity	1,167
Request did not have enough information to determine medical necessity	124
Other	24
Other PA Activity	
Duplicate Requests	16
Letters	4,420
No Process	248
Changes to existing PAs	0
Helpdesk initiated PA	2
PAs missing info	13

*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

10/1/2025 Through 10/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	1	0	1	0	0
Analgesics - Anti-Inflammatory	72	53	19	0	347
Analgesics - Nonnarcotic	4	0	4	0	0
Analgesics - Opioid	68	40	28	0	275
Androgens - Anabolic	68	26	42	0	234
Anthelmintics	6	1	5	0	183
Antiasthmatic and Bronchodilator Agents	153	55	98	0	250
Antibiotics	5	2	3	0	365
Anticonvulsants	18	9	9	0	452
Antidepressants	64	40	24	0	265
Antidiabetics	337	122	215	0	226
Antiemetics	3	0	3	0	0
Antihyperlipidemics	23	11	12	0	221
Anti-Infective Agents - Misc.	1	1	0	0	365
Antimalarials	1	0	1	0	0
Antineoplastics and Adjunctive Therapies	46	42	4	0	234
Anti-Obesity Agents	63	4	59	0	50
Antiparkinson and Related Therapy Agents	1	1	0	0	365
Antipsychotics/Antimanic Agents	5	0	5	0	0
Antivirals	6	3	3	0	56
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	11	9	2	0	328
Beta Blockers	1	1	0	0	365
Calcium Channel Blockers	1	0	1	0	0
Cardiovascular Agents - Misc.	39	20	19	0	286
Contraceptives	46	36	10	0	305
Corticosteroids	4	2	2	0	274
Dermatologicals	156	59	97	0	245
Diagnostic Products	25	18	7	0	299
Digestive Aids	1	0	1	0	0
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	35	20	15	0	261
Estrogens	6	2	4	0	107
Gastrointestinal Agents - Misc.	77	34	43	0	223
Gout Agents	2	0	2	0	0
Hematological Agents - Misc.	3	3	0	0	365
Hematopoietic Agents	12	1	11	0	112
Hypnotics/Sedatives/Sleep Disorder Agents	11	1	10	0	365
Laxatives	6	2	4	0	183
Medical Devices and Supplies	65	58	7	0	415
Migraine Products	143	83	60	0	185
Minerals and Electrolytes	1	0	1	0	0
Miscellaneous Therapeutic Classes	11	7	4	0	365
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	37	19	18	0	188
Nasal Agents - Systemic and Topical	1	1	0	0	729

*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
Neuromuscular Agents	21	17	4	0	322
Nutrients	1	1	0	0	92
Ophthalmic Agents	18	8	10	0	265
Other	3	2	1	0	365
Progestins	1	1	0	0	548
Psychotherapeutic and Neurological Agents - Misc.	41	25	16	0	229
Respiratory Agents - Misc.	13	12	1	0	342
Stimulants - Misc.	15	10	5	0	321
Thyroid Agents	2	1	1	0	183
Ulcer Drugs/Antispasmodics/Anticholinergics	38	9	29	0	231
Urinary Antispasmodics	15	2	13	0	219
Vitamins	43	3	40	0	186
Total	**1,853**	**879**	**974**	**0**	

Overrides					
High Dose	1	1	0	0	365
Ingredient Duplication	134	81	53	0	184
NDC vs Age	490	317	173	0	242
Opioid MME Limit	11	8	3	0	352
Opioid Quantity	7	6	1	0	491
Other	136	41	95	0	111
Quantity vs Days Supply	210	142	68	0	253
STBS/STBSM	515	11	504	0	10
Step Therapy Exception	352	157	195	0	166
Overrides Total	**1,856**	**764**	**1,092**	**0**	
Total Regular PAs + Overrides	**3,709**	**1,643**	**2,066**	**0**	

Denial Reasons	
Benefit	884
Medical Necessity	1,182

*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

10/1/2025 Through 10/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	1	1	0	365
Amphetamines	349	140	122	87	293
Analgesics - Anti-Inflammatory	85	47	22	16	362
Analgesics - Nonnarcotic	14	2	8	4	189
Analgesics - Opioid	324	116	146	62	180
Androgens - Anabolic	86	12	62	12	365
Anorectal and Related Products	1	0	0	1	0
Anorexiants Non-Amphetamine	3	0	0	3	0
Anthelmintics	4	0	4	0	0
Antianxiety Agents	19	5	10	4	194
Antiasthmatic and Bronchodilator Agents	221	71	128	22	220
Antibiotics	21	14	5	2	253
Anticoagulants	4	1	1	2	365
Anticonvulsants	58	22	26	10	321
Antidepressants	175	60	82	33	290
Antidiabetics	726	361	260	105	323
Antiemetics	21	12	3	6	105
Antifungals	2	1	0	1	365
Antihistamines	21	4	11	6	303
Antihyperlipidemics	26	4	19	3	272
Antihypertensives	3	1	1	1	365
Anti-Infective Agents - Misc.	13	3	3	7	303
Antineoplastics and Adjunctive Therapies	75	43	14	18	241
Anti-Obesity Agents	86	4	36	46	252
Antiparkinson and Related Therapy Agents	1	0	1	0	0
Antipsychotics/Antimanic Agents	163	71	60	32	303
Antivirals	3	0	1	2	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	140	74	47	19	363
Beta Blockers	4	3	0	1	175
Calcium Channel Blockers	11	8	1	2	309
Cardiovascular Agents - Misc.	32	12	17	3	333
Chemicals	2	1	0	1	180
Contraceptives	32	12	16	4	241
Corticosteroids	9	3	3	3	101
Cough/Cold/Allergy	7	2	0	5	63
Dermatologicals	388	119	171	98	247
Diagnostic Products	60	32	19	9	325
Dietary Products/Dietary Management Products	12	0	0	12	0
Diuretics	4	0	3	1	0
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	74	33	32	9	323
Estrogens	11	5	4	2	188
Gastrointestinal Agents - Misc.	102	38	58	6	239
Genitourinary Agents - Misc.	1	0	1	0	0
Gout Agents	1	0	1	0	0
Hematological Agents - Misc.	6	4	2	0	227

*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
Hematopoietic Agents	24	11	4	9	162
Hypnotics/Sedatives/Sleep Disorder Agents	37	18	14	5	179
Laxatives	11	3	4	4	271
Medical Devices and Supplies	138	88	24	26	281
Migraine Products	190	70	96	24	250
Minerals and Electrolytes	5	0	4	1	0
Miscellaneous Therapeutic Classes	24	14	5	5	259
Mouth/Throat/Dental Agents	1	0	0	1	0
Multivitamins	5	2	2	1	365
Musculoskeletal Therapy Agents	30	9	14	7	194
Nasal Agents - Systemic and Topical	15	6	8	1	247
Neuromuscular Agents	22	13	1	8	272
Ophthalmic Agents	39	13	18	8	246
Other	70	20	3	47	322
Otic Agents	25	5	15	5	298
Passive Immunizing and Treatment Agents	2	1	0	1	365
Progestins	2	0	2	0	0
Psychotherapeutic and Neurological Agents - Misc.	37	18	13	6	276
Respiratory Agents - Misc.	11	9	2	0	351
Stimulants - Misc.	243	137	55	51	270
Thyroid Agents	24	19	4	1	208
Ulcer Drugs/Antispasmodics/Anticholinergics	35	8	24	3	223
Urinary Antispasmodics	14	5	7	2	146
Vaccines	2	1	0	1	365
Vaginal and Related Products	3	0	0	3	0
Vasopressors	2	2	0	0	272
****Total**	**4,414**	**1,813**	**1,721**	**880**	

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

Denial Reasons	
Medical Necessity	1,721

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

Appendix D

Hepatitis C Program Update

Oklahoma Health Care Authority
November 2025

Background[1,2,3,4,5,6,7,8]

The availability of effective direct-acting antivirals (DAAs) for the treatment of hepatitis C virus (HCV) infection has led to the establishment of an international goal to eliminate HCV as a public health threat by 2030. However, despite broad and collaborative efforts, the annual number of new HCV cases in the United States has remained relatively stable from 2021 to the most recent analysis year of 2023 but has still fallen short of targets. A recently published analysis by the Centers for Disease Control and Prevention (CDC) estimated that the annual number of new HCV infections in the United States was 69,000 in 2023; this was above the target of 35,000 new infections, which was needed to stay on track to meet the longitudinal goal in 2030.

In addition to effective prevention initiatives, reducing barriers to treatment with DAAs has been shown to be essential for timely treatment of HCV infection. Some state Medicaid plans still impose coverage restrictions, such as prior authorization (PA) requirements and prescriber specialty requirements, which have been associated with decreased utilization of DAAs. In recent years, SoonerCare has greatly reduced barriers to accessing hepatitis C treatment. As of 07/01/2019, SoonerCare prescribers who are not gastroenterology, infectious diseases (ID), or transplant specialists may submit requests for hepatitis C treatment through Project ECHO (Extension for Community Healthcare Outcomes), an interdisciplinary education and outreach program designed to increase access to specialized care through provider training. Additionally, in an effort to increase access to treatment, the Oklahoma Health Care Authority (OHCA) entered into a value-based agreement (VBA) with AbbVie, the manufacturer of the DAA Mavyret® (glecaprevir/pibrentasvir), and the PA requirement for Mavyret® was removed as of 07/01/2022 for all SoonerCare members.

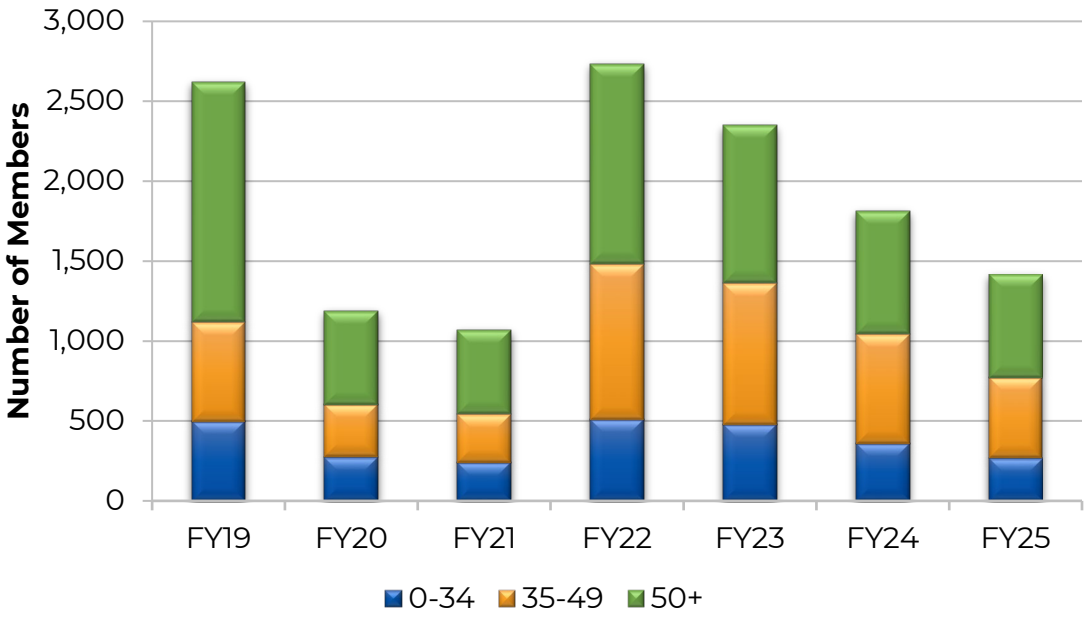
Mavyret® is a pangenotypic DAA that is recommended as a first line option for the treatment of HCV infection by clinical practice guidelines. It is dosed as 3 tablets once daily for 8 weeks for adults with chronic hepatitis C who qualify for the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of American (IDSA) simplified treatment algorithm. Patients eligible for simplified treatment are those who are treatment naïve, do not have decompensated cirrhosis, are not positive for hepatitis B surface antigen (HBsAg), are not pregnant, do not have known or suspected hepatocellular carcinoma, and have not had a liver transplant.

The purpose of this report is to conduct a retrospective review of SoonerCare claims data to track trends within the SoonerCare hepatitis C program and to elucidate the effects of the removal of the PA requirement for Mavyret®.

Results of Claims Analysis[9,10,11]

Claims between fiscal year (FY) 19 and FY25 (07/01/2018 to 06/30/2025) were included for members with a reported diagnosis of chronic HCV infection. Indian Health Services members and members dual eligible for Medicare were excluded. Of note, the SoonerSelect plans did not come into effect until 04/01/2024; therefore, data for these plans are only available from 04/01/2024 to 06/30/2025. From FY19 through FY25, a total of 13,178 unduplicated SoonerCare members had a reported diagnosis of chronic HCV infection. Of these members, 51.4% were male, 50.3% were older than 50 years of age, 18.74% had cirrhosis, and 3.05% had a concomitant diagnosis of human immunodeficiency virus (HIV). Due to inherent limitations of the claims analysis process utilizing reported diagnosis codes, members with compensated vs. decompensated cirrhosis could not be distinguished.

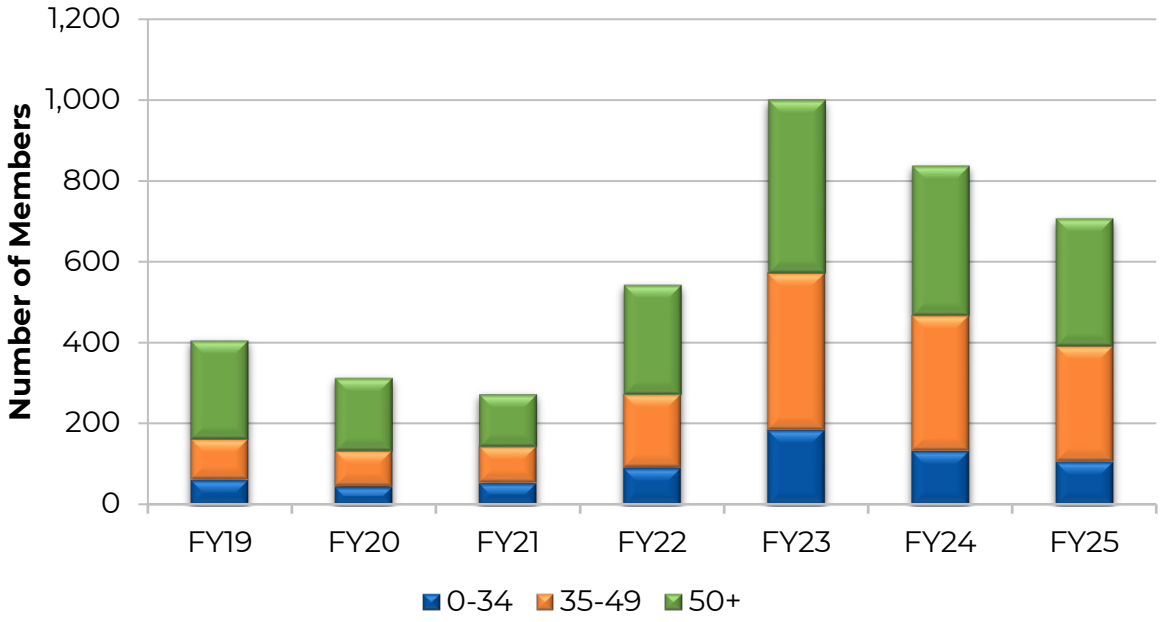
Demographics of Members with Chronic HCV Infection by Fiscal Year



The chart above shows the number of unduplicated members with a diagnosis of chronic HCV Infection per FY by age group. Members with a reported diagnosis in multiple FYs were assigned to the age group and FY that corresponded with the initial report. The data indicates a steady decline in the total number of members diagnosed with chronic HCV infection after a peak in FY22; however, FY20 (07/01/2019 to 06/30/2020) and FY21 (07/01/2020 to 06/30/2021) could have falsely low counts due to the Coronavirus 2019 (COVID-19) pandemic, which disrupted the continuity of care across the

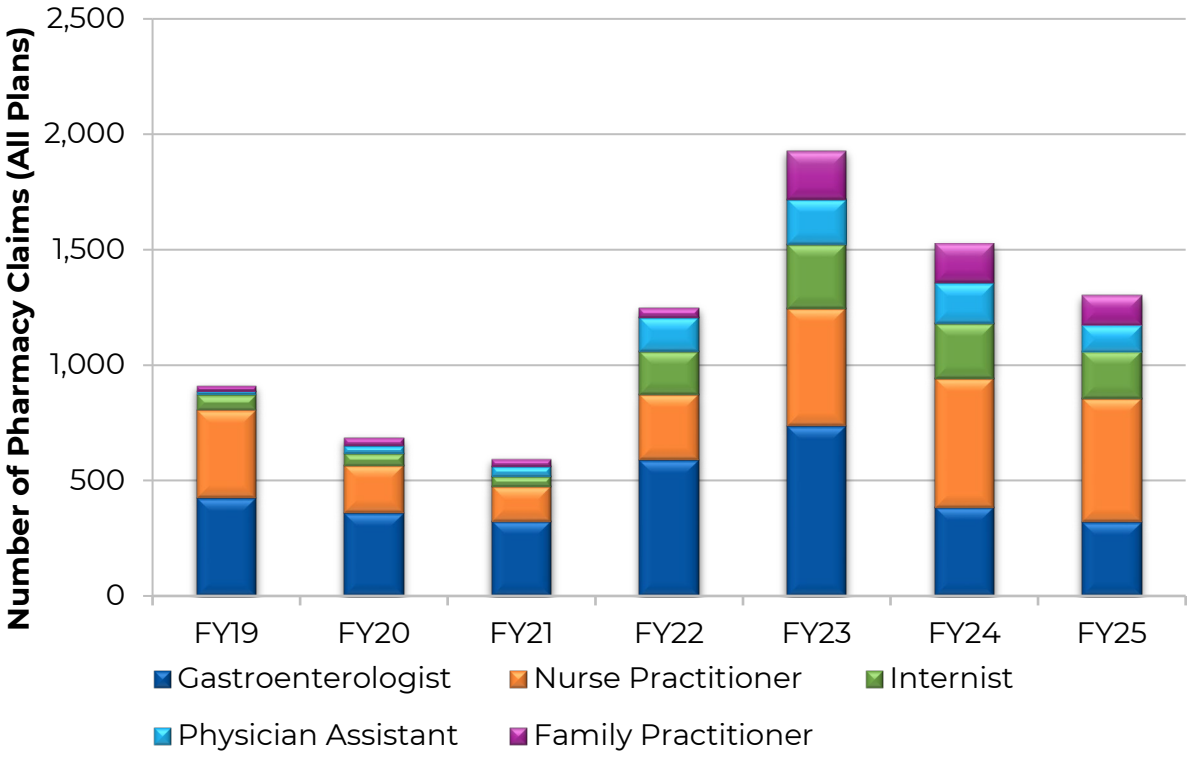
United States during this time. Additionally, there were other potential confounders in the following years. The Oklahoma Medicaid Expansion Initiative took effect at the beginning of FY22 (07/01/2021), which could have contributed to the increase in members at that time. Also, during 2023, SoonerCare completed the process of unwinding enrollment of members no longer eligible after the expiration of the continuous eligibility requirements under the COVID-19 federal public health emergency (PHE). The unwinding process was completed by 12/21/2023, which could have contributed to the decline in members from FY23 to FY24.

Demographics of Members with a DAA Claim by Fiscal Year



For the remainder of this report, the member counts for each FY represent unduplicated members, as members with multiple claims were counted in each FY in which they had a claim but were only counted once per FY. From FY19 through FY25, a total of 3,780 unique members had a paid pharmacy claim for a DAA. Of these members, 16.98% were younger than 34 years of age, 36.30% were between 25 and 49 years of age, and 46.72% were older than 50 years of age. Detailed age demographic data per FY is shown in the chart above. Additionally, of these 3,780 members, 51.51% were male, and 14.89% had cirrhosis. Furthermore, 98.28% were considered treatment-naïve, which were members with no prior paid claims for any HCV treatment during their history with SoonerCare.

Top 5 Prescriber Specialties of DAAs by Number of Pharmacy Claims per Fiscal Year (All Plans)



The chart above shows the top 5 prescriber specialties prescribing DAAs by number of pharmacy claims per FY for all SoonerCare Plans. The top prescriber specialty was gastroenterologist, which was followed by nurse practitioners who were mostly supervised by gastroenterologists or ID specialists, and internists practicing in specialty settings. Beginning in FY23, the number of claims prescribed by internists, family practitioners, nurse practitioners, and physician assistants increased, which suggests a diversification of providers involved in the treatment of HCV infection as result of the removal of the PA requirement for Mavyret®.

Table 1: Pharmacy Claims for DAAs by Fiscal Year (All Plans)

Fiscal Year	Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Member	Claims/ Member	Mavyret® Utilization
FY19	406	951	$21,891,521.30	$23,019.48	$53,920.00	2.34	18.61%
FY20	314	701	$15,466,286.35	$22,063.18	$49,255.69	2.23	26.68%
FY21	274	621	$11,811,880.75	$19,020.74	$43,109.05	2.27	24.80%
FY22	542	1,255	$12,348,264.82	$9,839.25	$22,782.78	2.32	27.73%
FY23	994	2,007	$24,287,815.37	$12,101.55	$24,434.42	2.02	82.76%
FY24	835	1,636	$20,933,759.30	$12,795.70	$25,070.37	1.96	87.47%
FY25	705	1,373	$17,404,441.98	$12,676.21	$24,687.15	1.95	84.63%

Costs do not reflect rebated prices or net costs.
DAA = direct-acting antiviral; FY = fiscal year

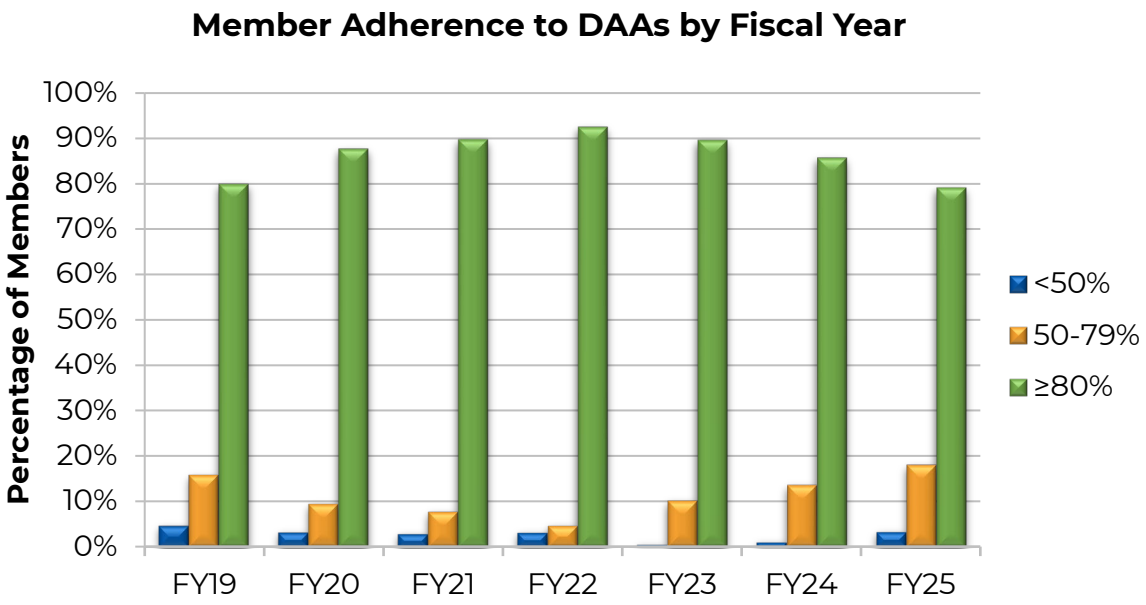
Data regarding cost of pharmacy claims for DAAs per FY are shown in Table 1. These costs do not reflect rebated prices or net costs. The results in Table 1 show that after the removal of the PA requirement on 07/01/2022, the proportion of DAA claims for Mavyret® increased from 27.73% to 82.76% from FY22 (07/01/2021 to 06/30/2022) to FY23 (07/01/2022 to 06/30/2023). Additionally, from FY22 to FY23, there was an 83.39% increase in total members with a claim for any DAA and a 59.92% increase in total claims for any DAA; this increase correlates with the removal of the PA requirement for Mavyret®. Despite a marked increase in total costs from FY22 to FY23, primarily a result of the spike in total claims, the cost per claim and cost per member increased by only 22.99% and 7.25%, respectively, and both have remained relatively stable in subsequent years. Across the entire analysis time frame, total costs have trended downward, with total costs in FY25 being $4,487,079.32, or 20.50%, less than total costs in FY19.

Table 2: Utilization of DAAs by Fiscal Year: Pharmacy Claims (All Plans)

DAA Product	2019	2020	2021	2022	2023	2024	2025
Mavyret® (glecaprevir/pibrentasvir)	177	187	154	348	1,661	1,431	1,162
Epclusa® (sofosbuvir/velpatasvir)	437	424	438	888	336	177	170
Harvoni® (ledipasvir/sofosbuvir)	237	77	21	3	0	0	7
Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)	24	13	8	16	10	25	28
Zepatier® (elbasvir/grazoprevir)	76	0	0	0	0	3	6

DAA = direct-acting antiviral; FY = fiscal year

Table 2 above shows the utilization of the available DAA products by number of pharmacy claims per FY from FY19 through FY25. The claims show a shift toward increased utilization of Mavyret® and Epclusa® (sofosbuvir/velpatasvir). This shift coincides with the introduction of the first simplified hepatitis C treatment algorithms for treatment-naïve persons (without cirrhosis or with compensated cirrhosis) in the 2019 version of the AASLD/IDSA clinical practice guidelines, which recommended universal treatment with Mavyret® or Epclusa® as first-line, pangenotypic regimens. While Mavyret® is the preferred DAA for SoonerCare, there is continued utilization of other DAA products, as it may be clinically appropriate for some members based on treatment guidelines (i.e., decompensated cirrhosis, retreatment).



The chart above shows member adherence to DAA regimens as a proportion of total members per FY stratified into adherence cohorts (e.g., ≥80%, 50% to 79%, <50%). Adherence was determined by comparing the length of treatment (i.e., days from the initial fill date through the end of the days' supply for the final fill date) to the typical length of treatment for the regimen (e.g., 8 weeks for Mavyret®, 12 weeks for Epclusa®). The Y-axis is the percentage of members per FY belonging to each adherence cohort. The data indicates that the proportion of members classified as >80% adherent had a slight upward trend from FY19 to FY22 but has since trended back down. The percentage of members classified as <50% adherent decreased from 4.58% in FY19 to a nadir of 0.53% in FY23; however, this has trended back up to 3.2% in FY25. Members falling into the 50% to 79% cohort followed a similar trend.

Conclusions

Although the scope of this analysis was limited by the lack of clinical detail inherent to claims data, the results of this retrospective claim review suggest that the removal of the PA requirement for Mavyret® at the beginning of FY23 may have improved outcomes in SoonerCare members diagnosed with chronic HCV infection. Supporting evidence includes a sharp increase in the total number of members utilizing DAAs and a decrease in the number of SoonerCare members with a diagnosis of chronic HCV since FY22, which coincides with the removal of the PA requirement for Mavyret®. Other positive findings include a decrease in total costs for pharmacy claims for DAAs during the overall review period and diversification of prescribers with a variety of practice specialties.

The College of Pharmacy will continue to monitor the SoonerCare hepatitis C program and provide recommended updates to the medication criteria as determined by continued assessment of claims data and evidence-based clinical practice guidelines, with the goal to continually improve member outcomes.

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Appendix E

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

Oklahoma Health Care Authority
November 2025

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

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

- **March 2025:** The FDA approved an Abbreviated New Drug Application (ANDA) for the first generic formulation of Xarelto® (rivaroxaban) 2.5mg oral tablets. Additionally, Lupin Limited announced the launch of rivaroxaban 2.5mg tablets on March 7, 2025.
- **April 2025:** The FDA approved an expanded indication for Eliquis® (apixaban) for the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least 5 days of initial anticoagulant treatment. Additionally, a new 0.5mg tablet for oral suspension and 0.15mg capsule for oral suspension were approved.

News:

- **April 2025:** A generic formulation of Brilinta® (ticagrelor) has been launched by various manufacturers in the 60mg and 90mg tablet strengths.
- **July 2025:** Ascend announced the launch of the AB-rated generic formulation of Xarelto® (rivaroxaban) oral suspension.

Recommendations

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

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

1. Eliquis® tablet for oral suspension and Eliquis® Sprinkle capsule for oral suspension will not require prior authorization for members 10 years of age or younger. For members 11 years of age or older, a patient-specific, clinically significant reason why the member cannot use Eliquis® tablets must be provided; and

2. Clinical exceptions for the age restriction may be considered for approval (e.g., documented dysphagia, weight-based dose cannot be achieved with the tablet formulation).

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

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

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

Brilinta® (Ticagrelor) Approval Criteria:

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

Pradaxa® (Dabigatran) Approval Criteria:

1. Pradaxa® (dabigatran) capsules require the following:
    a. An FDA approved indication of 1 of the following:
        i. Non-valvular atrial fibrillation; or
        ii. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) after treatment with a parenteral anticoagulant for 5 to 10 days; or
        iii. To reduce the risk of recurrent DVT or PE in members who have been previously treated; or
        iv. For the prophylaxis of DVT and PE in members who have undergone hip replacement surgery; or
        v. Treatment of venous thromboembolic events (VTE) in pediatric members 8 to 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; or

vi. To reduce the risk of recurrent VTE in pediatric members 8 to 18 years of age who have been previously treated.

b. A patient-specific, clinically significant reason why the member cannot use Eliquis® (apixaban) and Xarelto® (rivaroxaban) must be provided. ~~; and~~

~~c. Requests for generic dabigatran capsules will require a patient-specific, clinically significant reason why brand name Pradaxa® cannot be used.~~

2. Pradaxa® (dabigatran) oral pellets require the following:
   a. An FDA approved indication of 1 of the following:
      i. Treatment of VTE in members who have been treated with a parenteral anticoagulant for at least 5 days; or
      ii. To reduce the risk of recurrent VTE in members who have been previously treated; and
   b. Member must be 3 months of age or older; and
   c. Members older than 7 years of age require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
   d. A patient-specific, clinically significant reason why the member cannot use Xarelto® (rivaroxaban) oral suspension must be provided.

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[6] Xarelto® (Rivaroxaban) Oral Suspension – First-Time Generic. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/new-generics/newgeneric-xarelto-080125.pdf. Issued 07/09/2025. Last accessed 10/20/2025.

Appendix F

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

Oklahoma Health Care Authority
November 2025

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

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

- **October 2024:** The FDA approved Imuldosa® (ustekinumab-srlf) as a new biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **October 2024:** The FDA approved Selarsdi™ (ustekinumab-aekn) for new indications for the treatment of adults with moderately to severely active Crohn's disease (CD) or ulcerative colitis (UC). Additionally, a new formulation of Selarsdi™ was approved as a 130mg/26mL single-dose vial (SDV) for intravenous (IV) infusion. With this approval, Selarsdi™ is FDA approved for the treatment of all 6 different Stelara® indications.
- **October 2024:** The FDA approved an unbranded formulation of Selarsdi™ (ustekinumab-aekn) through a supplemental Biologics License Application (sBLA).
- **November 2024:** The FDA approved Bimzelx® (bimekizumab-bkzx) for a new indication for the treatment of adults with moderate to severe hidradenitis suppurative (HS).
- **November 2024:** The FDA approved Yesintek™ (ustekinumab-kfce) as a new biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **December 2024:** The FDA approved Steqeyma® (ustekinumab-stba) as a new biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **January 2025:** The FDA approved Omvoh® (mirikizumab-mrkz) for a new indication for the treatment of moderately to severely active CD in adults.
- **January 2025:** The FDA approved Avtozma® (tocilizumab-anoh) as a new biosimilar to Actemra® (tocilizumab) for the treatment of 5 of the 7 different Actemra® indications.

- **March 2025:** The FDA approved an unbranded formulation of Pyzchiva® (ustekinumab-ttwe) through an sBLA.
- **March 2025:** The FDA approved Tremfya® (guselkumab) for a new indication for the treatment of adult patients with moderately to severely active CD.
- **April 2025:** The FDA approved an unbranded formulation of Stelara® (ustekinumab) through an sBLA.
- **April 2025:** The FDA approved an unbranded formulation of Otulfi® (ustekinumab-aauz) through an sBLA.
- **April 2025:** The FDA approved Rinvoq® (upadacitinib) for a new indication for the treatment of adults with giant cell arteritis (GCA).
- **April 2025:** The FDA approved an unbranded formulation of Steqeyma® (ustekinumab-stba) through an sBLA.
- **May 2025:** The FDA approved an unbranded formulation of Tyenne® (tocilizumab-aazg) through an sBLA.
- **May 2025:** The FDA approved Starjemza™ (ustekinumab-hmny) as a new biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **June 2025:** The FDA approved Riabni® (rituximab-arrx), Ruxience® (rituximab-pvvr), and Truxima® (rituximab-abbs) all for new indications for the treatment of moderate to severe pemphigus vulgaris (PV) in adults.
- **June 2025:** The FDA approved Benlysta® (belimumab) for a label expansion to allow use of the subcutaneous (sub-Q) autoinjector formulation in children 5 years of age and older with active lupus nephritis. Prior to this approval, only the IV formulation of Benlysta® was FDA approved for pediatric patients with this indication.
- **June 2025:** The FDA approved an unbranded formulation of Hadlima™ (adalimumab-bwwd) through an sBLA.
- **June 2025:** The FDA approved Gamifant® (emapalumab-lzsg) for a new indication for the treatment of adult and pediatric (newborn and older) patients with hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic juvenile idiopathic arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.
- **July 2025:** The FDA approved Otezla® (apremilast) for an age expansion for the treatment of active psoriatic arthritis down to 6 years of age in patients weighing at least 20kg. Previously, Otezla® was only approved for the treatment of adults with active psoriatic arthritis.
- **July 2025:** The FDA approved Avtozma® (tocilizumab-anoh) for new indication for the treatment of adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS).

- **August 2025:** The FDA approved Actemra® (tocilizumab) for an age expansion for the treatment of hospitalized pediatric patients 2 years of age and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). With this approval, Actemra® is currently the only tocilizumab product indicated for pediatric patients with this indication.
- **August 2025:** The FDA approved Otezla XR™ (apremilast ER), a new ER formulation of apremilast intended for once daily dosing. Otezla XR™ is indicated for the same indications as the immediate-release (IR) formulation, except Otezla XR™ is only indicated for use in patients who weigh at least 50kg, while the IR formulation may be used in patients weighing at least 20kg. Otezla XR™ will be available as a 75mg oral tablet. The recommended dosing for all indications requires titration utilizing the IR formulation; however, the ER formulation may be used for maintenance dosing following initial dose titration. Otezla XR™ has not yet been launched on the market, and cost information is not yet available.

Cost Comparison: Currently Available Sub-Q Ustekinumab Products

Product	Cost Per Syringe	Cost Per Year*
Stelara® (ustekinumab) 90mg/mL syr	$28,373.55	$170,241.30
Ustekinumab-ttwe 90mg/mL syr (unbranded Pyzchiva®)	$15,742.08	$94,452.48
Ustekinumab 90mg/mL syr (unbranded Stelara®)	$7,288.00	$43,728.00
Pyzchiva® (ustekinumab-ttwe) 90mg/mL syr	$4,176.43	$25,058.58
Selarsdi™ (ustekinumab-aekn) 90mg/mL syr	$4,176.43	$25,058.58
Steqeyma® (ustekinumab-stba) 90mg/mL syr	$4,176.43	$25,058.58
Ustekinumab-aekn 90mg/mL syr (unbranded Selarsdi™)	$4,176.43	$25,058.58
Otulfi® (ustekinumab-aauz) 90mg/mL syr	$3,619.57	$21,717.42
Yesintek™ (ustekinumab-kfce) 90mg/mL syr	$2,999.98	$17,999.88
Imuldosa® (ustekinumab-srlf) 90mg/mL syr	$2,332.12	$13,992.72
Starjemza™ (ustekinumab-hmny) 90mg/mL syr	$500.00	$3,000.00

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 year based on the FDA approved maintenance dose of 90mg every 8 weeks for an adult with Crohn's disease or ulcerative colitis.
syr = syringe

Recommendations

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

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

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
6-mercaptopurine	adalimumab (Humira®)⁺± **- Branded Only**	abatacept (Orencia®, Orencia® ClickJect™)¤	**adalimumab (Humira®)⁺± - Unbranded Only**

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

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

DMARDs = disease modifying anti-rheumatic drugs; **ER = extended-release;** NSAIDs = nonsteroidal anti-inflammatory drugs
*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to participate in supplemental rebates.
‡Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.
+Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.
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).
πUnique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS), and systemic sclerosis-associated interstitial lung disease (SSc-ILD).
¤Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.
#Unique criteria applies for **Rinvoq® LQ** or for a diagnosis of atopic dermatitis (AD) or **giant cell arteritis (GCA)**.
€Unique criteria applies for a diagnosis of alopecia areata.
§Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).
ΔUnique criteria applies for a diagnosis of hidradenitis suppurativa (HS).
**Unique criteria applies to this medication for approval.

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

1. For a diagnosis of hidradenitis suppurativa (HS) or uveitis, the member must meet the unique adalimumab approval criteria for those indications; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason why the member cannot use ~~Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry® (adalimumab-aqvh)~~ a preferred Tier-2 adalimumab product must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
4. Previous failure of at least 2 of the following categories:
   a. Topical or systemic antibiotics; or
   b. Oral or intralesional corticosteroids; or
   c. Dapsone; or
   d. Cyclosporine; or
   e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
   f. Finasteride; or
   g. Surgery; and
5. For Special Prior Authorization (PA) adalimumab products, a patient-specific, clinically significant reason why the member cannot use a preferred Tier-2 adalimumab product must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

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

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

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

1. For a diagnosis of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS), giant cell arteritis (GCA), or systemic sclerosis-associated interstitial lung disease (SSc-ILD), the member must meet the unique tocilizumab approval criteria for those indications; or
2. Member must meet Special Prior Authorization (PA) approval criteria; and
3. A patient-specific, clinically significant reason why the member cannot use branded Tyenne® (tocilizumab-aazg) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. An FDA approved diagnosis of CAR T cell-induced CRS; and
2. Requests for Actemra®, Avtozma®, or unbranded Tyenne® will require a patient-specific, clinically significant reason why the member cannot use branded Tyenne®. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. History of erythrocyte sedimentation rate (ESR) of ≥30mm/hr or a history of C-reactive protein (CRP) ≥1mg/dL; and
4. Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and
5. Must be taken in combination with a tapering course of corticosteroids upon initiation; and

6. Member must have baseline liver enzymes, absolute neutrophil count (ANC), lipid panel, and platelet count and verification that they are acceptable to prescriber; and
7. Member must not have severe hepatic impairment; and
8. Should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
9. Requests for Actemra®, Avtozma®, ~~or~~ Tofidence™, or unbranded Tyenne® will require a patient-specific, clinically significant reason why the member cannot use branded Tyenne®. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
10. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

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

1. Member must meet Tier-3 trial requirements; and
2. A patient-specific, clinically significant reason why the member cannot use Inflectra® (infliximab-dyyb) and unbranded Remicade® (infliximab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 3 abscesses or inflammatory nodules (can refer to current number or a historical number prior to biologic treatment); and
4. Previous failure of at least 2 of the following categories:
    a. Topical or systemic antibiotics; or
    b. Oral or intralesional corticosteroids; or
    c. Dapsone; or
    d. Cyclosporine; or
    e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
    f. Finasteride; or
    g. Surgery; and
5. Previous failure of a preferred Tier-2 adalimumab product for at least 12 weeks at recommended dosing (or documented intolerance); and

6. A patient-specific, clinically significant reason why the member cannot use Cosentyx® (secukinumab) must be provided.

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

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

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

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. ~~An FDA approved diagnosis of moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); and~~
3. ~~Member must be 18 years of age or older; and~~
4. ~~A minimum of a 4-week trial of a Tier-2 tumor necrosis factor (TNF) blocker medications indicated for the treatment of CD or UC that did not yield adequate relief of symptoms or resulted in intolerable adverse effects. Current Tier-2 medications include the following:~~
   ~~a. CD: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or~~
   ~~b. UC: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or~~
5. ~~Prior stabilization on the medication documented within the last 100 days; and~~
6. For Entyvio® sub-Q administration, member must have received at least 2 initial intravenous (IV) doses of Entyvio®; and
   a. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue to use the IV formulation must be provided; and

7. A quantity limit of ~~300mg every 8 weeks will apply for the IV formulation and~~ 108mg every 2 weeks will apply for the sub-Q formulation~~. Approvals will be granted for titration quantities required for initial dosing~~; and
8. Initial approvals will be for the duration of 14 weeks as Entyvio® should be discontinued in patients who do not show evidence of therapeutic benefit by week 14.

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

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

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

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

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

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

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

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use ~~Stelara® (ustekinumab)~~ Imuldosa® (ustekinumab-srlf), branded Pyzchiva® (ustekinumab-ttwe), branded Selarsdi™ (ustekinumab-aekn), Starjemza™ (ustekinumab-hmny), branded Steqeyma® (ustekinumab-stba), and Yesintek™ (ustekinumab-kfce) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
3. Additionally, initial and continuation requests for branded Stelara® will require a patient-specific, clinically significant reason why unbranded Stelara® cannot be used.

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

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

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

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

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

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

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Appendix G

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

Oklahoma Health Care Authority
November 2025

Current Prior Authorization Criteria

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; and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

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

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

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

1. Relapsed/refractory light chain amyloidosis as a single agent; or
2. Newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone.

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

1. Diagnosis of multiple myeloma; and
2. Used in 1 of the following settings:
    a. In combination with lenalidomide and dexamethasone as primary therapy in members who are ineligible for autologous stem cell transplant (ASCT) or in members who have received at least 1 prior therapy; or
    b. In combination with bortezomib, melphalan, and prednisone as primary therapy in members who are ineligible for ASCT; or

c. In combination with bortezomib, thalidomide, and dexamethasone or bortezomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for ASCT; or
d. After at least 1 prior therapy, in combination with 1 of the following:
    i. Dexamethasone and bortezomib; or
    ii. Carfilzomib and dexamethasone; or
    iii. Dexamethasone and lenalidomide; or
    iv. Cyclophosphamide, bortezomib, and dexamethasone; or
    v. Pomalidomide and dexamethasone* [*previous therapy for this combination must include lenalidomide and a proteasome inhibitor (PI)]; or
    vi. Selinexor and dexamethasone; or
e. In combination with lenalidomide and dexamethasone for members who are ineligible for ASCT or with cyclophosphamide, bortezomib, and dexamethasone as primary therapy or for disease relapse after 6 months following primary induction therapy with the same regimen; or
f. As a single-agent in members who have received ≥3 prior therapies, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.

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.

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 the maintenance treatment of disease.

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

1. Diagnosis of multiple myeloma; and
    a. Used in the first line setting; and
    b. Used in combination with bortezomib, lenalidomide, and dexamethasone; and
    c. Member is considered ineligible for autologous stem cell transplantation; or
2. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
    a. Used in 1 of the following settings:
        i. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
        ii. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

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

1. Diagnosis of relapsed or refractory multiple myeloma; and

2. 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.

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

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 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.

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.

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 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	3	6	$73,496.46	$12,249.41	$437.48	18	168
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
2024 Total	**3**	**6**	**$73,496.46**	**$12,249.41**	**$437.48**	**18**	**168**
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**
% Change	**0.00%**	**-50.00%**	**-64.00%**	**-28.10%**	**6.00%**	**-55.60%**	**-66.10%**
Change	**0**	**-3**	**-$47,072.77**	**-$3,441.51**	**$26.09**	**-10**	**-111**

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

Comparison of Fiscal Years: Medical Claims (All Plans)

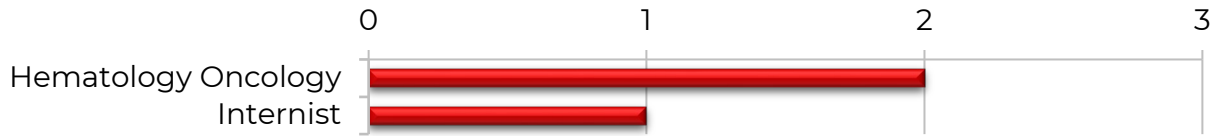
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	60	1,207	$2,062,511.52	$1,708.79	20.12
Aetna	2	14	$712.37	$50.88	7
Humana	3	18	$18,181.05	$1,010.06	6
OCH	5	49	$45,960.75	$937.97	9.8
2024 Total	**60**	**1,288**	**$2,127,365.69**	**$1,651.68**	**21.47**
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**
% Change	**-5.00%**	**-17.86%**	**61.82%**	**97.00%**	**-13.55%**
Change	**-3**	**-230**	**$1,315,158.61**	**$1,602.12**	**-2.91**

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

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

- Due to the limited number of members utilizing multiple myeloma medications during fiscal year 2025, detailed demographic information could not be provided.

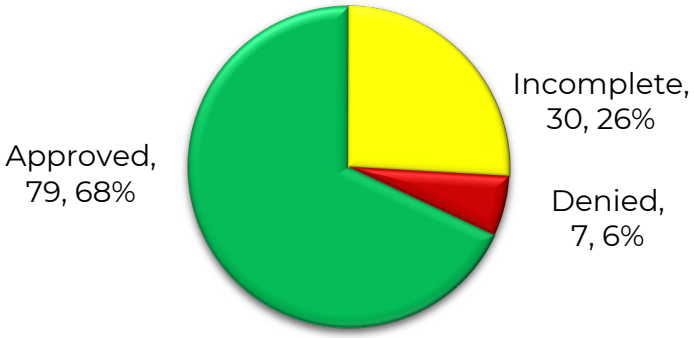
Top Prescriber Specialties of Multiple Myeloma Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Multiple Myeloma Medications

There were 116 prior authorization requests submitted for multiple myeloma medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	60	74%	21	26%	0	0%	**81**
Aetna	0	0%	1	50%	1	50%	**2**
Humana	7	78%	0	0%	2	22%	**9**
OCH	12	50%	8	33%	4	17%	**24**
Total	**79**	**68%**	**30**	**26%**	**7**	**6%**	**116**

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

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

Anticipated Patent Expiration(s):

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

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

- **August 2024:** The FDA approved Boruzu® (bortezomib) for the treatment of adult patients with multiple myeloma or mantle cell lymphoma. Boruzu® is a new formulation of bortezomib that does not have to be reconstituted. It is available as a 3.5mg/1.4mL solution in a single-dose vial (SDV). Boruzu® is approved for the same indications as Velcade® (bortezomib), which is available as generic formulations from several manufacturers.
- **June 2025:** The FDA announced the removal of the Risk Evaluation and Mitigation Strategies (REMS) programs for all currently approved Bispecific B-cell maturation antigen (BCMA)- and CD19-directed autologous chimeric antigen receptor (CAR) T-cell immunotherapies, including Abecma® (idecabtagene vicleucel) and Carvykti® (ciltacabtagene autoleucel). The FDA determined that the REMS were no longer necessary to ensure that the benefits of these therapies

outweigh their risks and to minimize the burden on the health care delivery system.

- **July 2025:** The FDA approved Lynozyfic™ (linvoseltamab-gcpt) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- **October 2025:** The FDA added a new *Boxed Warning* for Carvykti® (ciltacabtagene autoleucel) regarding the risk of immune effector cell-associated enterocolitis (IEC-EC), including fatal or life-threatening reactions, which have occurred following treatment with Carvykti®. The FDA determined that the overall benefits of Carvykti® continue to outweigh the potential risks, including an overall survival benefit in patients treated with Carvykti® for its approved use.
- **October 2025:** The FDA approved Blenrep (belantamab mafodotin-blmf), in combination with bortezomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 2 prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent. Blenrep was previously granted accelerated approval by the FDA in 2020 as a single agent for the treatment of relapsed or refractory multiple myeloma in patients who had received at least 4 prior lines of therapy; however, that indication was withdrawn by the FDA in 2023 because the confirmatory trial did not meet its primary endpoint to demonstrate superior progression-free survival.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for multiple myeloma allow for the use of:
    - Darzalex® (daratumumab) and Darzalex Faspro® (daratumumab/hyaluronidase-fihj) in relapsed/refractory light chain amyloidosis:
        - In combination with lenalidomide and dexamethasone; or
        - In combination with venetoclax for patients with t(11;14) translocation
    - Darzalex® and Darzalex Faspro® in smoldering myeloma diagnosis as a single agent
    - Darzalex® and Darzalex Faspro® in multiple myeloma:
        - In combination with carfilzomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for autologous stem cell transplant (ASCT); or
        - In combination with venetoclax and dexamethasone for patients with t(11:14) translocation; or

        - As maintenance therapy as a single agent or in combination with lenalidomide for stable or responsive disease after primary therapy or hematopoietic stem cell transplant (HSCT)
    - Ninlaro® (ixazomib) in symptomatic multiple myeloma and as a single agent for maintenance therapy following response to primary myeloma therapy in transplant candidates or following HSCT
    - Sarclisa® (isatuximab-irfc) as primary therapy in combination with carfilzomib, lenalidomide, and dexamethasone for transplant eligible patients or in combination with lenalidomide and dexamethasone for transplant deferred or in patients when transplant is not indicated
    - Talvey® (talquetamab-tgvs) in combination with Tecvayli® (teclistamab-cgyv) in patients who have received at least 3 prior lines of therapy
    - Xpovio® (selinexor) in combination with daratumumab and dexamethasone in patients who have failed at least 1 prior therapy

Lynozyfic™ (Linvoseltamab-gcpt) Product Summary[9]

Therapeutic Class: BCMA-directed CD3 T-cell engager

Indication(s):

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

How Supplied:

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

Dosing and Administration:

- Lynozyfic™ should be administered intravenously (IV) according to the step-up schedule to reduce the incidence and severity of cytokine release syndrome (CRS).
- Patients should be hospitalized for 24 hours after administration of the first and second step-up doses.
- The recommended dosage includes:
    - Step-Up Dosing: 5mg on day 1 + 25mg on day 8 + 200mg on day 15
    - Weekly Dosing: 200mg weekly from week 4 to week 13 for 10 doses

- Biweekly Dosing: 200mg at week 14 and every 2 weeks thereafter
- Every 4 Week Dosing: 200mg every 4 weeks for patients who achieved and maintained a very good partial response (VGPR) or better at or after week 24 and received at least 17 doses of 200mg

- Dosing should be continued until disease progression or unacceptable toxicity.

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

Cost Comparison: Bortezomib Products

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

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

Recommendations

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

Boruzu® (Bortezomib) Approval Criteria:

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

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

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; and
3. Member must be 18 years of age or older; and

4. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

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

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

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

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

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

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥2 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or

iv. Bone marrow plasma cells >30% of total bone marrow cells; and

c. Member must not have any central nervous system involvement with multiple myeloma.

2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

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

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

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

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

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

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

~~1. Diagnosis of multiple myeloma; and~~
~~2. Used in 1 of the following settings:~~
   ~~a. In combination with lenalidomide and dexamethasone as primary therapy in members who are ineligible for autologous stem cell transplant (ASCT) or in members who have received at least 1 prior therapy; or~~
   ~~b. In combination with bortezomib, melphalan, and prednisone as primary therapy in members who are ineligible for ASCT; or~~
   ~~c. In combination with bortezomib, thalidomide, and dexamethasone or bortezomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for ASCT; or~~
   ~~d. After at least 1 prior therapy, in combination with 1 of the following:~~
      ~~i. Dexamethasone and bortezomib; or~~
      ~~ii. Carfilzomib and dexamethasone; or~~
      ~~iii. Dexamethasone and lenalidomide; or~~
      ~~iv. Cyclophosphamide, bortezomib, and dexamethasone; or~~
      ~~v. Pomalidomide and dexamethasone* [*previous therapy for this combination must include lenalidomide and a proteasome inhibitor (PI)]; or~~
      ~~vi. Selinexor and dexamethasone; or~~
   ~~e. In combination with lenalidomide and dexamethasone for members who are ineligible for ASCT or with cyclophosphamide, bortezomib, and dexamethasone as primary therapy or for disease relapse after 6 months following primary induction therapy with the same regimen; or~~
   ~~f. As a single agent in members who have received ≥3 prior therapies, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.~~

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

1. Diagnosis of multiple myeloma; and
2. Used in 1 of the following settings:

a. As primary therapy in members who are ineligible for autologous stem cell transplant (ASCT) and used in combination with:
    i. Lenalidomide and dexamethasone; or
    ii. Bortezomib, melphalan, and prednisone; or
b. As primary therapy in members who are eligible for ASCT and used in combination with:
    i. Bortezomib and thalidomide or lenalidomide and dexamethasone; or
    ii. Carfilzomib, lenalidomide, and dexamethasone; or
c. As maintenance therapy for response or stable disease following hematopoietic stem cell transplant (HCT) or primary myeloma therapy; and
    i. Used as a single agent; or
    ii. Used in combination with lenalidomide; or
d. For disease relapse after 6 months following primary induction therapy with the same regimen and used in combination with:
    i. Lenalidomide and dexamethasone; or
    ii. Cyclophosphamide, bortezomib, and dexamethasone; or
e. After at least 1 prior therapy, in combination with 1 of the following:
    i. Bortezomib and dexamethasone; or
    ii. Carfilzomib and dexamethasone; or
    iii. Lenalidomide and dexamethasone; or
    iv. Pomalidomide and dexamethasone (if previous therapy for this combination included lenalidomide and a proteasome inhibitor); or
    v. Cyclophosphamide, bortezomib, and dexamethasone; or
    vi. Selinexor and dexamethasone; or
    vii. Venetoclax and dexamethasone for patients with t(11:14) translocation; or
f. Used as a single-agent in members who have received ≥3 prior therapies, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.

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

1. Diagnosis of symptomatic multiple myeloma; and
2. Used in 1 of the following settings:
    a. As primary therapy; or
    b. Following disease relapse after 6 months following primary induction therapy with the same regimen, used in combination with 1 of the following regimens:
        i. Lenalidomide and dexamethasone; or
        ii. Cyclophosphamide and dexamethasone for transplant candidates only; or

iii. Pomalidomide and dexamethasone if member has failed ≥2 prior therapies and demonstrated disease progression within 60 days; or

c. As a single agent for maintenance therapy following response to primary myeloma therapy in transplant candidates or following hematopoietic stem cell transplant.

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

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

1. Diagnosis of multiple myeloma; and
   a. ~~Used in the first line setting~~ As primary therapy; and
      i. Used in combination with bortezomib, lenalidomide, and dexamethasone; ~~and~~ or
      ii. Used in combination with carfilzomib, lenalidomide, and dexamethasone for transplant eligible members; or
      iii. Used in combination with lenalidomide and dexamethasone for transplant-deferred or when transplant is not indicated; or
   ~~b. Member is considered ineligible for autologous stem cell transplantation; or~~
2. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
   a. Used in 1 of the following settings:
      i. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
      ii. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

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

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

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

1. Diagnosis of relapsed or refractory multiple myeloma; and

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

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

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

Utilization Details of Multiple Myeloma Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IXAZOMIB PRODUCTS						
NINLARO CAP 4MG	2	2	$26,357.32	$13,178.66	1	99.75%
DEXAMETHASONE PRODUCTS						
HEMADY TAB 20MG	1	1	$66.37	$66.37	1	0.25%
TOTAL	**3**	**3***	**$26,423.69**	**$8,807.90**	**1**	**100%**

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

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9041 BORTEZOMIB INJ	646	34	$25,372.42	$39.28	19
J9144 DARATUM/HYALURON INJ	288	42	$2,575,182.74	$8,941.61	6.86
J9145 DARATUMUMAB INJ	63	4	$341,990.26	$5,428.42	15.75
J9380 TECLISTAMAB-CQYV INJ	51	2	$475,606.68	$9,325.62	25.5
J9176 ELOTUZUMAB INJ	7	1	$11,595.00	$1,656.43	7
J3055 TALQUETAMAB-TGVS INJ	2	1	$11,200.00	$5,600.00	2
J9227 ISATUXIMAB-IRFC INJ	1	1	$1,577.20	$1,577.20	1
TOTAL	**1,058**	**57**	**$3,442,524.30**	**$3,253.80**	**18.56**

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 2025 = 07/01/2024 to 06/30/2025

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[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 10/2025. Last accessed 10/14/2025.
[2] Amneal Pharmaceuticals, Inc. and Shilpa Medicare Limited. Amneal and Shilpa Announce U.S. FDA Approval of Boruzu®, the First Ready-to-Use Version of Bortezomib for Subcutaneous Administration. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-and-Shilpa-Announce-U.S.-FDA-Approval-of-BORUZU-the-First-Ready-to-Use-Version-of-Bortezomib-for-subcutaneous-administration/default.aspx. Issued 09/05/2024. Last accessed 10/14/2025.
[3] U.S. FDA. FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor (CAR) T cell Immunotherapies. Available online at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor. Issued 06/26/2025. Last accessed 10/14/2025.
[4] U.S. FDA. FDA Grants Accelerated Approval to Linvoseltamab-gcpt for Relapsed or Refractory Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-linvoseltamab-gcpt-relapsed-or-refractory-multiple-myeloma. Issued 07/02/2025. Last accessed 10/14/2025.
[5] U.S. FDA. FDA Approves Labeling Changes that Include a Boxed Warning for Immune Effector Cell-Associated Enterocolitis Following Treatment with Ciltacabtagene Autoleucel (Carvykti®, Janssen Biotech, Inc.). Available online at: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-labeling-changes-include-boxed-warning-immune-effector-cell-associated-enterocolitis. Issued 10/10/2025. Last accessed 10/14/2025.
[6] U.S. FDA. FDA Approves Belantamab Mafodotin-blmf for Relapsed or Refractory Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-belantamab-mafodotin-blmf-relapsed-or-refractory-multiple-myeloma. Issued 10/23/2025. Last accessed 10/28/2025.
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[8] National Comprehensive Cancer Network (NCCN). Multiple Myeloma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Last revised 07/16/2025. Last accessed 10/28/2025
[9] Lynozyfic™ (Linvoseltamab-gcpt) Prescribing Information. Regeneron Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761400s000lbl.pdf. Last revised 07/2025. Last accessed 10/14/2025.

Appendix H

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

Oklahoma Health Care Authority
November 2025

Current Prior Authorization Criteria

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax®)	alendronate + vitamin D tabs (Fosamax® + D)	abaloparatide inj (Tymlos®)
calcium + vitamin D†	risedronate tabs (Actonel®)	alendronate effervescent tabs (Binosto®)
ibandronate tabs (Boniva®)		alendronate soln (Fosamax®)
zoledronic acid inj (Reclast®)		denosumab inj (Prolia®)
		denosumab-bbdz inj (Jubbonti®)
		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.

Boniva® [Ibandronate Intravenous (IV) Solution], Jubbonti® (Denosumab-bbdz), and Prolia® (Denosumab) 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 Jubbonti®, a patient-specific, clinically significant reason why the member cannot use Prolia® (denosumab) 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.

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.

Wyost® (Denosumab-bbdz) and Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or
   b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
      i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or
   c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
      i. Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of Xgeva® therapy; and
2. For Wyost® (denosumab-bbdz), a patient-specific, clinically significant reason why the member cannot use Xgeva® (denosumab) 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.

Utilization of Bone Density Regulators: Fiscal Year 2025

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 2024							
FFS	977	2,695	$441,917.16	$163.98	$2.76	30,065	160,167
Aetna	61	72	$9,665.97	$134.25	$2.04	736	4,738
Humana	93	172	$16,749.21	$97.38	$2.91	737	5,746
OCH	56	89	$26,883.46	$302.06	$8.87	410	3,030
2024 Total	**1,032**	**3,028**	**$495,215.80**	**$163.55**	**$2.85**	**31,948**	**173,681**
Fiscal Year 2025							
FFS	621	1,792	$269,820.21	$150.57	$2.63	18,431	102,659
Aetna	143	425	$40,495.40	$95.28	$1.76	3,463	23,035
Humana	207	732	$130,194.38	$177.86	$3.67	5,377	35,446
OCH	155	449	$62,856.58	$139.99	$2.93	3,875	21,472
2025 Total	**1,046**	**3,398**	**$503,366.57**	**$148.14**	**$2.76**	**31,145**	**182,612**
% Change	**1.40%**	**12.20%**	**1.60%**	**-9.40%**	**-3.20%**	**-2.50%**	**5.10%**
Change	**14**	**370**	**$8,150.77**	**-$15.41**	**-$0.09**	**-803**	**8,931**

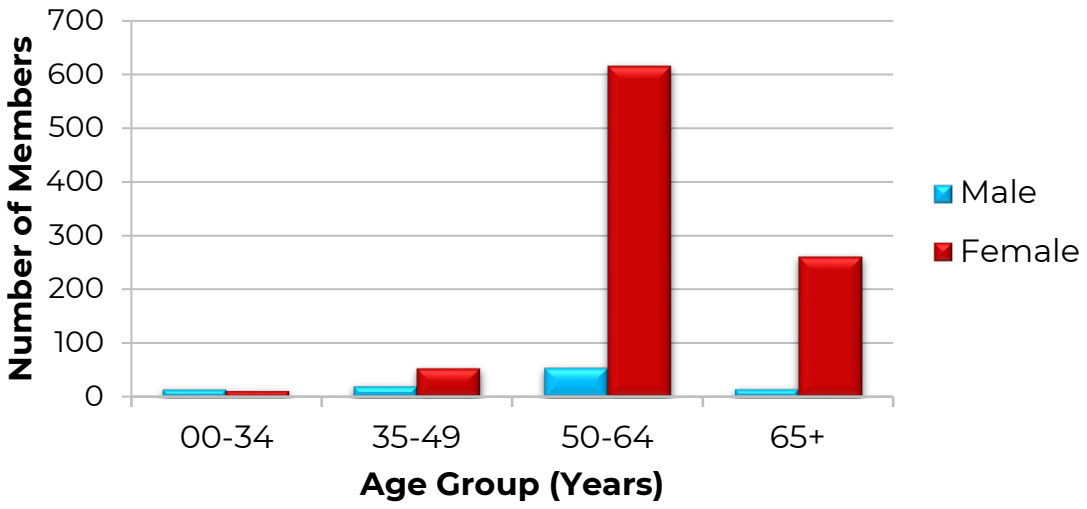
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective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

Comparison of Fiscal Years: Bone Density Regulators: Medical Claims (All Plans)

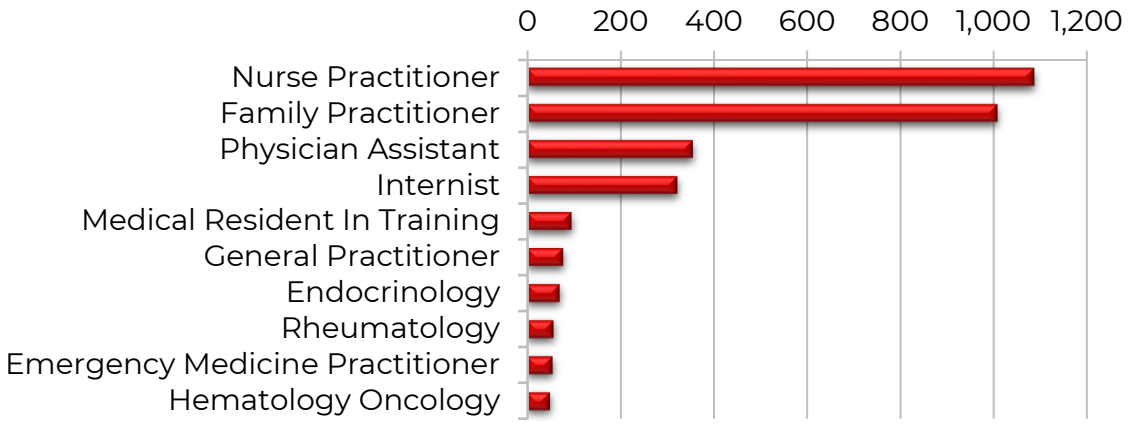
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	386	843	$1,084,578.31	$1,286.57	2.18
Aetna	4	4	$6,073.96	$1,518.49	1.00
Humana	3	3	$3,080.60	$1,026.87	1.00
OCH	13	14	$11,558.75	$825.63	1.08
2024 Total	**406**	**864**	**$1,105,291.62**	**$1,279.27**	**2.13**
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**
% Change	**-1.72%**	**-4.63%**	**-0.04%**	**4.81%**	**-2.96%**
Change	**-7**	**-40**	**-$456.42**	**$61.55**	**-0.06**

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

Demographics of Members Utilizing Bone Density Regulators: Pharmacy Claims (All Plans)



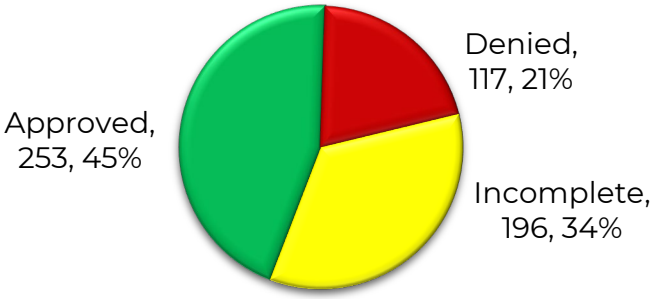
Top Prescriber Specialties of Bone Density Regulators by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Bone Density Regulators

There were 566 prior authorization requests submitted for bone density regulators during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	188	43%	178	41%	73	17%	**439**
Aetna	10	50%	8	40%	2	10%	**20**
Humana	29	62%	0	0%	18	38%	**47**
OCH	26	43%	10	17%	24	40%	**60**
Total	**253**	**45%**	**196**	**34%**	**117**	**21%**	**566**

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

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

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):

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

Pipeline:

- **AVT03:** Alvotech and Dr. Reddy's announced the FDA accepted their biologic license application (BLA) for review of AVT03, a biosimilar to Prolia® and Xgeva®, for all currently approved indications of the reference products. The anticipated date of the FDA's decision has not been announced.
- **MB09:** Amneal and mAbxience have submitted a BLA to the FDA requesting approval of MB09 as a biosimilar to the reference products Prolia® and Xgeva® for all currently approved indications. A decision is expected before the end of 2025.
- **TVB-099P:** Teva Pharmaceutical Industries announced that the FDA accepted their BLA for a Prolia® biosimilar, TVB-099P. The BLA requests approval for interchangeability and for the same indications as the reference product. Teva Pharmaceutical Industries is expecting a decision from the FDA in the second half of 2025.

Recommendations

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

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

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

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

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

1. A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or
2. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and

3. For Bildyos®, Conexxence®, ~~Jubbonti®,~~ and Stoboclo® a patient-specific, clinically significant reason why the member cannot use Jubbonti® or Prolia® must be provided.
    a. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

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

1. An FDA approved indication of 1 of the following:
    a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or
    b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
        i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or
    c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
        i. Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of ~~Xgeva®~~ therapy; and
2. For Bilprevda®, Bomyntra®, and Osenvelt® ~~Wyost® (denosumab-bbdz),~~ a patient-specific, clinically significant reason why the member cannot use Wyost® or Xgeva® must be provided.
    a. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.
3. These products will be covered as a medical benefit only.

Utilization Details of Bone Density Regulators: Fiscal Year 2025

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	2,656	826	$40,145.76	$15.12	3.22	7.98%
ALENDRONATE TAB 35MG	131	38	$1,684.94	$12.86	3.45	0.33%
ALENDRONATE TAB 10MG	92	37	$1,533.86	$16.67	2.49	0.30%
SUBTOTAL	**2,879**	**901**	**$43,364.56**	**$15.06**	**3.2**	**8.61%**
IBANDRONATE PRODUCTS						
IBANDRONATE TAB 150MG	307	94	$6,508.14	$21.20	3.27	1.29%
SUBTOTAL	**307**	**94**	**$6,508.14**	**$21.20**	**3.27**	**1.29%**
ZOLEDRONIC ACID PRODUCTS						
ZOLEDRONIC INJ 5MG/100ML	2	2	$92.56	$46.28	1	0.02%
SUBTOTAL	**2**	**2**	**$92.56**	**$46.28**	**1**	**0.02%**
TIER-1 SUBTOTAL	**3,188**	**997**	**$49,965.26**	**$15.67**	**3.2**	**9.93%**
TIER-2 PRODUCTS						
RISEDRONATE PRODUCTS						
RISEDRONATE TAB 35MG	7	1	$320.28	$45.75	7	0.06%
RISEDRONATE TAB 5MG	4	1	$58.40	$14.60	4	0.01%
TIER-2 SUBTOTAL	**11**	**2**	**$378.68**	**$34.43**	**5.5**	**0.07%**
SPECIAL PA PRODUCTS						
TERIPARATIDE PRODUCTS						
TERIPARATIDE INJ 600MCG/2.4ML	74	15	$136,763.69	$1,848.16	4.93	27.17%
FORTEO INJ 600MCG/2.4ML	43	15	$178,669.67	$4,155.11	2.87	35.49%
SUBTOTAL	**117**	**30**	**$315,433.36**	**$2,696.01**	**3.9**	**62.66%**
DENOSUMAB PRODUCTS						
PROLIA INJ 60MG/ML	49	36	$80,639.11	$1,645.70	1.36	16.02%
SUBTOTAL	**49**	**36**	**$80,639.11**	**$1,645.70**	**1.36**	**16.02%**
ROMOSOZUMAB PRODUCTS						
EVENITY INJ 105MG	17	4	$44,245.71	$2,602.69	4.25	8.79%
SUBTOTAL	**17**	**4**	**$44,245.71**	**$2,602.69**	**4.25**	**8.79%**
ALENDRONATE PRODUCTS						
ALENDRONATE SOL 70MG/75ML	12	2	$2,231.43	$185.95	6	0.44%
SUBTOTAL	**12**	**2**	**$2,231.43**	**$185.95**	**6**	**0.44%**
ABALOPARATIDE PRODUCTS						
TYMLOS INJ 3,120MCG/1.56ML	4	3	$10,473.02	$2,618.26	1.33	2.08%
SUBTOTAL	**4**	**3**	**$10,473.02**	**$2,618.26**	**1.33**	**2.08%**
SPECIAL PA SUBTOTAL	**199**	**75**	**$453,022.63**	**$2,276.50**	**2.65**	**90.00%**
TOTAL	**3,398**	**1,046***	**$503,366.57**	**$148.14**	**3.25**	**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 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZOLEDRONIC ACID (J3489)	399	206	$8,961.11	$22.46	1.94
PROLIA/XGEVA (J0897)	368	160	$966,776.55	$2,627.11	2.3
EVENITY (J3111)	57	19	$129,097.54	$2,264.87	3
TOTAL	**824**	**385**	**$1,104,835.20**	**$1,340.82**	**2.14**

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

[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 10/2025. Last accessed 10/28/2025.
[2] Celltrion. Celltrion Receives U.S. FDA Approval for Stoboclo® (Denosumab-bmwo) and Osenvelt® (Denosumab-bmwo) Biosimilars Referencing Prolia® and Xgeva®. Available online at: https://www.celltrion.com/en-us/company/media-center/press-release/3768. Issued 03/04/2025. Last accessed 10/28/2025.
[3] Fresenius Kabi. Fresenius Kabi Receives FDA Approval for Their Denosumab Biosimilars and Secures Global Settlement Agreement. Available online at: https://www.fresenius-kabi.com/us/news-and-events/fda-approval-denosumab-and-secures-global-settlement-agreement. Issued 03/27/2025. Last accessed 10/28/2025.
[4] Henlius. U.S. Food and Drug Administration (FDA) Approves Henlius and Organon's Bildyos® (Denosumab-nxxp) and Bilprevda® (Denosumab-nxxp), Biosimilars to Prolia® (Denosumab) and Xgeva® (Denosumab), Respectively. *PRNewswire.* Available online: https://www.prnewswire.com/apac/news-releases/us-food-and-drug-administration-fda-approves-henlius-and-organons-bildyos-denosumab-nxxp-and-bilprevda-denosumab-nxxp-biosimilars-to-prolia-denosumab-and-xgeva-denosumab-respectively-302543830.html. Issued 09/02/2025. Last accessed 10/28/2025.
[5] Prime Therapeutics. FDA Decisions Expected October 2025. Available online at: https://www.primetherapeutics.com/fda-decisions-expected-october-2025. Issued 09/17/2025. Last accessed 10/28/2025.
[6] Alvotech. Alvotech and Dr. Reddy's Announce FDA Acceptance of Biologic License Application for AVT03, a Proposed Biosimilar to Prolia® and Xgeva®. Available online at: https://investors.alvotech.com/news-releases/news-release-details/alvotech-and-dr-reddys-announce-fda-acceptance-biologic-license. Issued 03/18/2025. Last accessed 10/28/2025.
[7] Teva Investor Relations. Teva Prolia® (Denosumab) Biosimilar Candidate is Accepted for Review by U.S. FDA and EU EMA. Available online at: https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2024/Teva-Prolia-Denosumab-Biosimilar-Candidate-is-Accepted-for-Reviewby-U.S.-FDA-and-EU-EMA/default.aspx. Issued 10/08/2024. Last accessed 10/28/2025.

Appendix I

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

Oklahoma Health Care Authority
November 2025

Introduction[1,2,3,4]

Barth syndrome is a rare genetic condition caused by pathogenic mutations in the *TAFAZZIN* gene, which encodes a protein, tafazzin, that is located on the inner mitochondrial membrane in cells. Tafazzin plays an important role in the production of mature cardiolipin in cells. Cardiolipin is involved in maintaining mitochondrial shape, energy production, and protein transport within cells. Patients with Barth syndrome have decreased levels of functional cardiolipin in a variety of tissues. Because of this, high energy-requiring tissues, such as cardiac and skeletal muscle, are susceptible to reduced energy production and apoptosis. Barth syndrome is an X-linked disorder and primarily affects males. Estimates of the incidence and prevalence of Barth syndrome vary. In the United States, the incidence is estimated to be 1 in 300,000 to 1 in 400,000 people. The overall prevalence has been estimated to be approximately 1 in 1,000,000 male births, and 230-250 males with Barth syndrome had been identified worldwide as of 2020.

Signs and symptoms of Barth syndrome can include cardiomyopathy, neutropenia, skeletal myopathy, and growth delay, but the presentation can vary from patient to patient. Cardiovascular (CV) complications, such as dilated cardiomyopathy, hypertrophic cardiomyopathy, endocardial fibroelastosis, and left ventricular noncompaction, are typically present before 5 years of age. These CV issues are a significant cause of morbidity and mortality in patients. Skeletal myopathy and hypotonia in the hands and feet can lead to delays in the development of gross motor skills. Neutropenia can lead to mouth ulcers, pneumonia, or sepsis.

Historically, treatment options for patients with Barth syndrome have been limited to the management of specific clinical manifestations, such as the use of medications for treating heart failure, cardiac arrhythmias, or neutropenia. Additionally, physical therapy methods could be used to assist in the development of motor milestones. In September 2025, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Forzinity™ (elamipretide) to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30kg.

Forzinity™ (Elamipretide) Product Summary[5,6,7]

Therapeutic Class: Mitochondrial cardiolipin binder

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

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

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

Dosing and Administration:

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

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

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

strength was 124 newtons. At week 168, the median muscle strength had increased by 63 newtons.

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

Recommendations

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

Forzinity™ (Elamipretide) Approval Criteria:

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

[1] Ferreira C, Pierre G, Thompson R, and Vernon H. Barth Syndrome. *GeneReviews*®. Available online at: https://www.ncbi.nlm.nih.gov/books/NBK247162/. Last revised 07/09/2020. Last accessed 10/20/2025.
[2] National Organization for Rare Disorders (NORD). Barth Syndrome. Available online at: https://rarediseases.org/rare-diseases/barth-syndrome/. Last revised 09/22/2025. Last accessed 10/20/2025.
[3] Genetic and Rare Diseases Information Center (GARD). Barth Syndrome. Available online at: https://rarediseases.info.nih.gov/diseases/5890/index. Last revised 09/2025. Last accessed 10/20/2025.
[4] Stealth BioTherapeutics, Inc. Stealth BioTherapeutics Announces FDA Accelerated Approval of Forzinity™ (Elamipretide) Injection, the First Therapy for Progressive and Life-Limiting Ultra-Rare Genetic Disease Barth Syndrome. Available online at: https://stealthbt.com/stealth-biotherapeutics-announces-fda-accelerated-approval-of-forzinity-elamipretide-hcl-the-first-therapy-for-progressive-and-life-limiting-ultra-rare-genetic-disease-barth-syndrome/. Issued 09/19/2025. Last accessed 10/20/2025.
[5] Forzinity™ (Elamipretide) Prescribing Information. Stealth BioTherapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf. Last revised 09/2025. Last accessed 10/17/2025.
[6] Thompson WR, Hornby B, Manuel R, et al. A Phase 2/3 Randomized Clinical Trial Followed by an Open-Label Extension to Evaluate the Effectiveness of Elamipretide in Barth Syndrome, a Genetic Disorder of Mitochondrial Cardiolipin Metabolism. *Genet Med* 2021; 23(3):471-478. doi: 10.1038/s41436-020-01006-8.
[7] Thompson WR, Manual R, Abbruscato A, et al. Long-Term Efficacy and Safety of Elamipretide in Patients with Barth Syndrome: 168-Week Open-Label Extension Results of TAZPOWER. *Genet Med* 2024; 26(7):101138. doi: 10.1016/j.gim.2024.101138.

Appendix J

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

Oklahoma Health Care Authority
November 2025

Current Prior Authorization Criteria

Javygtor™ (Sapropterin) and Kuvan® (Sapropterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria (PKU); and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Member must not have 2 null mutations in *trans*; and
4. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
5. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Use of Javygtor™ (sapropterin) will require a patient specific, clinically significant reason why other generic formulations of sapropterin cannot be used; and
7. Initial approvals will be for the duration of 30 days. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
    a. If the member was initiated at 10mg/kg/day dose, then a subsequent trial of 20mg/kg/day for a duration of 30 days can be approved, after which time the prescriber must verify the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; or
    b. If the member was initiated at 20mg/kg/day dose, then no additional approvals will be granted after a trial period of 30 days if the member did not respond to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and

b. Verification from the prescriber of continued response to therapy.

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved indication to reduce blood phenylalanine concentrations in members with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations >600micromol/L on existing management; and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Concomitant use with Kuvan® (sapropterin) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
5. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
7. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
8. Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Members should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L. Slower dose titrations may be approved based on member's response and tolerability; and
    a. If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; and
    b. If after at least 16 weeks with the 40mg dose, member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 60mg once daily dosing for an additional 16 weeks of treatment; or
    c. If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, subsequent approvals will be for the duration of 1 year; and

9. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L after at least 16 weeks of continuous treatment with the maximum dosage of 60mg once daily will not be approved for subsequent approvals; and
10. Subsequent approvals will be for the duration of 1 year; and
11. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

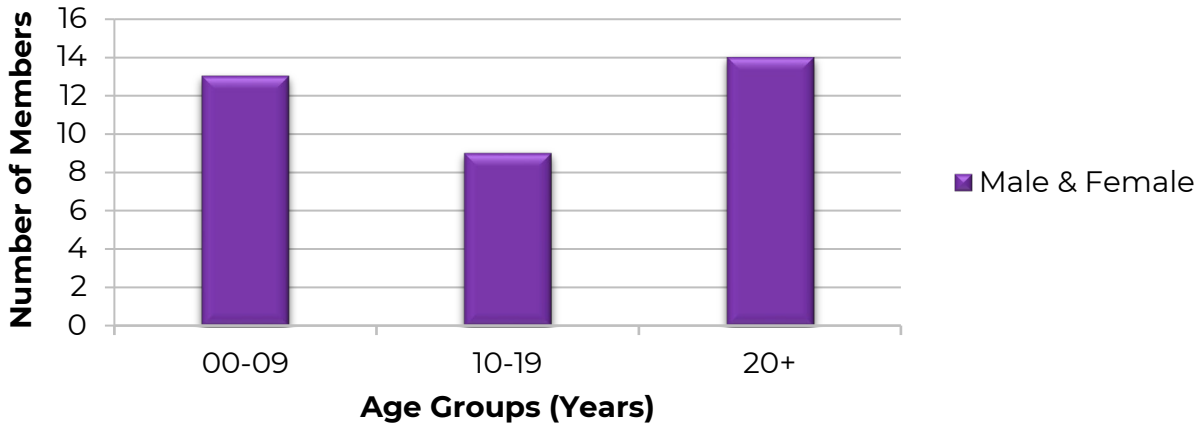
Utilization of Amino Acid Disorder Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

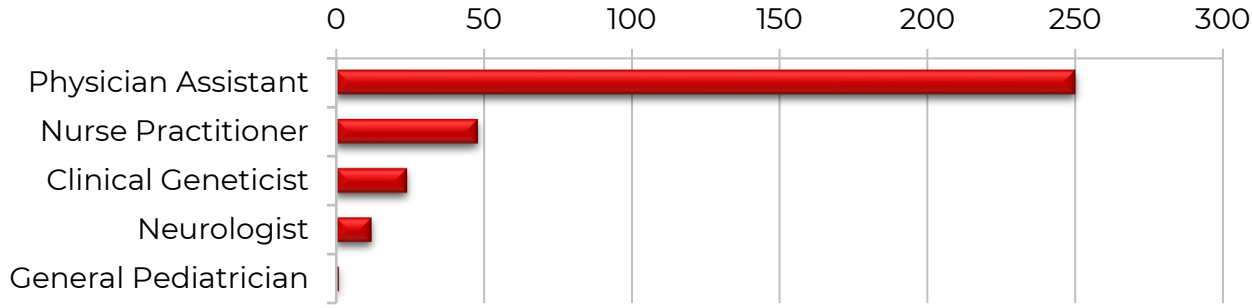
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	35	287	$3,693,037.03	$12,867.72	$442.17	51,064	8,352
Aetna	6	11	$298,745.51	$27,158.68	$969.95	1,302	308
Humana	7	22	$139,181.02	$6,326.41	$212.82	2,814	654
OCH	3	8	$79,471.28	$9,933.91	$331.13	315	240
2024 Total	**35**	**328**	**$4,210,434.84**	**$12,836.69**	**$440.70**	**55,495**	**9,554**
Fiscal Year 2025							
FFS	12	141	$1,875,587.30	$13,302.04	$454.80	14,421	4,124
Aetna	8	71	$1,339,050.11	$18,859.86	$628.66	6,210	2,130
Humana	10	63	$587,949.83	$9,332.54	$325.73	8,817	1,805
OCH	8	60	$539,738.60	$8,995.64	$307.37	3,878	1,756
2025 Total	**36**	**335**	**$4,342,325.84**	**$12,962.17**	**$442.42**	**33,326**	**9,815**
% Change	**2.90%**	**2.10%**	**3.10%**	**1.00%**	**0.40%**	**-39.90%**	**2.70%**
Change	**1**	**7**	**$131,891.00**	**$125.48**	**$1.72**	**-22,169**	**261**

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

Demographics of Members Utilizing Amino Acid Disorder Medications: Pharmacy Claims (All Plans)



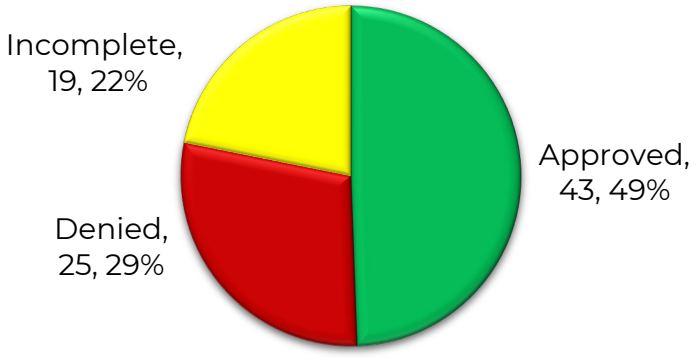
Top Prescriber Specialties of Amino Acid Disorder Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Amino Acid Disorder Medications

There were 87 prior authorization requests submitted for amino acid disorder medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	22	49%	18	40%	5	11%	**45**
Aetna	5	83%	0	0%	1	17%	**6**
Humana	7	58%	0	0%	5	42%	**12**
OCH	9	38%	1	4%	14	58%	**24**
Total	**43**	**49%**	**19**	**22%**	**25**	**29%**	**87**

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

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

Anticipated Patent Expiration(s):

- Nityr® (nitisinone): January 2035
- Sephience™ (sepiapterin): March 2042

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

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

Guideline Update(s):

- **January 2025:** Updated guidelines for the diagnosis and management of phenylalanine hydroxylase (PAH) deficiency (also known as PKU and HPA) were published by the American College of Medical Genetics and Genomics (ACMG). Some of the key recommendations included:
  - Treatment for PAH deficiency should be lifelong for individuals with untreated phenylalanine levels >360micromol/L.

- Blood phenylalanine should be maintained to ≤360micromol/L for life in individuals with PAH deficiency because it is associated with higher IQ levels.
- Achieving phenylalanine levels ≤360micromol/L before conception is strongly recommended to prevent pregnancy complications and negative outcomes for the offspring.
- Genetic testing for *PAH* variants is recommended at birth to confirm diagnosis and guide therapy.
- Treatment success should not only be measured by blood phenylalanine levels but also by the ability of individuals with a PAH deficiency to consume more natural protein and improve clinical symptoms.

Pipeline:

- **Palynziq® (Pegvaliase-pqpz):** In April 2025, BioMarin, the manufacturer of Palynziq® announced the results of the Phase 3 PEGASUS trial evaluating Palynziq® in adolescents 12 to 17 years of age with PKU. The results demonstrated a statistically significant lowering of blood phenylalanine levels in this age group compared to diet alone. The safety results were consistent with the known safety profile for this medication. Palynziq® is currently approved for adults 18 years of age and older. BioMarin stated they plan to submit to the FDA later this year.

Harliku™ (Nitisinone) Product Summary[13,14,15]

Therapeutic Class: Hydroxy-phenylpyruvate dioxygenase inhibitor

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

How Supplied: 2mg tablet

Dosing and Administration:

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

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

- Key Inclusion Criteria:
  - 30 to 80 years of age
  - Diagnosis of AKU based upon urinary HGA excretion >0.4g/24 hour
  - At least 1 hip joint remaining
  - Some evidence of hip involvement (e.g., pain or decreased range of motion)

- Intervention: 20 patients received no treatment and 20 patients received nitisinone 2mg orally once daily
- Outcome: Mean urine HGA excretion

- Results:
  - The mean HGA excretion in the no treatment group was 5.80 grams per day at baseline and stayed at that level for the duration of the study (range: 4.60-6.47 grams per day).
  - The mean HGA excretion in the nitisinone treated group decreased from 5.1 grams per day at baseline to 125mg per day by the 4th month and ranged from 113mg to 203mg per day for the remainder of the trial.
  - Overall, nitisinone reduced urinary HGA excretion by >95%.

Orfadin® (Nitisinone) Product Summary[16]

Therapeutic Class: Hydroxy-phenylpyruvate dioxygenase inhibitor

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

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

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

Efficacy: The safety and efficacy of Orfadin® were studied in 207 patients with HT-1 in an open-label, uncontrolled trial.
- Key Inclusion Criteria:
  - 0 to 22 years of age

    - Diagnosis of HT-1 based on the presence of succinylacetone in the urine or plasma
- Intervention: All patients were treated with Orfadin® for 22 months; doses were titrated based on clinical response.
- Outcome: Comparison of survival to historical controls
- Results:
    - For patients presenting with HT-1 prior to 2 months of age who were treated with dietary restriction and nitisinone, 2- and 4-year survival probabilities were 88% and 88%, respectively. Data from historical controls showed that patients presenting with HT-1 prior to 2 months of age and treated with dietary restriction alone had 2- and 4-year survival probabilities of 29% and 29%, respectively.
    - For patients presenting with HT-1 between 2 months and 6 months of age who were treated with dietary restriction and nitisinone, 2- and 4-year survival probabilities were 94% and 94%, respectively. Data for historical controls showed that patients presenting with HT-1 between 2 months and 6 months of age treated with dietary restriction alone had 2- and 4-year survival probabilities of 74% and 60%, respectively.

Nityr® (Nitisinone) Product Summary[17]

Therapeutic Class: Hydroxy-phenylpyruvate dioxygenase inhibitor

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

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

Dosing and Administration:

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

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

Cost Comparison: Nitisinone Products

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

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet or capsule
*Cost per 30 days is based on the recommended 2mg daily dose for the reduction of urine HGA in adult patients with AKU.

Sephience™ (Sepiapterin) Product Summary[18,19]

Therapeutic Class: Phenylalanine hydroxylase activator

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

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

Dosing and Administration:

- Patients treated with Sephience™ should be on a dietary protein and a phenylalanine restricted diet.
- Treatment with Sephience™ should be directed by a physician knowledgeable in the management of PKU.
- Phenylalanine levels should be obtained before initiating treatment with Sephience™ and patients should undergo regular dietary assessments by their health care provider.
- Sephience™ should be administered orally once daily with food.
- The recommended starting dose of Sephience™ is based on the patient's age:
  - Younger than 6 months: 7.5mg/kg per day
  - 6 months to younger than 1 year: 15mg/kg per day
  - 1 year to younger than 2 years: 30mg/kg per day
  - 2 years and older: 60mg/kg per day
- See full *Prescribing Information* for preparation and administration instructions.
- After initiating treatment with Sephience™, in patients younger than 2 years of age, blood phenylalanine levels should be checked within 2

weeks, and the dose should be titrated based on response to a maximum daily dose of 60mg/kg.
- Sephience™ should be discontinued in all patients whose blood phenylalanine levels do not decrease after 2 weeks of treatment at the maximum daily dose of 60mg/kg.

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

- Key Inclusion Criteria:
  - Clinical diagnosis of PKU with HPA documented by past medical history of at least 2 blood phenylalanine measurements ≥600micromol/L
  - Uncontrolled blood phenylalanine ≥360micromol/L on current therapy anytime during screening and uncontrolled blood phenylalanine level ≥360micromol/L on current therapy when taking the average of the 3 most recent phenylalanine levels from the participant's medical history (inclusive of the screening value)
  - Willing to continue current diet without changing it through the study
- Key Exclusion Criteria:
  - Confirmed diagnosis of a primary BH4 deficiency
  - Concomitant treatment or unwillingness to washout treatment with sapropterin dihydrochloride or pegvaliase-pqpz
- Intervention:
  - Part 1: 157 patients received Sephience™, dose based on age and weight, once daily for 14 days.
  - Part 2: After a 2-week washout period from Part 1, 98 patients age 2 years or older who had a ≥30% reduction in phenylalanine level with Sephience™ in Part 1 were randomized in a double-blind fashion to receive Sephience™ or placebo for 6 weeks.
- Outcome:
  - Part 1: 66% of patients had ≥30% reduction in phenylalanine level after 2 weeks.
  - Part 2:
    - The Sephience™ treated group had a baseline mean phenylalanine level of 646.1micromol/L and after weeks 5 to 6, the mean phenylalanine level was 236micromol/L compared to the placebo group, which had a baseline mean phenylalanine level of 654micromol/L and after weeks 5 to 6, the mean phenylalanine level was 637.9micromol/L.
    - The treatment difference in adjusted mean percent change in blood phenylalanine from baseline to weeks 5 and 6 was -64.2% [95% confidence interval (CI): -74.1%, -54.4%].

Cost Comparison: PKU Products

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

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
pak = packet
*Cost per 30 days is based on the FDA approved maximum dose of 60mg/kg per day for a 75kg patient.
±Cost per 30 days is based on the FDA approved maximum dose of 20mg/kg for a 75kg patient.

Recommendations

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

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

1. An indication to reduce urine homogentisic acid (HGA) in patients with alkaptonuria (AKU); and
    a. The diagnosis of AKU must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
        i. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the homogentisate 1,2-dioxygenase (HGD) gene; or
        ii. Urine test for HGA showing >0.4 grams of HGA excreted in 24 hours; and
2. Nitisinone must be prescribed by, or in consultation with, a geneticist, rheumatologist, or specialist with expertise in the treatment of AKU; and
3. The prescriber must confirm the member will receive a baseline ophthalmologic examination prior to initiating nitisinone treatment; and
4. The prescriber must confirm the member has been counseled to report any unexplained ocular, neurologic, or other symptoms to their health care provider; and
5. Use of Harliku™ will require a documented failed trial of both generic nitisinone 2mg capsules and Nityr® (nitisinone) 2mg tablets and clinical justification as to why Harliku™ would be expected to confer a different response since it contains the same active ingredient (nitisinone); and
6. A quantity limit of 30 tablets for 30 days will apply; and
7. Initial approvals will be for the duration of 6 months; and

8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
    a. Verification from the prescriber of continued response to therapy (i.e., decrease in urine HGA levels, improvement in joint pain, decrease in visible ochronosis).

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

1. An FDA approved diagnosis of HT-1; and
    a. The diagnosis of HT-1 must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
        i. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the fumarylacetoacetase (FAH) gene; or
        ii. Elevated succinylacetone concentrations in the blood or urine; and
2. Documentation of active management with a tyrosine and phenylalanine restricted diet; and
3. Nitisinone must be prescribed by, or in consultation with, a geneticist or specialist with expertise in the treatment of HT-1; and
4. The prescriber must verify the member will receive appropriate ophthalmologic examinations; and
5. The prescriber must confirm the member has been counseled to report any unexplained ocular, neurologic, or other symptoms to their health care provider; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
7. Initial approvals will be for the duration of 6 months; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
    a. Documentation of active management with a tyrosine and phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., decrease in plasma and/or urine succinylacetone concentration).

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

Sephience™ (Sepiapterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria (PKU); and
2. Documentation of active management with a phenylalanine restricted diet; and

3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Sephience must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
5. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Member must meet 1 of the following (documentation must be provided):
    a. A 3-month trial with sapropterin with inadequate response, defined as blood phenylalanine ≥360micromol/L, despite consistent use in combination with dietary phenylalanine restriction; or
    b. Member is a non-responder to sapropterin defined as ≤30% decrease in phenylalanine after 30 days of sapropterin therapy in combination with dietary phenylalanine restriction; or
    c. A diagnosis of classic PKU (blood phenylalanine ≥1,200micromol/L at diagnosis or 2 null mutations in *trans*); or
    d. A patient specific, clinically significant reason why the member cannot use generic Kuvan® (sapropterin) must be provided; and
7. Initial approvals will be for 2 weeks. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and
    a. Members younger than 2 years of age will be approved for a longer dosage titration per the package labeling up to the maximum daily dosage of 60mg/kg/day. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; or
    b. If the member was initiated at 60mg/kg/day, then no additional approvals will be granted after a trial period of 2 weeks if the member did not respond to treatment as defined by laboratory documentation of ≥30% reduction in blood phenylalanine levels from baseline; and
8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization requires the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

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

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

1. An FDA approved diagnosis of phenylketonuria (PKU); and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Member must not have 2 null mutations in *trans*; and
4. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
5. Sapropterin must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
6. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
7. Use of Javygtor™ (sapropterin) or Zelvysia™ (sapropterin) will require a patient specific, clinically significant reason why other generic formulations of sapropterin cannot be used; and
8. Initial approvals will be for the duration of 30 days. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
    a. If the member was initiated at 10mg/kg/day dose, then a subsequent trial of 20mg/kg/day for a duration of 30 days can be approved, after which time the prescriber must verify the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; or
    b. If the member was initiated at 20mg/kg/day dose, then no additional approvals will be granted after a trial period of 30 days if the member did not respond to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
9. Subsequent approvals will be for the duration of 1 year; and
10. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy (i.e., blood phenylalanine level, increase in dietary phenylalanine tolerance, improvement in clinical symptoms).

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved indication to reduce blood phenylalanine concentrations in members with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations >600micromol/L on existing management; and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Palynziq® must be prescribed by, or in consultation with, a geneticist, neurologist, or specialist with expertise in the treatment of PKU; and
5. Concomitant use with Kuvan® (sapropterin) or Sephience™ (sepiapterin) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
8. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
9. ~~Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Members should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L. Slower dose titrations may be approved based on member's response and tolerability; and~~
    a. ~~If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; and~~
    b. ~~If after at least 16 weeks with the 40mg dose, member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 60mg once daily dosing for an additional 16 weeks of treatment; or~~
    c. ~~If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, subsequent approvals will be for the duration of 1 year; and~~

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

Utilization Details of Amino Acid Disorder Medications: Fiscal Year 2025

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SAPROPTERIN PRODUCTS						
SAPROPTERIN POW 100MG	93	15	$230,279.72	$2,476.13	6.2	5.30%
SAPROPTERIN POW 500MG	54	8	$432,913.58	$8,016.92	6.75	9.97%
KUVAN POW 100MG	35	4	$96,913.20	$2,768.95	8.75	2.23%
SAPROPTERIN TAB 100MG	23	5	$337,131.15	$14,657.88	4.6	7.76%
KUVAN POW 500MG	13	2	$157,648.33	$12,126.79	6.5	3.63%
KUVAN TAB 100MG	3	2	$41,614.23	$13,871.41	1.5	0.96%
JAVYGTOR PAK 100MG	1	1	$3,791.41	$3,791.41	1	0.09%
SUBTOTAL	**222**	**37**	**$1,300,291.62**	**$5,857.17**	**6**	**29.94%**
PEGVALIASE-PQPZ PRODUCTS						
PALYNZIQ INJ 20MG/ML	84	10	$2,679,390.33	$31,897.50	8.4	61.70%
PALYNZIQ INJ 10MG/0.5ML	23	5	$349,801.43	$15,208.76	4.6	8.06%
PALYNZIQ INJ 2.5MG/0.5ML	6	2	$12,842.46	$2,140.41	3	0.30%
SUBTOTAL	**113**	**17**	**$3,042,034.22**	**$26,920.66**	**6.65**	**70.06%**
TOTAL	**335**	**36***	**$4,342,325.84**	**$12,962.17**	**9.31**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PAK = packet; POW = powder; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix K

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

Oklahoma Health Care Authority
November 2025

Introduction[1,2,3,4,5]

Bronchiectasis is a chronic, progressive inflammatory lung disease that refers to abnormal and usually permanent dilation of the bronchi. Bronchiectasis is heterogenous and coexists with a number of etiologies, such as post-infective disease, nontuberculous mycobacteria (NTM), cystic fibrosis (CF), primary ciliary dyskinesia, and various autoimmune or immune deficiency diseases, but the cause of bronchiectasis in some patients is unknown. Non-cystic fibrosis bronchiectasis (NCFB) refers to bronchiectasis that is not associated with CF. Bronchiectasis typically presents with a chronic cough, sputum production, recurrent infections, and exacerbations. Multiple factors can lead to the development of bronchiectasis resulting in a vicious vortex consisting of chronic airway inflammation, airway destruction, impaired mucociliary clearance, and chronic airway infection. Once this cycle is established, the disease becomes progressive over time and irreversible damage to the airways continues.

Bronchiectasis affects approximately 350,000 to 500,000 adults in the United States with the risk increasing with age. Due to its overlap with various other conditions such as asthma, chronic obstructive pulmonary disease (COPD), and bronchitis, diagnosis can be difficult and is often delayed. A distinguishing feature of diagnosis is the productive cough with a pattern of exacerbations, but chest imaging, specifically with a chest computed tomography (CT) scan, is required to make the diagnosis. In order for the clinical syndrome to be diagnosed, the patient must have a cough that produces sputum on most days of the week, a history of exacerbations, and at least 1 of the following findings on high-resolution CT with a slice thickness of 1mm or less: a ratio of the inner or outer airway diameter to the artery diameter of ≥1.0, a lack of tapering of the airways, or the presence of radiographically visible airways in the perimeter. Frequency of exacerbations, increased levels of neutrophilic inflammatory biomarkers, and chronic infections with *Pseudomonas aeruginosa* are key markers for disease severity.

Current treatment for bronchiectasis varies and revolves around symptom and exacerbation reduction, improvement in quality of life, and preservation of lung function. Current intervention options include inhaled mucolytics, oral

and inhaled antibiotics, bronchodilators, pulmonary rehabilitation, and treatment of underlying conditions in order to prevent disease progression. In August 2025, the U.S. Food and Drug Administration (FDA) approved Brinsupri™ (brensocatib) for the treatment of NCFB in adult and pediatric patients 12 years of age and older. Brinsupri™ is the first FDA approved medication for the treatment of NCFB.

Brinsupri™ (Brensocatib) Product Summary[6,7,8]

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

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

How Supplied: 10mg and 25mg oral tablet

Dosing and Administration:

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

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

- Key Inclusion Criteria:
  - ASPEN: 12 years of age or older
  - WILLOW: 18 years of age or older
  - Clinical history consistent with NCFB (i.e., cough, chronic sputum production, and/or recurrent respiratory infections) that is confirmed by chest CT scan
  - History of pulmonary exacerbation(s) defined by the need for antibiotic prescription for the signs and symptoms of respiratory infections in the past 12 months
    - ASPEN: ≥1 pulmonary exacerbation for adolescents or ≥2 pulmonary exacerbations for adults
    - WILLOW: ≥2 pulmonary exacerbations
- Key Exclusion Criteria:
  - A primary diagnosis of COPD or asthma
  - Bronchiectasis due to CF
- Intervention(s): Patients were randomized 1:1:1 (2:2:1 in adolescents) to receive brensocatib 10mg or 25mg or placebo once daily
- Primary Endpoint(s):
  - ASPEN: Annualized rate of pulmonary exacerbations over 52-week treatment period
  - WILLOW: Time to first pulmonary exacerbation over 24-week treatment period
  - Pulmonary exacerbations were defined as ≥3 of the following major symptoms over 48 hours resulting in a health care provider's

decision to prescribe systemic antibiotics: increased cough, increased sputum volume or change in sputum consistency, increased sputum purulence, increased breathlessness, decreased exercise tolerance, fatigue and/or malaise, and hemoptysis.

- Results:
  - ASPEN:
    - Annualized rate of pulmonary exacerbation was 1.02 for the 10mg group vs. 1.29 for placebo [treatment difference: 0.79; 95% confidence interval (CI): 0.68, 0.92; adjusted P=0.04] and 1.04 for the 25mg group vs. 1.29 for placebo (treatment difference: 0.81; 95% CI: 0.69, 0.94; adjusted P=0.005)
  - WILLOW:
    - The median time to the first exacerbation was 189 days in the placebo group, but because of the low number of exacerbations in the 2 brensocatib groups, the median time to the first exacerbation could not be estimated in those groups. The 25th percentile of the time to the first exacerbation was 67 days in the placebo group, 134 days in the 10mg brensocatib group, and 96 days in the 25mg brensocatib group.
    - The adjusted hazard ratio in the comparison of Brinsupri™ vs. placebo was 0.58 (95% CI: 0.35, 0.95; P=0.03) in the 10mg group and 0.62 (95% CI: 0.38, 0.99; P=0.046) in the 25mg group.

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

Recommendations

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

Brinsupri™ (Brensocatib) Approval Criteria:

1. An FDA approved diagnosis of non-cystic fibrosis bronchiectasis (NCFB). Diagnosis must be confirmed by both of the following:
   a. Chest computed tomography (CT) scan; and
   b. Clinical history consistent with NCFB (e.g., cough, chronic sputum production, and/or recurrent respiratory infections); and
2. Member must be 12 years of age or older; and
3. Member must not have cystic fibrosis; and
4. Member must have a history of pulmonary exacerbation(s) (e.g., required treatment with antibiotics and/or required hospitalization or

emergency room visit) in the last 12 months according to member's age:
   a. Members 18 years of age or older: ≥2 exacerbations; or
   b. Members 12-17 years of age: ≥1 exacerbation; and
5. Prescriber must verify that any underlying cause of NCFB is adequately treated, if applicable; and
6. Brinsupri™ must be prescribed by, or in consultation with, a pulmonary or infectious disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary or infectious disease specialist); and
7. Initial approvals will be for the duration of 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Brinsupri™ as demonstrated by a decrease in NFCB symptoms and/or exacerbations. Subsequent approvals will be for 1 year.

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Appendix L

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

Oklahoma Health Care Authority
November 2025

Current Prior Authorization Criteria

Approval criteria for Dupixent® (dupilumab injection) for indications other than AD can be found in the Fiscal Year 2025 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications report, which is also being presented at the November 2025 Drug Utilization Review (DUR) Board meeting. Dupixent® is reviewed annually with the asthma and COPD maintenance medications. Utilization data for Rinvoq® (upadacitinib) and approval criteria for indications other than AD can be found in the October 2025 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.

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 Adbry® (tralokinumab-ldrm), Dupixent® (dupilumab), or Ebglyss® (lebrikizumab-lbkz) 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. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and
6. 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
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 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. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) and Dupixent® (dupilumab) must be provided; 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 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
8. Initial approvals will be for a quantity limit override for the initial dosing for the duration of 16 weeks; and
9. 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. Members must meet all of the following criteria:
    a. An FDA approved indication:
        i. Elidel®: Short-term and intermittent treatment for mild-to-moderate atopic dermatitis (eczema); or
        ii. Protopic®: Short-term and intermittent treatment for moderate-to-severe atopic dermatitis (eczema); and
    b. Age restrictions:
        i. Elidel® 1% is restricted to 2 years of age and older; and
        ii. Protopic® 0.03% is restricted to 2 years of age and older; and
        iii. Protopic® 0.1% is restricted to 15 years of age and older; or
7. Clinical exceptions for the trial requirement may be considered for the following:
    a. Documented adverse effect, drug interaction, or contraindication to Tier-1 topical corticosteroids; or
    b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids; or
8. Clinical exceptions for the age restrictions (for members younger than the FDA approved age) may be considered for the following:
    a. Prescribed by a dermatologist.

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 [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 12 years of age or older; and
3. Member must not be immunocompromised; and
4. Member must have a body surface area (BSA) involvement ≤20%; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all 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
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% Cream) Approval Criteria:

1. An FDA approved diagnosis of mild-to-moderate atopic dermatitis; and
2. Member must be 6 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 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 6 years of age or older; and
3. Member must have a body surface (BSA) involvement of ≤20%; and
4. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
5. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
6. 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
7. 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
8. A quantity limit of 60 grams per 30 days will apply.

Zoryve® (Roflumilast 0.3% Foam) Approval Criteria:

1. An FDA approved diagnosis of seborrheic dermatitis; and
2. Prescriber must confirm member's condition is moderate or severe; and
3. Member must be 9 years of age or older; and
4. Member must have a body surface area (BSA) involvement of ≤20%; and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. If the affected area is limited to the scalp, member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
   a. Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione); and
   b. OTC coal tar shampoo; and
   c. Tier-1 prescription antifungal shampoo (e.g., ketoconazole 2% shampoo); and
   d. Tier-1 topical corticosteroid; and
8. If the affected area includes the face or body, member must have documented trials within the last 6 months for a minimum of at least 2 weeks that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
   a. Tier-1 topical antifungal (e.g., ketoconazole, ciclopirox); and
   b. Tier-1 topical corticosteroid; and
   c. Topical calcineurin inhibitor (e.g., pimecrolimus 1% cream, tacrolimus 0.1% ointment); and
9. Initial approvals will be for a duration of 8 weeks. After 8 weeks, the prescriber will need to provide clinical documentation that the member is improving on the medication and provide justification for continuation of therapy; and
10. A quantity limit of 60 grams per 30 days will apply.

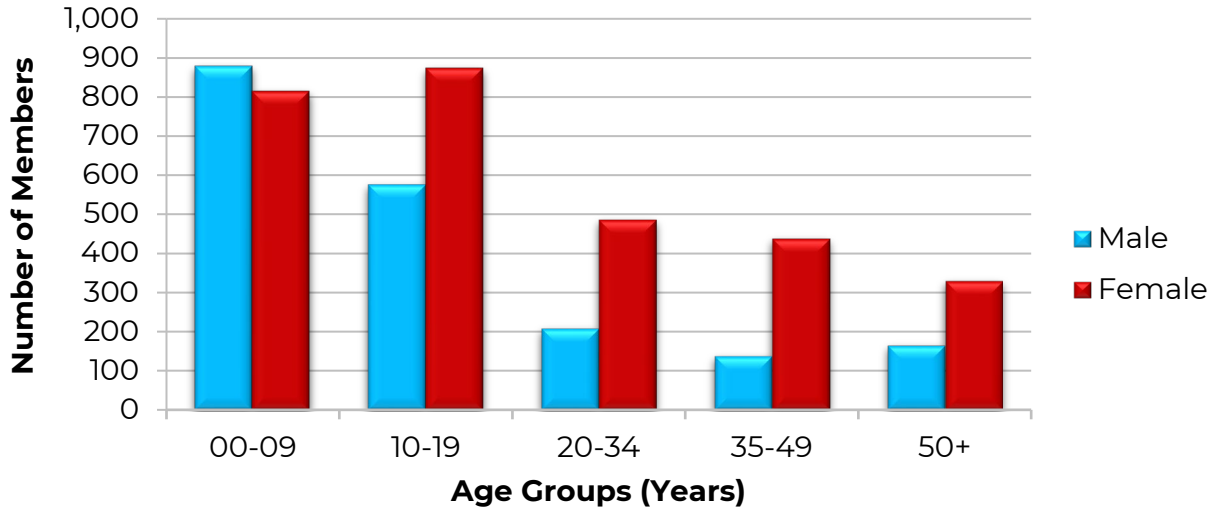
Utilization of AD Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

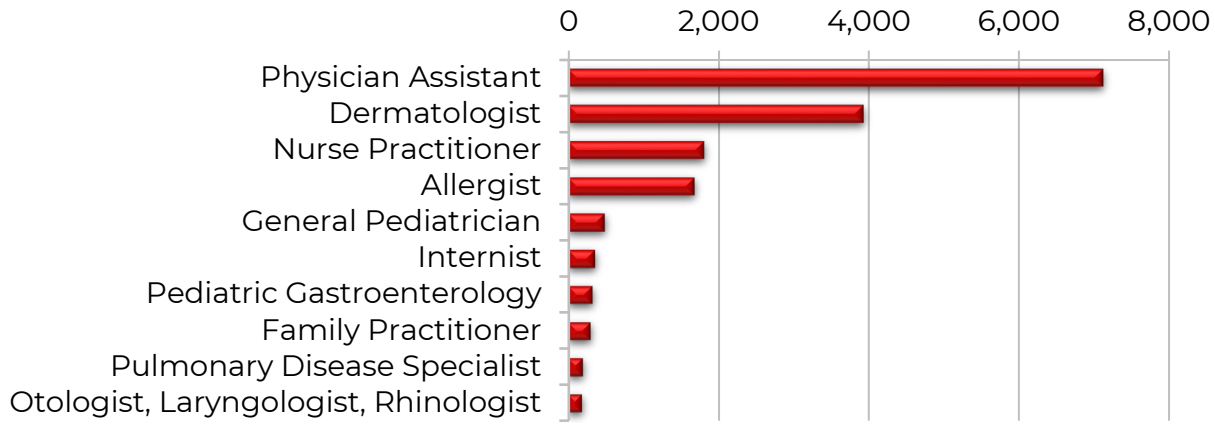
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	3,398	9,731	$22,044,614.57	$2,265.40	$71.49	227,166	308,347
Aetna	482	808	$1,766,343.47	$2,186.07	$76.42	21,265	23,114
Humana	522	874	$1,962,452.08	$2,245.37	$79.43	23,779	24,708
OCH	491	797	$1,809,339.51	$2,270.19	$72.40	20,419	24,992
2024 Total	**4,071**	**12,210**	**$27,582,749.63**	**$2,259.03**	**$72.37**	**292,629**	**381,161**
Fiscal Year 2025							
FFS	1,554	5,082	$14,039,782.95	$2,762.65	$87.21	92,255	160,985
Aetna	1,254	3,807	$9,179,706.81	$2,411.27	$81.10	96,518	113,185
Humana	1,303	4,387	$11,289,459.66	$2,573.39	$88.83	102,756	127,084
OCH	1,113	3,507	$9,164,797.50	$2,613.29	$82.49	75,445	111,103
2025 Total	**4,904**	**16,783**	**$43,673,746.92**	**$2,602.26**	**$85.24**	**366,974**	**512,357**
% Change	**20.50%**	**37.50%**	**58.30%**	**15.20%**	**17.80%**	**25.40%**	**34.40%**
Change	**833**	**4,573**	**$16,090,997.29**	**$343.23**	**$12.87**	**74,345**	**131,196**

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



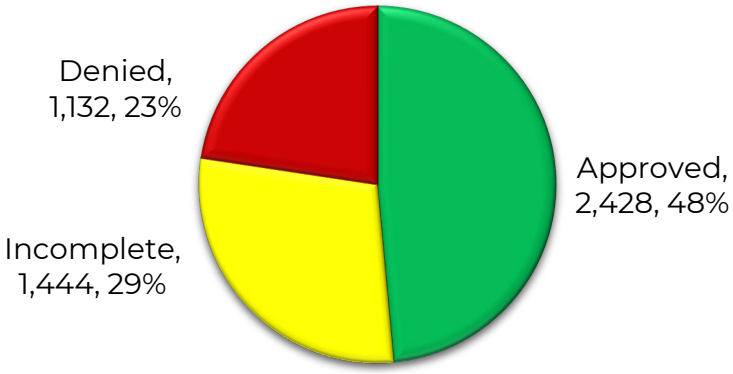
Top Prescriber Specialties of AD Medications by Number of Claims (All Plans)



Prior Authorization of AD Medications

There were 5,004 prior authorization requests submitted for AD medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	1,166	41%	1,098	39%	574	20%	**2,838**
Aetna	415	56%	176	24%	149	20%	**740**
Humana	262	72%	0	0%	102	28%	**364**
OCH	585	55%	170	16%	307	29%	**1,062**
Total	**2,428**	**48%**	**1,444**	**29%**	**1,132**	**23%**	**5,004**

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

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

Anticipated Patent Expiration(s):

- Eucrisa® (crisaborole): July 2030
- Anzupgo® (delgocitinib 2% cream): September 2031
- Cibinqo® (abrocitinib): February 2034
- Zoryve® (roflumilast cream): June 2037
- Rinvoq® (upadacitinib): March 2038
- Vtama® (tapinarof 1% cream): November 2039
- Opzelura® (ruxolitinib): May 2041
- Zoryve® (roflumilast 0.3% foam): December 2041

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

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

Guideline Update(s):

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

guideline updates for topical therapies (from 2023) and phototherapy and systemic therapies (from 2024). The new recommendations made include:

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

Pipeline:

- **Zoryve® (Roflumilast 0.3% Cream):** Arcutis Biotherapeutics, the manufacturer of Zoryve, has submitted a supplemental New Drug Application (sNDA) for Zoryve® 0.3% cream for the treatment of children 2 to 5 years of age with plaque psoriasis. A Prescription Drug User Fee Act (PDUFA) target date has not been announced. Zoryve 0.3% cream is currently FDA approved for plaque psoriasis in patients as young as 6 years of age.

Anzupgo® (Delgocitinib 2% Cream) Product Summary[9,10]

Therapeutic Class: Janus kinase (JAK) inhibitor

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

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

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

Dosing and Administration:

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

Efficacy: The efficacy of Anzupgo® was assessed primarily in 2 Phase 3 studies (DELTA 1 and DELTA 2) which were randomized, double-blind, vehicle-controlled studies. The studies enrolled a total of 960 adult patients with

moderate to severe CHE with a history of inadequate response to TCS, or for whom TCS were not advisable. In both studies, patients were randomized to apply Anzupgo® or vehicle twice daily to affected areas on the hands and wrists for 16 weeks.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Diagnosis of CHE (e.g., hand eczema has persisted for >3 months or returned twice or more within the past 12 months)
  - Disease is moderate to severe [e.g., Investigator's Global Assessment for chronic hand eczema (IGA-CHE) score of 3 or 4 at baseline on a scale from 0-4]
  - Hand Eczema Symptom Diary (HESD) itch score (weekly average) ≥4 points at baseline on a scale from 0-10
  - Documented recent history of inadequate response to treatment with TCS or for whom TCS are documented to be otherwise medically inadvisable (e.g., due to important side effects or safety risks)
- Primary Endpoint(s):
  - Proportion of patients achieving an IGA-CHE score of 0 ("clear skin") or 1 ("almost clear skin") and at least a 2-point improvement from baseline at week 16
- Results:
  - DELTA 1: Achieved by 20% of patients who received Anzupgo® vs. 10% of patients who received vehicle [treatment difference: 10%; 95% confidence interval (CI): 4%, 16%]
  - DELTA 2: Achieved by 29% of patients who received Anzupgo® vs. 7% of patients who received vehicle (treatment difference: 22%; 95% CI: 16%, 29%)

Cost Comparison: Injectable Products

Product	Cost Per Pen	Cost Per 1st 16 Weeks*	Cost Per Year⁺
Ebglyss® (lebrikizumab-lbkz) 250mg/2mL	$3,500.00	$35,000.00	$66,500.00
Nemluvio® (nemolizumab-ilto) 30mg	$4,240.00	$21,200.00	$59,360.00
Adbry® (tralokinumab-ldrm) 300mg/2mL	$2,034.69	$18,312.21	$54,936.63
Dupixent® (dupilumab) 300mg/2mL	$1,920.72	$17,286.48	$51,859.44

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per first 16 weeks based on the initial FDA approved dosing for AD for each product, including required loading doses.
⁺Cost per year based on the initial year of treatment, including required loading doses and the maximum maintenance dosing of 30mg every 4 weeks (for Nemluvio®), 250mg every 4 weeks (for Ebglyss™) or 300mg every 2 weeks (for Adbry® and Dupixent®).

Cost Comparison: Oral Products

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
Rinvoq® (upadacitinib) 30mg tablet	$218.73	$6,561.90	$78,742.80
Cibinqo® (abrocitinib) 200mg tablet	$194.86	$5,845.80	$70,149.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost based on the maximum FDA approved dose for AD for each product: 30mg once daily for Rinvoq® or 200mg once daily for Cibinqo®.

Cost Comparison: Topical Products

Product	Cost Per Gram	Cost Per Tube	Cost Per Year*
Anzupgo® (delgocitinib 2% cream) 30g tube	$66.20	$1,986.00	$23,832.00
Vtama® (tapinarof 1% cream) 60g tube	$24.12	$1,447.20	$17,366.40
Zoryve® (roflumilast 0.05% cream) 60g tube	$16.09	$965.40	$11,584.80
Zoryve® (roflumilast 0.15% cream) 60g tube	$14.79	$887.4	$10,648.80
Eucrisa® (crisaborole 2% ointment) 60g tube	$12.65	$759.00	$9,108.00
Opzelura® (ruxolitinib 1.5% cream) 60g tube	$33.48	$2,008.80	$8,035.20
pimecrolimus 1% cream 60g tube	$2.72	$163.20	$652.80
tacrolimus 0.03% ointment 60g tube	$0.84	$50.40	$201.60
triamcinolone 0.1% ointment 80g tube	$0.04	$3.20	$38.40
triamcinolone 0.1% cream 80g tube	$0.03	$2.40	$28.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per year is based on the use of 1 tube per month for all products except Opzelura®, pimecrolimus, and tacrolimus which are based on the use of 1 tube every 3 months as these products are only FDA approved for the short-term and non-continuous chronic treatment of atopic dermatitis.

Recommendations

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

Anzupgo® (Delgocitinib 2% Cream) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe chronic hand eczema (CHE) meeting 1 of the following:
   a. Hand eczema has persisted for >3 months; or
   b. Hand eczema has returned twice or more within the last 12 months; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and

4. Prescriber must attest that the member has been counseled regarding standard non-medicated skin care, including but not limited to:
    a. Frequent use of emollients/moisturizers; and
    b. Washing hands in lukewarm (not hot) water; and
    c. Avoidance of known and relevant irritants and allergens where possible; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
    b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
6. Concurrent use with other Janus kinase (JAK) inhibitors or potent immunosuppressants will not generally be approved; and
7. Member must be counseled to apply Anzupgo® only to the hands and wrists. Anzupgo® will not be approved for application to any other area; and
8. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
9. A quantity limit of 60 grams per 30 days will apply.

The College of Pharmacy also recommends updating the Nemluvio® (nemolizumab-ilto), Opzelura® (ruxolitinib 1.5% cream), and Zoryve® (roflumilast) approval criteria based on recent FDA approvals (changes shown in red):

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

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies; and
2. Member must be 12 years of age or older; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member must agree to continue using a topical corticosteroid and/or a topical calcineurin inhibitor in combination with Nemluvio® until the disease has sufficiently improved; and

5. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
6. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and
7. Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
8. Requests for concurrent use of Nemluvio® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Nemluvio® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the initial dosing for the duration of 16 weeks; and
10. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
    a. A dosage of 30mg every 8 weeks will be approved for reauthorization; or
    b. If a dosage of 30mg every 4 weeks is requested for reauthorization, additional patient-specific information will be required to support the need for continuing the every 4 week dosing regimen.

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

1. An FDA approved indication for short-term and non-continuous treatment of mild-to-moderate atopic dermatitis; and
2. Member must be ~~12~~ 2 years of age or older; and
3. Member must not be immunocompromised; and
4. Member must have a body surface area (BSA) involvement ≤20%; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all 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
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.

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

1. An FDA approved diagnosis of mild-to-moderate atopic dermatitis; and
~~2. Member must be 6 years of age or older; and~~
3. Requested product must be FDA approved for the member's age; and
    a. 0.15% Cream: Member must be 6 years of age or older; or
    b. 0.05% Cream: Member must be 2 to 5 years of age; and
4. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
    b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
    c. Eucrisa® (crisaborole); and
5. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 grams per 30 days will apply.

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

1. An FDA approved diagnosis of plaque psoriasis; and
~~2. Member must be 6 years of age or older; and~~
3. Requested product must be FDA approved for the member's age; and
    a. 0.3% Cream: Member must be 6 years of age or older; or
    b. 0.3% Foam: Member must be 12 years of age or older; and
4. Member must have a body surface (BSA) involvement of ≤20% (or ≤25% if both the scalp and body are being treated); and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and

6. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
    a. An ultra-high to high potency topical corticosteroid (TCS); or
    b. A generic topical calcipotriene product; or
    c. A topical tazarotene product; and
8. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
9. A quantity limit of 60 grams per 30 days will apply.

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

1. An FDA approved diagnosis of seborrheic dermatitis; and
2. Prescriber must confirm member's condition is moderate or severe; and
3. Member must be 9 years of age or older; and
4. Member must have a body surface area (BSA) involvement of ≤20%; and
5. Member must not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. If the affected area is limited to the scalp, member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
    a. Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione); and
    b. OTC coal tar shampoo; and
    c. Tier-1 prescription antifungal shampoo (e.g., ketoconazole 2% shampoo); and
    d. Tier-1 topical corticosteroid; and
8. If the affected area includes the face or body, member must have documented trials within the last 6 months for a minimum of at least 2 weeks that resulted in failure with at least 1 product from all of the following categories (or have a contraindication or documented intolerance):
    a. Tier-1 topical antifungal (e.g., ketoconazole, ciclopirox); and
    b. Tier-1 topical corticosteroid; and

c. Topical calcineurin inhibitor (e.g., pimecrolimus 1% cream, tacrolimus 0.1% ointment); and

9. Initial approvals will be for a duration of 8 weeks. After 8 weeks, the prescriber will need to provide clinical documentation that the member is improving on the medication and provide justification for continuation of therapy; and
10. A quantity limit of 60 grams per 30 days will apply.

Utilization Details of AD Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	5,725	999	$22,896,265.29	$3,999.35	5.73	52.43%
DUPIXENT INJ 300MG/2ML SYR	1,780	342	$6,998,213.52	$3,931.58	5.2	16.02%
DUPIXENT INJ 200MG/1.14ML PEN	1,434	262	$5,407,246.83	$3,770.74	5.47	12.38%
DUPIXENT INJ 200MG/1.14ML SYR	1,222	269	$4,601,884.32	$3,765.86	4.54	10.54%
ADBRY INJ 300MG/2ML AUTO	224	70	$907,421.02	$4,050.99	3.2	2.08%
ADBRY INJ 150MG/ML SYR	209	53	$572,050.85	$2,737.09	3.94	1.31%
EBGLYSS INJ 250MG/2ML PEN	28	10	$196,319.48	$7,011.41	2.8	0.45%
NEMLUVIO INJ 30MG PEN	17	7	$101,953.97	$5,997.29	2.43	0.23%
SUBTOTAL	**10,639**	**1,787***	**$41,681,355.28**	**$3,917.79**	**5.95**	**95.44%**
TOPICAL PRODUCTS						
TACROLIMUS OIN 0.03%	1,692	1,112	$93,779.38	$55.43	1.52	0.21%
TACROLIMUS OIN 0.1%	1,538	1,079	$86,559.57	$56.28	1.43	0.20%
PIMECROLIMUS CREAM 1%	1,521	1,065	$202,643.49	$133.23	1.43	0.46%
EUCRISA OIN 2%	778	501	$629,317.77	$808.89	1.55	1.44%
ZORYVE FOAM 0.3%	182	93	$160,316.09	$880.86	1.96	0.37%
ZORYVE CREAM 0.3%	115	56	$101,719.70	$884.52	2.05	0.23%
OPZELURA CREAM 1.5%	107	39	$218,539.65	$2,042.43	2.74	0.50%
ZORYVE CREAM 0.15%	85	46	$76,061.95	$894.85	1.85	0.17%
VTAMA CREAM 1%	65	38	$93,509.58	$1,438.61	1.71	0.21%
DOXEPIN HCL CREAM 5%	3	2	$1,122.33	$374.11	1.5	0.00%
SUBTOTAL	**6,086**	**3,795***	**$1,663,569.51**	**$273.34**	**1.6**	**3.81%**
ORAL PRODUCTS						
CIBINQO TAB 100MG	27	8	$152,262.69	$5,639.36	3.38	0.35%
CIBINQO TAB 200MG	24	3	$137,229.96	$5,717.92	8	0.31%
CIBINQO TAB 50MG	7	2	$39,329.48	$5,618.50	3.5	0.09%
SUBTOTAL	**58**	**11***	**$328,822.13**	**$5,669.35**	**4.46**	**0.75%**
TOTAL	**16,783**	**4,904***	**$43,673,746.92**	**$2,602.26**	**3.42**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; HCL = hydrochloride; 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 2025 = 07/01/2024 to 06/30/2025

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Appendix M

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

Oklahoma Health Care Authority
November 2025

Current Prior Authorization Criteria

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (QVAR® RediHaler®)	budesonide/formoterol (Symbicort Aerosphere®)
budesonide (Pulmicort Flexhaler®)	ciclesonide (Alvesco®)
budesonide/formoterol (Symbicort®)β – **Brand Preferred**	fluticasone propionate (Flovent®)
fluticasone furoate (Arnuity® Ellipta®)	fluticasone furoate/vilanterol (Breo® Ellipta®) – **Brand Preferred**
fluticasone propionate/salmeterol (Advair®)	fluticasone propionate/salmeterol (AirDuo RespiClick®)
mometasone furoate (Asmanex®)	mometasone furoate/formoterol 50mcg/5mcg (Dulera®)
mometasone furoate/formoterol (Dulera®)◊	

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

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.

Symbicort Aerosphere® (Budesonide/Formoterol Fumarate) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. A patient-specific, clinically significant reason why the member cannot use brand name Symbicort® and Advair® 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)	
salmeterol inhalation powder (Serevent®)	arformoterol nebulizer solution (Brovana®)
	formoterol nebulizer solution (Perforomist®)
	formoterol nebulizer solution kit
	olodaterol inhalation spray (Striverdi® Respimat®)
Long-Acting Muscarinic Antagonists (LAMA)	
aclidinium inhalation powder (Tudorza® PressAir®)	revefenacin inhalation solution (Yupelri®)
tiotropium inhalation powder (Spiriva® HandiHaler®) – **Brand Preferred**	
tiotropium soft mist inhaler (Spiriva® Respimat®)	
umeclidinium inhalation powder (Incruse® Ellipta®)	

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

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.

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

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting $beta_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components must be provided.

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. 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.

Daliresp® (Roflumilast) Approval Criteria:

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

Ohtuvayre® (Ensifentrine) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and

3. Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; 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) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment of members with severe asthma with an eosinophilic phenotype; and
2. Member must be 18 years of age or older; and
3. Member must have a blood eosinophil count ≥400cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. Cinqair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
8. Cinqair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; 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. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and
6. 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
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 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 [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and
4. Member must have a blood eosinophil count of ≥300 cells/mcL; 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 after which time 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 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 if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 2 syringes every 28 days will apply.

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

1. An FDA approved diagnosis of eosinophilic esophagitis (EoE) defined as:
    a. The presence of clinical symptoms of EoE ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
    b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf) in the esophagus]; and
2. Member must be 1 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 both 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 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 after which time compliance will be evaluated for continued approval; and
9. Quantities approved must not exceed FDA recommended dosing requirements.

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

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have a Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist for PN within the last 12

months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritus have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted 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 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 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.

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

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Nucala in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist,

pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; 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.

Tezspire® (Tezepelumab-ekko) Approval Criteria:

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. For authorization of Tezspire® in a health care facility, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or
7. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and
8. Tezspire® must be prescribed by a pulmonologist or pulmonary specialist, or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Xolair® (Omalizumab Injection) Approval Criteria [Asthma Diagnosis]:

1. Diagnosis of severe persistent asthma [as per National Asthma Education and Prevention Program (NAEPP) guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least 1 perennial aeroallergen (positive perennial aeroallergens must be listed on the prior authorization request); and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and
5. Member's weight must be between 20kg and 150kg; and

6. Member must have failed a medium-to-high-dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
7. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
8. For authorization of Xolair® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
9. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
10. Xolair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
11. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
12. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval.

Xolair® (Omalizumab Injection) Approval Criteria [Chronic Idiopathic Urticaria (CIU) Diagnosis]:

1. An FDA approved diagnosis of CIU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. For authorization of Xolair® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
7. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and

   b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
   c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
8. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
9. A trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
10. 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 at which time compliance will be evaluated for continued approval.

Xolair® (Omalizumab) 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 (documentation of allergy testing results must be submitted); and
4. Prescriber must confirm member will use Xolair® with an allergen-avoidant diet; and
5. Member must have a pretreatment serum IgE level between 30 and 1,850 IU/mL; and
6. Member's weight must be between 10kg and 150kg; and
7. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
9. For authorization of Xolair® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and

    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
11. Xolair® must be prescribed by an allergist or immunologist or the member must have been evaluated by an allergist or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
12. 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.

Xolair® (Omalizumab Injection) Approval Criteria [Nasal Polyps Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/ pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
6. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
7. Member must have a pretreatment serum IgE level between 30 and 1,500 IU/mL; and
8. Member's weight must be between 31kg and 150kg; and
9. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
10. For authorization of Xolair® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
11. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and

c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and

12. Xolair® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
13. 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. Additionally, compliance will be evaluated for continued approval.

Utilization of Asthma and COPD Maintenance Medications: Fiscal Year 2025

Comparison of Fiscal Years: Asthma and COPD Maintenance Medications Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	38,832	116,235	$35,310,718.71	$303.79	$8.65	3,199,321	4,082,633
Aetna	3,771	6,084	$1,605,769.83	$263.93	$7.79	160,365	206,085
Humana	4,410	7,602	$2,145,277.40	$282.20	$8.24	211,432	260,430
OCH	4,172	6,662	$1,757,987.23	$263.88	$7.80	176,535	225,252
2024 Total	**42,357**	**136,583**	**$40,819,753.17**	**$298.86**	**$8.55**	**3,747,654**	**4,774,400**
Fiscal Year 2025							
FFS	16,254	51,859	$15,003,556.11	$289.31	$8.47	1,511,860	1,771,827
Aetna	8,638	26,686	$6,985,960.40	$261.78	$7.77	712,159	899,406
Humana	9,554	31,373	$8,683,982.32	$276.80	$8.14	851,265	1,066,367
OCH	9,873	28,543	$7,811,326.53	$273.67	$7.69	787,331	1,015,268
2025 Total	**40,744**	**138,461**	**$38,484,825.36**	**$277.95**	**$8.10**	**3,862,616**	**4,752,868**
% Change	**-3.80%**	**1.40%**	**-5.70%**	**-7.00%**	**-5.30%**	**3.10%**	**-0.50%**
Change	**-1,613**	**1,878**	**-$2,334,927.81**	**-$20.91**	**-$0.45**	**114,962**	**-21,532**

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

- Aggregate drug rebates collected during fiscal year 2025 for the asthma and COPD maintenance medications totaled $26,722,878.05.[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 2024							
FFS	1,237	6,257	$22,936,685.68	$3,665.76	$114.55	21,935	200,238
Aetna	227	480	$1,833,144.83	$3,819.05	$129.38	1,633	14,169
Humana	263	541	$2,068,003.40	$3,822.56	$129.57	1,840	15,960
OCH	249	466	$1,782,793.54	$3,825.74	$113.21	1,648	15,747
2024 Total	**1,442**	**7,744**	**$28,620,627.45**	**$3,695.85**	**$116.29**	**27,056**	**246,114**
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	3,010	$11,742,483.45	$3,901.16	$128.22	10,366	91,580
OCH	495	2,423	$9,538,521.65	$3,936.66	$115.87	8,229	82,322
2025 Total	**1,956**	**11,719**	**$45,718,920.98**	**$3,901.26**	**$122.42**	**40,580**	**373,462**
% Change	**35.60%**	**51.30%**	**59.70%**	**5.60%**	**5.30%**	**50.00%**	**51.70%**
Change	**514**	**3,975**	**$17,098,293.53**	**$205.41**	**$6.13**	**13,524**	**127,348**

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

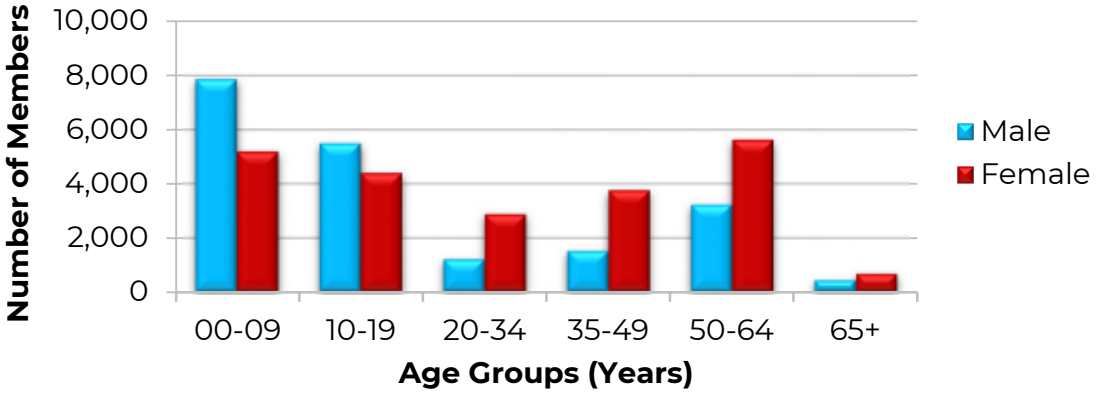
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	80	557	$1,311,128.15	$2,353.91	6.96
Aetna	8	14	$19,877.40	$1,419.81	1.75
Humana	1	2	$1.20	$0.60	2
OCH	5	10	$14,909.25	$1,490.93	2
2024 Total	**85**	**583**	**$1,345,916.00**	**$2,308.60**	**6.86**
Fiscal 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**
% Change	**50.59%**	**19.90%**	**14.08%**	**-4.85%**	**-20.38%**
Change	**43**	**116**	**$189,475.22**	**-$112.05**	**-1.4**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.
Utilization data includes all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

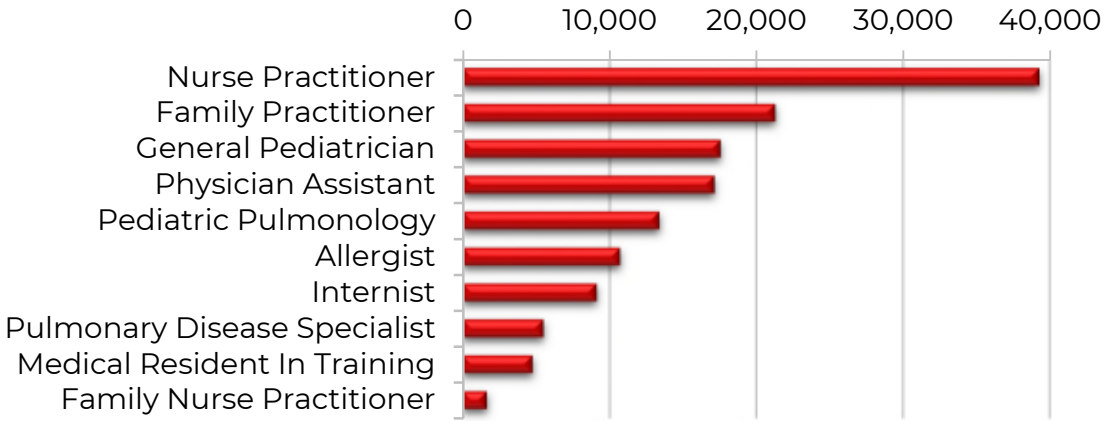
- Aggregate drug rebates collected during fiscal year 2025 for the asthma-indicated monoclonal antibodies totaled $10,046,138.19.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Asthma and COPD Maintenance Medications: Pharmacy Claims (All Plans)



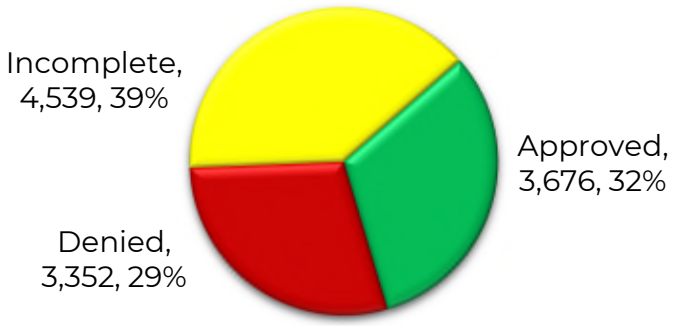
Top Prescriber Specialties of Asthma and COPD Maintenance Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Asthma and COPD Maintenance Medications

There were 11,567 prior authorization requests submitted for asthma and COPD maintenance medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	2,039	29%	3,794	54%	1,245	18%	**7,078**
Aetna	411	30%	423	31%	532	39%	**1,366**
Humana	419	36%	0	0%	753	64%	**1,172**
OCH	807	41%	322	17%	822	42%	**1,951**
Total	**3,676**	**32%**	**4,539**	**39%**	**3,352**	**29%**	**11,567**

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

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17]

Anticipated Patent Expiration(s):

- Spiriva® HandiHaler® (tiotropium inhalation powder): July 2026
- 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
- Symbicort Aerosphere® (budesonide/formoterol inhalation aerosol): May 2030
- 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
- 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):

- **March 2025:** The FDA approved Omlyclo® (omalizumab-igec) as the first and only interchangeable biosimilar to Xolair® (omalizumab) for the treatment of all 4 different Xolair® indications.

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

Guideline Update(s):

- **American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Guideline Update:** The AAO-HNSF released a clinical practice guideline update for adult sinusitis to replace the previous 2015 guideline that includes new evidence from 14 guidelines, 194 systematic reviews, and 133 randomized controlled trials as well as a new algorithm to clarify decision making, watchful waiting, and action statement relationships. This update includes some notable statements including:
    - Aspirin exacerbated respiratory disease (AERD) has been added as a chronic condition that modifies management of chronic rhinosinusitis (CRS).
    - Biologics should not routinely be prescribed for the treatment of adults with CRS without polyps.
    - Patients with CRSwNP should be educated about the role of biologics as a means to improve disease-specific quality of life

when either prior medical and surgical therapy has failed or when surgery is not a viable option because of disease status or patient preference.
    - Clinicians should not routinely prescribe antimicrobial therapy for adults with CRS without acute exacerbation or as a mandatory prerequisite for paranasal sinus imaging or surgery.
- **American College of Gastroenterology (ACG) Guideline Update:** The ACG released an update to the 2013 guideline for the diagnosis and management of eosinophilic esophagitis (EoE). Some notable updates include:
    - Proton-pump inhibitors (PPIs) are now positioned as a treatment of EoE over diagnostic criterion. Previously, a failed trial of a PPI was required before a definitive diagnosis of EoE could be established.
        - EoE is diagnosed with the following 3 criteria: symptoms of esophageal dysfunction; at least 15 eosinophils per high-power field (eos/hpf) on esophageal biopsy; and an evaluation for non-EoE disorders that cause or potentially contribute to esophageal eosinophilia.
    - High-dose PPIs and swallowed respiratory corticosteroids are still recommended as treatment options for EoE.
    - Dupilumab treatment is suggested as a treatment for EoE in patients 1 year of age or older who are non-responsive or intolerant to PPI therapy. Additionally, it is advised that providers use dupilumab as step-up therapy in difficult-to-treat patients.
- **Global Initiative for Asthma (GINA) Guideline Update:** GINA has released its annual guideline update for 2025. Some notable updates include:
    - Results of the ORACLE2 study have now been included. ORACLE2 supports the longstanding recommendation by GINA that multiple factors, including type 2 biomarkers, should be considered in the assessment of patients' risk of future exacerbations.
    - Treatment recommendations for adults and adolescents still include the two-track treatment recommendations.
        - Track 1 with inhaled corticosteroid (ICS)-formoterol anti-inflammatory reliever remains the preferred treatment approach (if available), because it substantially reduces the risk of severe exacerbations, systemic corticosteroid exposure, and need for urgent health care, compared with short-acting beta$_2$ agonist-based regimens. In addition, it is a simpler regimen, with a single combination medication [ICS plus formoterol, a rapid onset, long-acting beta$_2$ agonist (LABA)] used across steps 1 to 4, to both relieve symptoms and reduce risk.

- **Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guideline Update:** The GOLD guidelines have been updated for 2025 and now include new recommendations for dupilumab and ensifentrine in their treatment algorithms.
    - For patients with persistent breathlessness or exercise limitations on bronchodilator monotherapy, the use of 2 long-acting bronchodilators is recommended. If the addition of a second long-acting bronchodilator does not improve symptoms, the addition of ensifentrine can be considered.
    - In patients treated with a LABA/long-acting muscarinic agonist (LAMA)/ICS who still have exacerbations and have eosinophils ≥300 cells/mcL and symptoms of chronic bronchitis, dupilumab can be considered.

Pipeline:

- **Depemokimab:** Depemokimab is an investigational monoclonal antibody that targets interleukin (IL)-5, a key cytokine in type 2 inflammation, being studied for add-on maintenance treatment of asthma in patients 12 years of age and older with an eosinophilic phenotype and as add-on maintenance treatment of CRSwNP in adults. The safety and efficacy of depemokimab were studied in 4 Phase 3 clinical trials. SWIFT-1 and SWIFT-2 were both multicenter, randomized, double-blind, placebo-controlled trials that evaluated depemokimab in 762 patients with severe asthma and an eosinophilic phenotype characterized by a high eosinophil count and a history of exacerbations despite receiving medium- or high-dose ICS. The annualized rate of exacerbations over 52 weeks was lower in the depemokimab-treated patients compared to those receiving placebo in both trials. ANCHOR-1 and ANCHOR-2 were randomized, double-blind, placebo-controlled, parallel-group clinical trials that evaluated depemokimab in 528 patients with inadequately controlled CRSwNP. The results showed improvements from baseline in the depemokimab group versus placebo in total nasal polyps score and mean nasal obstruction verbal response scale score. A Prescription Drug User Fee Act (PDUFA) date has been set for December 16, 2025 for these 2 indications.
- **Itepekimab:** Itepekimab is an investigational monoclonal antibody that targets IL-33, an initiator and amplifier of broad inflammation in COPD. Itepekimab is being studied in 2 Phase 3 trials, AERIFY-1 and AERIFY-2, to evaluate its safety and efficacy in adults with moderate to severe COPD. AERIFY-1 met its primary endpoint of a statistically significant reduction in moderate or severe exacerbations in former smokers regardless of eosinophilic phenotype and provided a clinically meaningful benefit. AERIFY-2 did not meet the primary endpoint

despite a benefit seen earlier in the study. Sanofi and Regeneron are reviewing the data and will discuss with regulatory authorities to evaluate next steps.

- **Tezspire® (Tezepelumab-ekko):** Tezspire® is a monoclonal antibody that targets and blocks thymic stromal lymphopoietin (TSPL) and is being studied in Phase 3 trials for COPD, OCS-dependent asthma, and EoE. Two Phase 3 trials for moderate to very severe COPD and a baseline eosinophil count of ≥150 cells/mcL have been initiated. Primary results from a Phase 3b trial showed Tezspire® reduced or eliminated OCS use in OCS-dependent patients with severe uncontrolled asthma. Additionally, a Phase 3 trial for patients with EoE has completed enrollment, and Tezspire® was granted Orphan Drug designation by the FDA in 2021 for this indication.

Recommendations

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

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

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

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

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

1. An FDA approved diagnosis of ~~CIU~~ CSU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. For authorization ~~of Xolair®~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
7. For authorization of the ~~Xolair®~~ prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and

b. Member must have had at least 3 doses ~~of Xolair®~~ under the guidance of a health care provider with no hypersensitivity reactions; and
c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage ~~of Xolair®~~; and

8. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
9. A trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
10. For Omlyclo® (omalizumab-igec), a patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
11. Initial dosing will only be approved for 150mg every 4 weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every 4 weeks; and
12. ~~Initial approvals will be for the duration of 3 months at which time compliance will be evaluated for continued approval.~~
13. Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

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

1. An FDA approved diagnosis of IgE-mediated food allergy for the reduction of allergic reactions; and
2. Member must be 1 year of age or older; and
3. Member must have a diagnosis of peanut, milk, egg, wheat, cashew, hazelnut, or walnut allergy confirmed by a positive skin test, positive in vitro test for food-specific IgE, or positive clinician-supervised oral food challenge; and
4. Prescriber must confirm member will use the requested product ~~Xolair®~~ with an allergen-avoidant diet; and
5. Member must have a pretreatment serum IgE level between 30 and 1,850 IU/mL; and

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

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

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

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

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

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

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

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

1. An FDA approved diagnosis of CSU; and

2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. 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
7. 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
8. A patient-specific, clinically significant reason why the member cannot use Xolair® (omalizumab) must be provided; and
9. 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
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 (e.g., improvement in baseline UAS score, improvement in symptoms, reduction in exacerbations). Additionally, compliance will be evaluated for continued approval.

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

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member has moderate to severe disease [i.e., GOLD 2-4 ~~GOLD 2 or GOLD 3~~ airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ~~≥30% and~~ <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and
4. Member must have a blood eosinophil count of ≥300 cells/mcL (can apply to either a recent level or a historical level prior to treatment); and
5. Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and
6. Member is inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated; and

7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
8. Dupixent® must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. Quantities approved must not exceed FDA recommended dosing requirements.

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

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

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

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and

2. Member must be 18 years of age or older; and
3. Member has moderate to severe disease [i.e., GOLD 2-4 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) of <80% predicted]; 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 after which time 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.

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

1. An FDA approved indication for add-on maintenance treatment in members with inadequately controlled CRSwNP; and
2. Member must be 12 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and

5. Tezspire® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Tezspire® in a health care facility, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or
10. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire; and
11. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

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

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

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

Ohtuvayre® (Ensifentrine) Approval Criteria:

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

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

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

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

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

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

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

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (QVAR® RediHaler®)	budesonide/formoterol (Symbicort Aerosphere®)
budesonide (Pulmicort Flexhaler®)	ciclesonide (Alvesco®)
budesonide/formoterol (Symbicort®)$^{\beta}$ – **Brand Preferred**	fluticasone propionate (Flovent®)
fluticasone furoate (Arnuity® Ellipta®) – **Brand Preferred**	fluticasone furoate/vilanterol (Breo® Ellipta®) – **Brand Preferred**

fluticasone propionate/salmeterol (Advair®)	fluticasone propionate/salmeterol (AirDuo RespiClick®)
mometasone furoate (Asmanex®)	mometasone furoate/formoterol 50mcg/5mcg (Dulera®)
mometasone furoate/formoterol (Dulera®)◊	

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

Utilization Details of Asthma and COPD Maintenance Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ICS/LABA COMBO PRODUCTS						
TIER-1 UTILIZATION						
SYMBICORT AER 160/4.5MCG	17,008	5,658	$4,655,326.00	$273.71	3.01	12.10%
SYMBICORT AER 80/4.5MCG	9,259	3,841	$2,125,573.68	$229.57	2.41	5.52%
FLUTIC/SALME AER 250/50MCG	9,147	3,579	$1,000,387.62	$109.37	2.56	2.60%
FLUTIC/SALME AER 115/21MCG	6,115	2,377	$1,663,173.39	$271.98	2.57	4.32%
DULERA AER 200/5MCG	4,221	1,171	$1,532,333.08	$363.03	3.6	3.98%
ADVAIR HFA AER 115/21MCG	3,892	1,390	$1,252,893.47	$321.92	2.8	3.26%
FLUTIC/SALME AER 100/50MCG	3,262	1,374	$284,925.07	$87.35	2.37	0.74%
FLUTIC/SALME AER 500/50MCG	2,989	1,034	$460,723.22	$154.14	2.89	1.20%
DULERA AER 100/5MCG	2,815	937	$1,015,635.69	$360.79	3	2.64%
FLUTIC/SALME AER 45/21MCG	2,231	839	$482,127.20	$216.10	2.66	1.25%
ADVAIR DISKUS AER 250/50MCG	2,071	897	$503,657.81	$243.20	2.31	1.31%
FLUTIC/SALME AER 230/21MCG	1,872	680	$697,966.80	$372.85	2.75	1.81%
ADVAIR HFA AER 45/21MCG	920	359	$227,853.94	$247.67	2.56	0.59%
WIXELA INHUB AER 250/50MCG	902	573	$108,837.99	$120.66	1.57	0.28%
ADVAIR DISKUS AER 500/50MCG	806	297	$270,590.02	$335.72	2.71	0.70%
ADVAIR HFA AER 230/21MCG	786	303	$363,886.97	$462.96	2.59	0.95%
ADVAIR DISKUS AER 100/50MCG	628	291	$111,989.83	$178.33	2.16	0.29%
WIXELA INHUB AER 100/50MCG	411	258	$36,187.02	$88.05	1.59	0.09%
BUDES/FORMOT AER 80/4.5MCG	397	222	$69,971.29	$176.25	1.79	0.18%
BUDES/FORMOT AER 160/4.5MCG	313	230	$71,605.46	$228.77	1.36	0.19%
BREYNA AER 80/4.5MCG	297	168	$58,296.47	$196.28	1.77	0.15%
WIXELA INHUB AER 500/50MCG	291	169	$45,450.00	$156.19	1.72	0.12%
BREYNA AER 160/4.5MCG	274	146	$59,058.16	$215.54	1.88	0.15%
FLUTIC/SALME INH 113/14MCG	12	8	$1,387.90	$115.66	1.5	0.00%
FLUTIC/SALME INH 55/14MCG	9	5	$1,066.81	$118.53	1.8	0.00%
FLUTIC/SALME INH 232/14MCG	9	7	$1,023.88	$113.76	1.29	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**70,937**	**26,813**	**$17,101,928.77**	**$241.09**	**2.65**	**44.44%**
TIER-2 UTILIZATION						
BREO ELLIPTA INH 100/25MCG	269	93	$106,650.31	$396.47	2.89	0.28%
BREO ELLIPTA INH 200/25MCG	216	68	$84,215.03	$389.88	3.18	0.22%
FLUTIC/VILAN INH 100/25MCG	23	13	$5,889.89	$256.08	1.77	0.02%
FLUTIC/VILAN INH 200/25MCG	23	17	$5,844.48	$254.11	1.35	0.02%
DULERA AER 50/5MCG	13	6	$4,413.61	$339.51	2.17	0.01%
BREO ELLIPTA INH 50/25MCG	9	8	$3,616.75	$401.86	1.13	0.01%
AIRDUO RESPICLICK INH 55/14MCG	3	2	$1,642.63	$547.54	1.5	0.00%
SUBTOTAL	**556**	**207**	**$212,272.70**	**$381.79**	**2.69**	**0.55%**
ICS/LABA TOTAL	**71,493**	**27,020**	**$17,314,201.47**	**$242.18**	**2.65**	**44.99%**
INDIVIDIUAL COMPONENT ICS PRODUCTS						
TIER-1 UTILIZATION						
BUDESONIDE SUS 0.5MG/2ML	3,473	1,727	$246,850.87	$71.08	2.01	0.64%
BUDESONIDE SUS 0.25MG/2ML	2,755	1,680	$206,908.03	$75.10	1.64	0.54%
ASMANEX HFA AER 100MCG	1,944	1,296	$213,397.46	$109.77	1.5	0.55%
PULMICORT INH 90MCG	1,144	579	$255,644.66	$223.47	1.98	0.66%
QVAR REDIHALER AER 40MCG	737	546	$162,355.85	$220.29	1.35	0.42%
ASMANEX HFA AER 50MCG	695	495	$69,677.23	$100.26	1.4	0.18%
PULMICORT INH 180MCG	686	331	$195,325.32	$284.73	2.07	0.51%
BUDESONIDE SUS 1MG/2ML	454	155	$140,153.13	$308.71	2.93	0.36%
QVAR REDIHALER AER 80MCG	392	251	$112,346.10	$286.60	1.56	0.29%
ARNUITY ELLIPTA INH 100MCG	383	176	$78,408.68	$204.72	2.18	0.20%
ASMANEX HFA AER 200MCG	302	178	$37,591.37	$124.47	1.7	0.10%
ARNUITY ELLPITA INH 200MCG	126	50	$34,713.79	$275.51	2.52	0.09%
ASMANEX 60 AER 220MCG	116	59	$15,505.21	$133.67	1.97	0.04%
ARNUITY ELLIPTA INH 50MCG	96	64	$19,926.75	$207.57	1.5	0.05%
ASMANEX 120 AER 220MCG	79	36	$14,824.75	$187.66	2.19	0.04%
ASMANEX 30 AER 110MCG	75	54	$7,733.62	$103.11	1.39	0.02%
ASMANEX 30 AER 220MCG	63	28	$7,928.16	$125.84	2.25	0.02%
PULMICORT SUS 0.25MG/2ML	3	3	$1,040.96	$346.99	1	0.00%
PULMICORT SUS 0.5MG/2ML	2	1	$612.92	$306.46	2	0.00%
SUBTOTAL	**13,525**	**7,709**	**$1,820,944.86**	**$134.64**	**1.75**	**4.73%**
TIER-2 UTILIZATION						
FLUTICASONE HFA AER 110MCG	12,838	5,518	$2,405,214.73	$187.35	2.33	6.25%
FLUTICASONE HFA AER 44MCG	11,797	5,423	$1,661,094.56	$140.81	2.18	4.32%
FLUTICASONE HFA AER 220MCG	1,104	484	$326,791.99	$296.01	2.28	0.85%
FLUTICASONE AER 100MCG	233	107	$35,992.65	$154.47	2.18	0.09%
FLUTICASONE AER 50MCG	205	90	$29,261.79	$142.74	2.28	0.08%
FLUTICASONE AER 250MCG	124	47	$26,211.43	$211.38	2.64	0.07%
FLOVENT HFA AER 110MCG	46	26	$12,610.96	$274.15	1.77	0.03%
FLOVENT HFA AER 44MCG	33	28	$7,090.02	$214.85	1.18	0.02%
ALVESCO AER 80MCG	24	11	$6,587.43	$274.48	2.18	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALVESCO AER 160MCG	18	4	$4,941.32	$274.52	4.5	0.01%
FLOVENT HFA AER 220MCG	7	5	$3,732.77	$533.25	1.4	0.01%
FLOVENT DISKUS AER 250MCG	3	2	$821.13	$273.71	1.5	0.00%
FLOVENT DISKUS AER 100MCG	1	1	$207.41	$207.41	1	0.00%
FLOVENT DISKUS AER 50MCG	1	1	$197.19	$197.19	1	0.00%
SUBTOTAL	**26,434**	**11,747**	**$4,520,755.38**	**$171.02**	**2.25**	**11.75%**
ICS TOTAL	**39,959**	**19,456**	**$6,341,700.24**	**$158.71**	**2.05**	**16.48%**
INDIVIDUAL COMPONENT LAMA PRODUCTS						
TIER-1 UTILIZATION						
SPIRIVA SPR 2.5MCG	9,048	2,351	$4,643,971.85	$513.26	3.85	12.07%
SPIRIVA AER 1.25MCG	4,788	1,288	$2,430,657.78	$507.66	3.72	6.32%
SPIRIVA CAP HANDIHALER 18MCG	4,545	1,514	$2,756,884.59	$606.58	3	7.16%
INCRUSE ELLIPTA INH 62.5MCG	801	259	$278,754.28	$348.01	3.09	0.72%
TUDORZA PRESSAIR AER 400MCG/ACT	69	18	$31,027.79	$449.68	3.83	0.08%
TIOTROPIUM BROM CAP 18MCG	52	34	$30,205.43	$580.87	1.53	0.08%
SUBTOTAL	**19,303**	**5,464**	**$10,171,501.72**	**$526.94**	**3.53**	**26.43%**
TIER-2 UTILIZATION						
YUPELRI SOL 175MCG/3ML	95	24	$137,208.95	$1,444.30	3.96	0.36%
SUBTOTAL	**95**	**24**	**$137,208.95**	**$1,444.30**	**3.96**	**0.36%**
LAMA TOTAL	**19,398**	**5,488**	**$10,308,710.67**	**$531.43**	**3.53**	**26.79%**
LABA/LAMA/ICS COMBINATION PRODUCTS						
TRELEGY AER 100/62.5/25MCG	2,240	588	$1,454,696.42	$649.42	3.81	3.78%
TRELEGY AER 200/62.5/25MCG	2,169	489	$1,416,959.54	$653.28	4.44	3.68%
BREZTRI AEROSPHERE 160/9/4.8MCG	1,319	390	$847,680.20	$642.67	3.38	2.20%
LABA/LAMA/ICS TOTAL	**5,728**	**1,467**	**$3,719,336.16**	**$649.33**	**3.9**	**9.66%**
INDIVIDUAL COMPONENT LABA PRODUCTS						
TIER-1 UTILIZATION						
SEREVENT DISKUS AER 50MCG	681	284	$358,272.54	$526.10	2.4	0.93%
SUBTOTAL	**681**	**284**	**$358,272.54**	**$526.10**	**2.4**	**0.93%**
TIER-2 UTILIZATION						
ARFORMOTEROL NEB 15MCG/2ML	108	24	$11,950.17	$110.65	4.5	0.03%
FORMOTEROL NEB 20MCG/2ML	75	19	$25,427.91	$339.04	3.95	0.07%
STRIVERDI AER 2.5MCG	7	2	$1,862.05	$266.01	3.5	0.00%
PERFOROMIST NEB 20MCG	3	1	$3,378.09	$1,126.03	3	0.01%
BROVANA NEB 15MCG	1	1	$1,164.09	$1,164.09	1	0.00%
SUBTOTAL	**194**	**47**	**$43,782.31**	**$225.68**	**4.13**	**0.11%**
LABA TOTAL	**875**	**331**	**$402,054.85**	**$459.49**	**2.64**	**1.04%**
LABA/LAMA COMBINATION PRODUCTS						
ANORO ELLIPTA AER 62.5/25MCG	346	93	$163,155.71	$471.55	3.72	0.42%
STIOLTO AER 2.5/2.5MCG	268	87	$127,140.00	$474.40	3.08	0.33%
UMECLID/VILAN INH 62.5/25MCG	16	12	$5,222.60	$326.41	1.33	0.01%
BEVESPI AER 9/4.8MCG	14	6	$5,950.61	$425.04	2.33	0.02%
LABA/LAMA TOTAL	**644**	**198**	**$301,468.92**	**$468.12**	**3.25**	**0.78%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PDE4 INHIBITOR PRODUCTS						
ROFLUMILAST TAB 500MCG	274	50	$5,702.20	$20.81	5.48	0.01%
ROFLUMILAST TAB 250MCG	57	14	$4,180.80	$73.35	4.07	0.01%
DALIRESP TAB 250MCG	4	1	$1,622.16	$405.54	4	0.00%
PDE4 INHIBITOR TOTAL	**335**	**65**	**$11,505.16**	**$34.34**	**5.15**	**0.03%**
PDE3/PDE4 INHIBITOR PRODUCTS						
OHTUVAYRE SUS 3MG/2.5ML	29	15	$85,847.89	$2,960.27	1.93	0.22%
PDE3/PDE4 INHIBITOR TOTAL	**29**	**15**	**$85,847.89**	**$2,960.27**	**1.93**	**0.22%**
TOTAL	**138,461**	**40,744***	**$38,484,825.36**	**$277.95**	**3.4**	**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; 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; TAB = tablet; UMECLID = umeclidinium; VILAN = vilanterol
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Utilization Details of Asthma-Indicated Monoclonal Antibodies: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DUPILUMAB PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	5,725	999	$22,896,265.29	$3,999.35	5.73	50.08%
DUPIXENT INJ 300MG/2ML SYR	1,780	342	$6,998,213.52	$3,931.58	5.2	15.31%
DUPIXENT INJ 200MG/1.14ML PEN	1,434	262	$5,407,246.83	$3,770.74	5.47	11.83%
DUPIXENT INJ 200MG/1.14ML SYR	1,222	269	$4,601,884.32	$3,765.86	4.54	10.07%
SUBTOTAL	**10,161**	**1,872**	**$39,903,609.96**	**$3,927.13**	**5.43**	**87.28%**
OMALIZUMAB PRODUCTS						
XOLAIR INJ 150MG/ML SYR	258	47	$678,272.73	$2,628.96	5.49	1.48%
XOLAIR INJ 300MG/2ML PEN	136	33	$453,903.32	$3,337.52	4.12	0.99%
XOLAIR INJ 75MG/0.5ML SYR	94	16	$92,190.16	$980.75	5.88	0.20%
XOLAIR INJ 300MG/2ML SYR	84	20	$255,316.30	$3,039.48	4.2	0.56%
XOLAIR INJ 75MG/0.5ML PEN	53	10	$51,391.15	$969.64	5.3	0.11%
XOLAIR INJ 150MG/ML PEN	39	9	$75,277.12	$1,930.18	4.33	0.16%
XOLAIR SOL 150MG	19	5	$85,412.62	$4,495.40	3.8	0.19%
SUBTOTAL	**683**	**140**	**$1,691,763.40**	**$2,476.96**	**4.88**	**3.70%**
BENRALIZUMAB PRODUCTS						
FASENRA INJ 30MG/ML PEN	257	72	$1,484,985.51	$5,778.15	3.57	3.25%
FASENRA INJ 30MG/ML SYR	91	21	$525,752.36	$5,777.50	4.33	1.15%
FASENRA INJ 10MG/0.5ML SYR	4	2	$7,671.41	$1,917.85	2	0.02%
SUBTOTAL	**352**	**95**	**$2,018,409.28**	**$5,734.12**	**3.71**	**4.41%**
MEPOLIZUMAB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NUCALA INJ 100MG/ML PEN	198	32	$765,997.75	$3,868.68	6.19	1.68%
NUCALA INJ 100MG	29	7	$101,831.56	$3,511.43	4.14	0.22%
NUCALA INJ 40MG/0.4ML SYR	29	5	$43,564.25	$1,502.22	5.8	0.10%
NUCALA INJ 100MG/ML SYR	7	2	$26,676.30	$3,810.90	3.5	0.06%
SUBTOTAL	**263**	**46**	**$938,069.86**	**$3,566.81**	**5.72**	**2.05%**
TEZEPELUMAB-EKKO PRODUCTS						
TEZSPIRE INJ 210MG/1.91ML PEN	210	49	$965,353.38	$4,596.92	4.29	2.11%
TEZSPIRE SOL 210MG/1.91ML SYR	50	13	$201,715.10	$4,034.30	3.85	0.44%
SUBTOTAL	**260**	**62**	**$1,167,068.48**	**$4,488.72**	**4.19**	**2.55%**
TOTAL	**11,719**	**1,956***	**$45,718,920.98**	**$3,901.26**	**5.99**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution; SYR = syringe
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
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 INJ (J2357)	452	78	$804,128.53	$1,779.05	5.79
TEZEPELUMAB-EKKO INJ (J2356)	120	19	$382,983.03	$3,191.53	6.32
MEPOLIZUMAB INJ (J2812)	64	10	$106,920.05	$1,670.63	6.4
BENRALIZUMAB INJ (J0517)	63	22	$241,359.61	$3,831.10	2.86
TOTAL	**699**	**128**	**$1,535,391.22**	**$2,196.55**	**5.46**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: Utilization data includes all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

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Appendix N

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

Oklahoma Health Care Authority
November 2025

Current Prior Authorization Criteria

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

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. For authorization consideration of Firazyr® (icatibant) or Kalbitor® (ecallantide), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) must be provided; or
4. For authorization consideration of Ruconest® (C1 esterase inhibitor) or Sajazir™ (icatibant), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor), Firazyr® (icatibant), or Kalbitor® (ecallantide) must be provided.

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

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and

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

Market News and Updates[1,2,3]

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

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

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

Therapeutic Class: FXIIA inhibitor monoclonal antibody

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

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

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

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

- Key Inclusion Criteria:
  - Diagnosis of HAE Type 1 or 2
  - 12 years of age and older
  - At least 3 documented HAE attacks within the 3 months prior to screening or before commencing any prophylactic therapy before screening
  - Willing to discontinue current longer-term prophylactic treatments at least 2 weeks before the run-in period
- Key Exclusion Criteria:
  - Concomitant diagnosis of another form of angioedema

- Intervention(s):
  - Andembry® 400mg loading dose followed by 200mg once monthly vs. volume-matched placebo
- Primary Endpoint(s):
  - Number of HAE attacks per month during the 6-month treatment period
- Results:
  - Statistically significant lower mean number of HAE attacks per month in the Andembry® group [0.27; 95% confidence interval (CI): 0.05, 0.49] vs. placebo (2.01; 95% CI: 1.44, 2.57), which is a difference of -87% (95% CI: -96, -58; P<0.0001)

Dawnzera™ (Donidalorsen) Product Summary[6]

Therapeutic Class: Prekallikrein-directed antisense oligonucleotide

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

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

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

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

- Key Inclusion Criteria:
  - Diagnosis of HAE Type 1 or 2
  - 12 years of age and older
  - ≥2 investigator-confirmed HAE attacks during the 8-week run-in period
  - Willing to discontinue current longer-term prophylactic treatments prior to the trial
- Intervention(s):
  - Dawnzera™ 80mg once sub-Q every 4 weeks, Dawnzera™ 80mg sub-Q once every 8 weeks, or matching placebo
- Primary Endpoint(s):
  - Number of HAE attacks per 4 weeks from week 0 to week 24
- Results:
  - Statistically significantly lower mean number of HAE attacks every 4 weeks in the Dawnzera™ group dosed every 4 weeks (0.44; 95% CI: 0.27, 0.73; P<0.001) and Dawnzera group dosed every 8 weeks (1.02; 95% CI: 0.65, 1.49; P=0.004) vs. placebo (2.26; 95% CI: 1.66, 3.09)

Cost Comparison: HAE Prophylaxis Products

Product	Cost Per Year*
Andembry® (garadacimab-gxii) 200mg/1.2mL autoinjector	**$799,399.99**
Dawnzera™ (donidalorsen) 80mg/0.8mL autoinjector	**$747,006.00**
Takhzyro® (lanadelumab-flyo) 300mg/2mL prefilled syringe	$680,815.20
Cinryze® (C1 esterase inhibitor) 500 IU/5mL vial	$665,223.52
Haegarda® (C1 esterase inhibitor) 2,000 and 3,000 IU vials	$629,323.76
Orladeyo® (berotralstat) 150mg capsule	$571,941.39

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

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

Therapeutic Class: Plasma kallikrein inhibitor

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

How Supplied: 300mg film-coated tablets

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

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

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

- Key Inclusion Criteria:
  - Diagnosis of HAE Type 1 or 2
  - 12 years of age and older
  - If receiving long-term prophylaxis, must be on a stable regimen and remain on that regimen for the duration of the trial
  - At least 2 documented HAE attacks within 3 months prior to screening or randomization
- Key Exclusion Criteria:
  - Concomitant diagnosis of another form of chronic angioedema

    - Clinically significant history of poor response to other on-demand therapies for HAE
    - Use of angiotensin-converting enzyme (ACE) inhibitors within 7 days prior to randomization
- Intervention(s):
    - 3-way crossover of Ekterly® 600mg vs. 300mg vs. placebo
    - A second dose could be administered after 3 hours
    - Participants were required to treat an HAE attack prior to crossover to the next treatment period
    - Laryngeal attacks determined to be severe by the participant were not treated in the trial
- Primary Endpoint(s):
    - Time-to-event analysis of time to symptom relief
- Results:
    - Statistically significant median faster time to the beginning of symptom relief with the 300mg dose (1.61 hours) and 600mg dose (1.79 hours) vs. placebo (6.72 hours) (P<0.001 and P=0.001 for the individual treatment doses, respectively)

Cost Comparison (HAE Treatment Products):

Product	Cost Per Treatment Dose*
Ekterly® (sebetralstat) 300mg tablet	**$16,720.00**
Kalbitor® (ecallantide) 10mg/mL vial	$17,119.73
Ruconest® (C1 esterase inhibitor) 2,100 IU vial	$15,441.72
Berinert® (C1 esterase inhibitor) 500 IU vial	$11,378.85
Firazyr® (icatibant) 30mg/3mL prefilled syringe	$3,759.51
Sajazir™ (icatibant) 30mg/3mL prefilled syringe (branded generic)	$3,759.51

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

Estimation of Savings

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

Differences in cost between utilization of a lower tiered product versus a higher tiered product as a result of the Tier structure represents cost savings. The following estimations are based on the proposed recommendations for placement of the products into a Tier structure and the costs listed in the Cost Comparison tables in the Product Summary sections, which do not represent rebated prices or net costs. For the HAE prophylaxis products, the cost difference between Andembry® (the highest cost option) and Orladeyo® (the lowest cost option) is $227,458.60 per member per year based on the FDA recommended dosing for each product. For the HAE treatment products, the cost difference between Kalbitor® (the highest cost option) and Firazyr® (the lowest cost option) is $13,360.22 per treatment dose.

Recommendations

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

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

PA = prior authorization

Initial Approval Criteria for All HAE Prophylaxis Products:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Prescriber must verify the member or caregiver has been trained by a health care professional on proper storage and administration of the prescribed product; and
7. For products requiring weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
8. Quantity limits will apply based on FDA-approved dosing.

HAE Prophylaxis Products Tier-2 Approval Criteria:

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

HAE Prophylaxis Products Tier-3 Approval Criteria:

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

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

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

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

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

PA = prior authorization

Initial Approval Criteria for All HAE Treatment Products:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. Prior authorization requests for products administered via injection must indicate if the product is to be self-administered or to be administered by a health care provider; and
    a. For products approved for self-administration per FDA package labeling, the prescriber must verify the member or caregiver has

been trained by a health care professional on proper storage and administration of the prescribed product; or

b. For products not recommended for self-administration by FDA package labeling, the prescriber must verify the product will be administered by a health care provider; and

4. For products requiring weight-based dosing, the member's recent weight must be provided on the prior authorization request.

HAE Treatment Products Tier-2 Approval Criteria:

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

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

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

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

Appendix O

30-Day Notice to Prior Authorize Rhapsido® (Remibrutinib)

Oklahoma Health Care Authority
November 2025

Introduction[1,2,3]

Chronic spontaneous urticaria (CSU) is a recurrent inflammatory skin condition that is characterized by unpredictable and persistent hives and/or angioedema that lasts >6 weeks. CSU is predominantly a mast-cell driven disease, and histamine and other mediators, such as platelet-activating factor (PAF) and cytokines released from activated skin mast cells, result in sensory nerve activation, vasodilatation, and plasma extravasation as well as cell recruitment to urticarial lesions. Patients with CSU may experience a variety of symptoms along with the hives and angioedema such as itching, sleep disturbance, anxiety, depression, and negative impact on their quality of life.

Estimates of the prevalence of CSU in the United States vary but was previously reported as a point prevalence of 0.1-0.23% but has increased to an estimated 0.78%. Management of CSU focuses on treating until resolution as efficiently and safely as possible by eliminating underlying causes, avoidance of triggers, tolerance induction, and pharmacological treatment. First line recommended treatments include second generation histamine-1 (H1) antihistamines up to 4 times the standard dose, if needed. For patients who do not benefit from H1 antihistamines, Xolair® (omalizumab) or Dupixent® (dupilumab) are U.S. Food and Drug Administration (FDA)-approved treatment options. Approval criteria and utilization data for Xolair® and Dupixent® can be found in the Fiscal Year 2025 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications report, which is also being presented at the November 2025 Drug Utilization Review (DUR) Board meeting.

On September 30, 2025, Rhapsido® (remibrutinib) was approved by the FDA for the treatment of CSU in adults who remain symptomatic despite H1 antihistamine treatment.

Rhapsido® (Remibrutinib) Product Summary[4,5]

Therapeutic Class: Kinase inhibitor

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

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

How Supplied: 25mg oral tablet

Dosing and Administration:

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

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

- Key Inclusion Criteria:
  - Diagnosis of CSU inadequately controlled by second generation H1 antihistamines as defined by the presence of itch and hives for ≥6 consecutive weeks
  - Weekly urticaria activity score (UAS) ≥16, a weekly itch severity score (ISS7) ≥6, and a weekly hives severity score (HSS7) ≥6 for 7 days prior to randomization
- Intervention(s): Patients were randomized 2:1 to Rhapsido® 25mg or placebo twice daily.
- Primary Endpoint(s): The co-primary endpoints were absolute change from baseline in ISS7 and HSS7 at week 12.
  - The ISS7 (range 0 to 21) was defined as the sum of the daily itch severity scores (range 0 to 3) recorded over a 7-day period.
  - The HSS7 (range 0 to 21) was defined as the sum of the daily hive severity scores (range 0 to 3) recorded over a 7-day period.
- Results:
  - REMIX-1:
    - Change from baseline in ISS7 was -9.52 in the Rhapsido® group vs. -6.89 in the placebo group [treatment difference: -2.63; 95% confidence interval (CI): -3.70, -1.56; P<0.001]
    - Change from baseline in HSS7 was -10.47 in the Rhapsido® group vs. -6.86 in the placebo group (treatment difference: -3.61; 95% CI: -4.85, -2.36; P<0.001)
  - REMIX-2:
    - Change from baseline in ISS7 was -8.95 in the Rhapsido® group vs. -5.72 in the placebo group (treatment difference: -3.23; 95% CI: -4.29, -2.16; P<0.001)
    - Change from baseline in HSS7 was -10.47 in the Rhapsido® group vs. -6.00 in the placebo group (treatment difference: -4.47; 95% CI: -5.71, -3.23; P<0.001)

Cost Comparison:

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Rhapsido® (remibrutinib) 25mg tablet	**$75.35**	**$4,521.00***	**$54,252.00**
Dupixent® (dupilumab) 300mg/2mL	$962.38	$3,849.52⁺	$50,043.76
Xolair® (mepolizumab) 300mg/2mL	$1,337.88	$2,675.76^	$34,784.88

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

Recommendations

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

Rhapsido® (Remibrutinib) Approval Criteria

1. An FDA approved diagnosis of chronic spontaneous urticaria (CSU); and
2. Member must be 18 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. 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
7. Member must have a documented trial of (or have a contraindication or documented intolerance to) all of the following therapies:
    a. Second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
    b. Xolair® (omalizumab) for at least 12 weeks at recommended dosing; and
    c. Dupixent® (dupilumab) for at least 12 weeks at recommended dosing; and
8. 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.

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Appendix P

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: October 29, 2025

FDA Moves to Accelerate Biosimilar Development and Lower Drug Costs

The FDA announced significant action to make it faster and less costly to develop biosimilar medications, which are lower-cost "generic" alternatives to biologic drugs that treat serious and chronic diseases.

In a new draft guidance, the FDA proposes major updates to simplify biosimilarity studies and reduce unnecessary clinical testing. The FDA through a separate initiative also plans to make it easier for biosimilars to be developed as interchangeable with brand-name biologics, helping patients and pharmacists choose lower-cost options more easily.

Expensive biologic medications make up only 5% of prescriptions in the U.S. but account for 51% of total drug spending as of 2024. FDA-approved biosimilars are as safe and effective as the branded drugs, yet their market share remains below 20%. To date, the FDA has approved 76 biosimilars, corresponding to a small fraction of approved biologics. By contrast, there are more than 30,000 approved generics, exceeding the number of approved brand drugs. Only about 10% of biologic drugs expected to lose patent protection in the next decade currently have a biosimilar in development.

Today's new FDA draft guidance, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies," is based on the FDA's accrued data and experience since the first biosimilar was approved in 2015. Despite requiring 1-3 years and costing $24 million on average, comparative efficacy studies generally have low sensitivity compared to many other analytical assessments. The FDA's new guidance reduces this unnecessary resource-intensive requirement for developers to conduct comparative human clinical studies, allowing them to rely instead on analytical testing to demonstrate product differences.

Currently, in some circumstances, developers perform "switching studies" for biosimilars licensed as interchangeable – a step not required for generic drugs. These additional studies can slow development and create public confusion about biosimilar safety. The FDA now generally does not recommend switching studies.

The approval pathway for biosimilars was established by Congress in 2010 through the Biologics Price Competition and Innovation Act (BPCIA) to promote competition in markets dominated by high-cost biologics. Since then, the FDA has approved 76 biosimilars that provide Americans additional

treatment options for conditions such as cancer, rheumatoid arthritis, diabetes, Crohn's disease, and osteoporosis.

With today's action, the FDA aims to help more companies bring affordable, high-quality biosimilars to market and reduce costs for the American people.

FDA NEWS RELEASE

For Immediate Release: October 16, 2025

FDA Awards First-Ever National Priority Vouchers to 9 Sponsors

The FDA announced 9 voucher recipients under the new Commissioner's National Priority Voucher (CNPV) pilot program. Each recipient has a product with significant potential to address a major national priority, such as meeting a large unmet medical need, reducing downstream health care utilization, addressing a public health crisis, boosting domestic manufacturing, or increasing medication affordability with Most Favored Nation pricing.

Voucher recipients will receive a decision within 1-2 months following filing of a complete application for a drug or biologic. In addition, sponsors will receive enhanced communications with review staff throughout the development process prior to their final submission and during the review period. If necessary, FDA scientists reserve the right to extend the review time if an application is incomplete, there are manufacturing violations, or as they otherwise deem appropriate.

The new CNPV process accelerates the standard 10-12 month timeline by convening a multidisciplinary team of physicians and scientists for a team-based review, interacting frequently with the sponsor to clarify questions, and completing review of the application concurrently. Once all streamlined review steps are complete, the team will convene for a 1-day "tumor board style" meeting.

Each drug review division within the FDA has been charged with nominating a product that they believe meets the stated national priority goals of the program. Sponsors can also apply and have their request reviewed by the designated review division.

The following products were selected:

- Pergoveris® for infertility
- Teplizumab for Type I diabetes
- Cytisinicline for nicotine vaping addiction
- DB-OTO for deafness
- Cenegermin-bkbj for blindness
- RMC-6236 for pancreatic cancer
- Bitopertin for porphyria
- Ketamine for domestic manufacturing of a critical drug for general anesthesia

- Augmentin XR® for domestic manufacturing of a common antibiotic

The FDA anticipates announcing another group of CNPV recipients in the coming months.

FDA NEWS RELEASE

For Immediate Release: September 25, 2025

FDA Removes Risk Evaluation and Mitigation Strategies (REMS) for Caprelsa® (vandetanib)

The FDA removed the Risk Evaluation and Mitigation Strategies (REMS) program for Caprelsa® (vandetanib), a thyroid cancer medication manufactured by Genzyme Corporation (now Sanofi).

The FDA first approved Caprelsa® in 2011 to treat medullary thyroid cancer in patients whose disease has spread or cannot be surgically removed. At the time, a REMS program was required to ensure appropriate heart rhythm monitoring and safe use. After over more than a decade of oversight, REMS assessments reported no cases of Torsades de pointes or unexplained sudden deaths among U.S. patients taking Caprelsa®. Clinical data also showed no concerning patterns of heart rhythm problems.

Caprelsa® will remain available with the same prescribing information, but health care providers will no longer need special certification or extra monitoring beyond standard clinical care.

A REMS is a safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The safety requirements for Caprelsa® included mandatory training for health care providers and monitoring of patients.

Current Drug Shortages Index (as of October 28, 2025):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***

Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***

Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***