OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
October 8, 2025
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – October 8, 2025

DATE: October 1, 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 October meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on the Medication Coverage Authorization Unit – Appendix B

Fall Pipeline Update – Appendix C

Action Item – Vote to Prior Authorize Attruby™ (Acoramidis) and Update the Approval Criteria for the Amyloidosis Medications – Appendix D

Action Item – Vote to Prior Authorize Alyftrek™ (Vanzacaftor/Tezacaftor/Deutivicaftor) and Update the Approval Criteria for the Cystic Fibrosis (CF) Medications – Appendix E

Action Item – Vote to Prior Authorize Vote to Prior Authorize Encelto™ (Revakinagene Taroretcel-lwey) – Appendix F

Action Item – Vote to Prior Authorize Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet and Update the Approval Criteria for the Hyperphosphatemia Medications – Appendix G

Action Item – Vote to Prior Authorize Photrexa®/Photrexa® Viscous (Riboflavin 5'-Phosphate) – Appendix H

Action Item – Vote to Prior Authorize Datroway® (Datopotamab Deruxtecan-dlnk) and Itovebi™ (Inavolisib) and Update the Approval Criteria for the Breast Cancer Medications – Appendix I

Annual Review of Myeloproliferative Neoplasm Medications – Appendix J

Action Item – Annual Review of *Clostridioides difficile* (*C. difficile*) Medications – Appendix K

Action Item – Annual Review of Allergen Immunotherapies – Appendix L

Action Item – Annual Review of Cushing's Syndrome Medications – Appendix M

Action Item – Annual Review of Ophthalmic Anti-Inflammatory Products – Appendix N

Action Item – Annual Review of Hyperoxaluria Medications – Appendix O

Action Item – Annual Review of Anemia Medications – Appendix P

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) – Appendix Q

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 – Appendix R

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 – Appendix S

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – October 8, 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. 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. September 10, 2025 DUR Board Meeting Minutes
   B. September 10, 2025 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit – See Appendix B**
   A. Pharmacy Help Desk Activity for September 2025
   B. Medication Coverage Activity for September 2025

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

5. **Fall Pipeline Update – See Appendix C**
   A. Introduction
   B. Product Summaries
   C. Pipeline Table

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

6. **Action Item – Vote to Prior Authorize Attruby™ (Acoramidis) and Update the Approval Criteria for the Amyloidosis Medications – See Appendix D**
   A. Market News and Updates
   B. Attruby™ (Acoramidis) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Alyftrek® (Vanzacaftor/Tezacaftor/Deutivicaftor) and Update the Approval Criteria for the Cystic Fibrosis (CF) Medications – See Appendix E**
   A. Market News and Updates
   B. Alyftrek® (Vanzacaftor/Tezacaftor/Deutivicaftor) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Encelto™ (Revakinagene Taroretcel-lwey) – See Appendix F**
   A. Encelto™ (Revakinagene Taroretcel-lwey) Product Summary
   B. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet and Update the Approval Criteria for the Hyperphosphatemia Medications – See Appendix G**
   A. Cost Comparison: Lanthanum Carbonate Products
   B. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Photrexa®/Photrexa® Viscous (Riboflavin 5'-Phosphate) – See Appendix H**
    A. Photrexa®/Photrexa® Viscous (Riboflavin 5'-phosphate) Product Summary
    B. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Datroway® (Datopotamab Deruxtecan-dlnk) and Itovebi™ (Inavolisib) and Update the Approval Criteria for the Breast Cancer Medications – See Appendix I**
    A. Market News and Updates
    B. Product Summaries
    C. Cost Comparison: Trastuzumab Products
    D. College of Pharmacy Recommendations

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

12. **Annual Review of Myeloproliferative Neoplasm (MPN) Medications – See Appendix J**
    A. Current Prior Authorization Criteria
    B. Utilization of MPN Medications
    C. Prior Authorization of MPN Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of MPN Medications

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

13. **Action Item – Annual Review of *Clostridioides difficile (C. difficile)* Medications – See Appendix K**
    A. Current Prior Authorization Criteria
    B. Utilization of *C. difficile* Medications
    C. Prior Authorization of *C. difficile* Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of *C. difficile* Medications

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

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

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

15. **Action Item – Annual Review of Cushing's Syndrome Medications – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Cushing's Syndrome Medications
    C. Prior Authorization of Cushing's Syndrome Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Cushing's Syndrome Medications

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

16. **Action Item – Annual Review of Ophthalmic Anti-Inflammatory Products – See Appendix N**
    A. Current Prior Authorization Criteria
    B. Utilization of Ophthalmic Anti-Inflammatory Products
    C. Prior Authorization of Ophthalmic Anti-Inflammatory Products
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Ophthalmic Anti-Inflammatory Products

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

17. **Action Item – Annual Review of Hyperoxaluria Medications – Appendix O**
    A. Current Prior Authorization Criteria
    B. Utilization of Hyperoxaluria Medications
    C. Prior Authorization of Hyperoxaluria Medications

D. Market News and Updates
E. College of Pharmacy Recommendations

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

18. Action Item – Annual Review of Anemia Medications – See Appendix P

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

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

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) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Targeted Immunomodulator Agents
C. Prior Authorization of Targeted Immunomodulator Agents
D. Market News and Updates
E. Cost Comparison
F. College of Pharmacy Recommendations
G. Utilization Details of Targeted Immunomodulator Agents

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

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 – See Appendix R

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

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

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 – See Appendix S

A. Current Prior Authorization Criteria
B. Utilization of Anticoagulants and Platelet Aggregation Inhibitors
C. Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Anticoagulants and Platelet Aggregation Inhibitors

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

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

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

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

A. Amino Acid Disorder Medications
B. Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications
C. Atopic Dermatitis Medications
D. Brinsupri™ (Brensocatib)
E. Butalbital Medications
F. Multiple Myeloma Medications
G. Osteoporosis Medications and Denosumab Products

*Future product and class reviews subject to change.

24. 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 SEPTEMBER 10, 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, Pharm.D.	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director		X
Christina Foss, Chief of Staff; State Medicaid Director		X
Gentry Kincade, 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:	
Taha Khan, Vertex	Kenneth Berry, Alkermes
Irene Chung, Aetna	Jenna Doerr, Artia Solutions
Adriana Sanchez, Bridge Bio	Tania Gregorian, Bridge Bio
Heather Higgins, Glaukos	Jay Milton, Bayer
Andrew Delgado, Bristol Myers Squibb	Craig Klein
Porscha Showers, Gilead	Deidra Williams, Humana
Jennifer Lauper, Bristol Myers Squibb	Kristen Winters, Centene
Roberto Pedraza, Vertex	Scott Burns, Johnson & Johnson
JJ Roth, Mirum	David Prather, Novo Nordisk
Bryan Steffan, Boehringer	Brent Parker, Merck
Melissa Abbott, Galderma	

PRESENT FOR PUBLIC COMMENT:	
Taha Khan, Vertex	

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 19 TAHA KHAN

ACTION: NONE REQUIRED

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

3A: JULY 9, 2025 DUR MINUTES

3B: JULY 9, 2025 DUR BOARD RECOMMENDATIONS MEMORANDUM

3C: AUGUST 13, 2025 DUR BOARD RECOMMENDATIONS MEMORANDUM

Materials included in agenda packet; presented by Dr. Haymore

Dr. Holderread moved to approve; seconded by Dr. Weakley

ACTION: MOTION CARRIED

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

4A: PHARMACY HELPDESK ACTIVITY FOR AUGUST 2025

4B: MEDICATION COVERAGE ACTIVITY FOR AUGUST 2025

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **IMPACT OF CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) MODULATORS**

5A: INTRODUCTION

5B: CFTR MODULATORS

5C: CFTR MODULATOR IMPACT

5D: SOONERCARE IMPACT
5E: CONCLUSIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE AZMIRO™ (TESTOSTERONE CYPIONATE) AND UNDECATREX™ (TESTOSTERONE UNDECANOATE) AND UPDATE THE APPROVAL CRITERIA FOR THE TESTOSTERONE PRODUCTS
6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: COST COMPARISON: TESTOSTERONE PRODUCTS
6D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ZEVASKYN™ (PRADEMAGENE ZAMIKERACEL) AND UPDATE THE APPROVAL CRITERIA FOR THE EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS
7A: MARKET NEWS AND UPDATES
7B: ZEVASKYN™ (PRADEMAGENE ZAMIKERACEL) PRODUCT SUMMARY
7C: COST COMPARISON: EB MEDICATIONS
7D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Dr. Weakley
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE ZUNVEYL® (BENZGALANTAMINE)
8A: MARKET NEWS AND UPDATES
8B: COST COMPARISON: BENZGALANTAMINE AND GALANTAMINE PRODUCTS
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE BLUJEPA (GEPOTIDACIN), EMBLAVEO™ (AZTREONAM/AVIBACTAM), LIKMEZ™ (METRONIDAZOLE ORAL SUSPENSION), AND METRONIDAZOLE 125MG TABLET AND 375MG CAPSULE AND UPDATE THE APPROVAL CRITERIA FOR THE VARIOUS SYSTEMIC ANTIBIOTICS
9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: COST COMPARISON: METRONIDAZOLE PRODUCTS
9D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Patatanian moved to approve; seconded by Dr. Weakley
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE TRAMADOL 75MG TABLET AND UPDATE THE APPROVAL CRITERIA FOR THE OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
10A: MARKET NEWS AND UPDATES

10B: COST COMPARISON: TRAMADOL
10C: 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

AGENDA ITEM NO. 11: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE TOPICAL CORTICOSTEROIDS
11A: 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. 12: VOTE TO PRIOR AUTHORIZE RYONCIL® (REMESTEMCEL-L-RKND) AND UPDATE THE APPROVAL CRITERIA FOR THE MISCELLANEOUS CANCER MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: RYONCIL® (REMESTEMCEL-L-RKND) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF CAMZYOS® (MAVACAMTEN)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF CAMZYOS® (MAVACAMTEN)
13C: PRIOR AUTHORIZATION OF CAMZYOS® (MAVACAMTEN)
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF CAMZYOS® (MAVACAMTEN)
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF SYNAGIS® (PALIVIZUMAB)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF SYNAGIS® (PALIVIZUMAB)
14C: PRIOR AUTHORIZATION OF SYNAGIS® (PALIVIZUMAB)
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS
14F: UTILIZATION DETAILS OF SYNAGIS® (PALIVIZUMAB)
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF JYNARQUE® (TOLVAPTAN)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF JYNARQUE® (TOLVAPTAN)
15C: PRIOR AUTHORIZATION OF JYNARQUE® (TOLVAPTAN)
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF JYNARQUE® (TOLVAPTAN)
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Holderread

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF BREAST CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DATROWAY® (DATOPOTAMAB DERUXTECAN-DLNK) AND ITOVEBI™ (INAVOLISIB)

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF BREAST CANCER MEDICATIONS
16C: PRIOR AUTHORIZATION OF BREAST CANCER MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: COST COMPARISON: TRASTUZUMAB PRODUCTS
16G: COLLEGE OF PHARMACY RECOMMENDATIONS
16H: UTILIZATION DETAILS OF BREAST CANCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko

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

<u>AGENDA ITEM NO. 17:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE ENCELTO™ (REVAKINAGENE TARORETCEL-LWEY)

17A: INTRODUCTION
17B: ENCELTO™ (REVAKINAGENE TARORETCEL-LWEY) PRODUCT SUMMARY
17C: COLLEGE OF PHARMACY RECOMMENDATION

Materials included in agenda packet; presented by Dr. Moss

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

<u>AGENDA ITEM NO. 18:</u> ANNUAL REVIEW OF HYPERPHOSPHATEMIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE FOSRENOL® (LANTHANUM CARBONATE) 750MG AND 1,000MG ORAL POWDER PACKET

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF HYPERPHOSPHATEMIA MEDICATIONS
18C: PRIOR AUTHORIZATION OF HYPERPHOSPHATEMIA MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: COST COMPARISON: LANTHANUM CARBONATE PRODUCTS
18F: COLLEGE OF PHARMACY RECOMMENDATIONS
18G: UTILIZATION DETAILS OF HYPERPHOSPHATEMIA MEDICATIONS

Materials included in agenda packet; presented by Dr. DeRemer

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

<u>AGENDA ITEM NO. 19:</u> ANNUAL REVIEW OF CYSTIC FIBROSIS (CF) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALYFTREK™ (VANZACAFTOR/TEZACAFTOR/DEUTIVICAFTOR)

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF CF MEDICATIONS
19C: PRIOR AUTHORIZATION OF CF MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: ALYFTREK™ (VANZACAFTOR/TEZACAFTOR/DEUTIVICAFTOR) PRODUCT SUMMARY
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF CF MEDICATIONS

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

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

<u>AGENDA ITEM NO. 20:</u> ANNUAL 20. ANNUAL REVIEW OF AMYLOIDOSIS MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ATTRUBY™ (ACORAMIDIS)

20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF AMYLOIDOSIS MEDICATIONS
20C: PRIOR AUTHORIZATION OF AMYLOIDOSIS MEDICATIONS
20D: MARKET NEWS AND UPDATES
20E: ATTRUBY™ (ACORAMIDIS) PRODUCT SUMMARY
20F: COLLEGE OF PHARMACY RECOMMENDATIONS
20G: UTILIZATION DETAILS OF AMYLOIDOSIS MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER

AGENDA ITEM NO. 21: 30-DAY NOTICE TO PRIOR AUTHORIZE PHOTREXA®/PHOTREXA® VISCOUS (RIBOFLAVIN 5'-PHOSPHATE)
21A: INTRODUCTION
21B: PHOTREXA®/PHOTREXA® VISCOUS (RIBOFLAVIN 5'-PHOSPHATE) PRODUCT SUMMARY
21C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER

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

AGENDA ITEM NO. 23: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
23A: ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
23B: ALLERGEN IMMUNOTHERAPIES
23C: ANEMIA MEDICATIONS
23D: *CLOSTRIDIOIDES DIFFICILE* (*C. DIFFICILE*) MEDICATIONS
23E: CUSHING'S DISEASE MEDICATIONS
23F: HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS
23G: MYELOPROLIFERATIVE NEOPLASM MEDICATIONS
23H: OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
23I: TARGETED IMMUNOMODULATOR AGENTS
*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: ADJOURNMENT
The meeting was adjourned at 5:01pm.

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

Memorandum

Date: September 12, 2025

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

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

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

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Azmiro™ (Testosterone Cypionate) and Undecatrex™ (Testosterone Undecanoate) and Update the Approval Criteria for the Testosterone Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Testosterone Products Product Based Prior Authorization (PBPA) category based on current product availability and net costs (changes shown in red in the following Tier chart):

1. Prior authorization of Azmiro™ (testosterone cypionate) and Undecatrex™ (testosterone undecanoate) and placement into the Special Prior Authorization (PA) Tier based on net costs; and

2. Moving testosterone topical gel 1% packet and tube (Testim®, Vogelxo®) and testosterone topical solution (Axiron®) from Tier-1 to Tier-2 based on net cost.

Testosterone Products		
Tier-1	**Tier-2**	**Special PA**
testosterone cypionate IM inj (Depo Testosterone®)	testosterone enanthate sub-Q auto-injector (Xyosted®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone topical gel 1%, 1.62% packet**, tube** (Androgel®, **Testim®, Vogelxo®**)	**testosterone cypionate IM inj (Azmiro™)**
~~**testosterone topical gel 1% packet, tube (Testim®, Vogelxo®)**~~	testosterone topical gel 1% pump (Vogelxo®)	testosterone nasal gel (Natesto®)
testosterone topical gel 1.62% pump (Androgel®)	testosterone topical gel 2% pump (Fortesta®)	testosterone pellets (Testopel®)
~~**testosterone topical solution (Axiron®)**~~	**testosterone topical solution (Axiron®)**	testosterone undecanoate IM inj (Aveed®)
		testosterone undecanoate oral cap (Jatenzo®, Kyzatrex®, Tlando®**, Undecatrex™**)

cap = capsule; IM = intramuscular; inj = injection; PA = prior authorization; sub-Q = subcutaneous; tab = tablet

Recommendation 4: Vote to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Zevaskyn™ (prademagene zamikeracel) with the following criteria (shown in red):

Zevaskyn™ (Prademagene Zamikeracel) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members with recessive dystrophic epidermolysis bullous (RDEB); and
2. Diagnosis must be confirmed by biallelic pathogenic variants in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of the genetic testing must be submitted); and
3. Zevaskyn™ must be prescribed by a dermatologist at a qualified treatment center with expertise in the treatment of RDEB; and
4. Member must have the presence of partial-thickness RDEB wounds open chronically for ≥6 months; and
5. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and

6. Prescriber must confirm that the member has been counseled and will not use other epidermolysis bullous products (e.g., Vyjuvek®, Filsuvez®) on wounds treated with Zevaskyn™; and
7. Zevaskyn™ must be administered at a Zevaskyn™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zevaskyn™ from receipt to storage to administration; and
8. Approval will be granted for 1 year for 1 treatment cycle; and
9. A new prior authorization may be considered for any previously untreated wounds. For consideration, the prescriber must attest Zevaskyn™ will not be used on wounds previously treated by Zevaskyn™ and the member responded well to treatment with Zevaskyn™ as indicated by the presence of wound healing; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's response to therapy and ongoing treatment plan.

The College of Pharmacy recommends updating the approval criteria for Filsuvez® (birch triterpenes 10% topical gel) and Vyjuvek® (beremagene geperpavec-svdt) based on the recent FDA approval of Zevaskyn™ (prademagene zamikeracel) and to be consistent with clinical practice (changes shown in red):

Filsuvez® (Birch Triterpenes 10% Topical Gel) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members 6 months of age and older with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB); and
2. Diagnosis must be confirmed by a pathogenic variant in the *COL7A1* gene for DEB or biallelic pathogenic variants in the *COL17A1*, *ITGA3*, *ITGA6*, *ITGB4*, *LAMA3*, *LAMB3*, or *LAMC2* genes for JEB (results of genetic testing must be submitted); and
3. Filsuvez® must be prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB or JEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB or JEB); and
4. Member must have the presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days; and
5. Filsuvez® must be applied to open partial-thickness wounds at dressing changes at least once every 4 days or up to once daily; and
6. Prescriber must attest that member and/or caregiver has been counseled on the appropriate administration and storage of Filsuvez® based on package labeling including that each sterile tube is for one-time use only; and

7. Member and/or caregiver has been advised on possible hypersensitivity reactions with Filsuvez® and to discontinue use and contact the prescriber if symptoms of a hypersensitivity reaction develop; and
8. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
9. Filsuvez® will not be approved for concomitant use with Vyjuvek® (beremagene geperpavec-svdt) or for use on wounds treated with Zevaskyn™ (prademagene zamikeracel); and
10. A maximum approval quantity of 1 tube (23.4 grams) per day or 702 grams per 30 days will apply; and
    a. A quantity limit override will be considered for approval of quantities greater than 1 tube per day if the provider documents the number and size of wounds being treated to justify the need for a larger quantity; and
11. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Filsuvez® will not be applied to closed wounds; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan.

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek® must be prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and
4. Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering provider via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and
5. Vyjuvek® must be administered by a health care professional (HCP) trained in the administration of Vyjuvek®. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health); and

6. Prescriber must attest that Vyjuvek® gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and
7. Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek® that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings for 24 hours following administration; and
8. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy; and
9. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
10. Vyjuvek® will not be approved for concomitant use with Filsuvez® (birch triterpenes 10% topical gel) or for use on wounds treated with Zevaskyn™ (prademagene zamikeracel); and
11. A maximum approval quantity of 1 carton (2.5mL) per week will apply; and
12. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Vyjuvek® will not be applied to closed wounds; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan; and
    b. Vyjuvek® must continue to be administered by an HCP. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health).

Recommendation 5: Vote to Prior Authorize Zunveyl® (Benzgalantamine)

MOTION CARRIED by unanimous approval.

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

Zunveyl® (Benzgalantamine) Approval Criteria:

1. An FDA approved diagnosis of mild-to-moderate Alzheimer's type dementia; and
2. A patient-specific, clinically significant reason why the member cannot use galantamine immediate-release tablets, which are available without a prior authorization, and galantamine extended-release capsules must be provided; and

3. A quantity limit of 60 tablets per 30 days will apply.

Recommendation 6: Vote to Prior Authorize Blujepa (Gepotidacin), Emblaveo™ (Aztreonam/Avibactam), Likmez™ (Metronidazole Oral Suspension), and Metronidazole 125mg Tablet and 375mg Capsule and Update the Approval Criteria for the Various Systemic Antibiotics

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Blujepa (gepotidacin), Emblaveo™ (aztreonam/avibactam), and Likmez™ (metronidazole oral suspension) with the following criteria (shown in red):

Blujepa (Gepotidacin) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by designated microorganisms (culture/sensitivity results must be submitted); and
2. Member must be a female 12 years of age or older and weigh ≥40kg; and
3. Member must have an estimated glomerular filtration rate (eGFR) >30mL/min/1.73m^2) and must not be on dialysis; and
4. Member must not have severe hepatic impairment (Child Pugh C); and
5. Prior to and during treatment, the potential for drug interactions should be evaluated, including:
    a. Avoid concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole) or inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
    b. Avoid concomitant administration with CYP3A4 substrates with a narrow therapeutic index (e.g., quinidine, cyclosporine); and
    c. Monitor digoxin serum concentrations as clinically indicated; and
    d. Monitor for adverse effects with concomitant administration with acetylcholinesterase inhibitors, anticholinergic medications, or non-depolarizing neuromuscular blocking agents; and
6. Prescriber must verify that members with medical conditions that may be exacerbated by acetylcholinesterase inhibition will be monitored for adverse effects; and
7. If administration of Blujepa cannot be avoided in members with a history of QTc interval prolongation, taking antiarrhythmic medications, or taking other medications that may prolong the QTc interval, prescriber must verify that serum electrolyte abnormalities will be corrected and monitored and an ECG should be collected prior to administration and duration treatment, as clinically indicated; and
8. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
9. A quantity limit of 20 tablets per 5 days will apply.

Emblaveo™ (Aztreonam/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of complicated intra-abdominal infections (cIAI) caused by susceptible gram-negative microorganisms (e.g., *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca*, *Enterobacter cloacae* complex, *Citrobacter freundii* complex, *Serratia marcescens*) in adults who have limited or no alternative treatment options (culture/sensitivity results must be submitted); and
2. Member must 18 years of age or older; and
3. Must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, a fluoroquinolone (e.g., ciprofloxacin or levofloxacin) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 57 vials per 14 days will apply.

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

1. A patient-specific clinically significant reason (beyond convenience) must be provided regarding why the member cannot use the 250mg and 500mg tablets, which are available without prior authorization, including but not limited to:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Treatment course was initiated inpatient; and
2. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request; and
3. A quantity limit of 200mL per 10 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of metronidazole 125mg tablets and 375mg capsules based on net costs within the Oral Antibiotic Special Formulation Approval Criteria (changes shown in red):

Oral Antibiotic Special Formulation Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.
2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:
    - Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)

- Cephalexin 250mg and 500mg tablets
- Cephalexin 750mg capsules
- Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)
- Doxycycline hyclate 50mg tablet (Targadox®)
- Doxycycline hyclate delayed-release (DR) tablets (Doryx®, Doryx® MPC)
- Doxycycline monohydrate 75mg capsules
- Doxycycline monohydrate 150mg capsules and tablets
- Doxycycline monohydrate DR 40mg capsules (Oracea®)
- Metronidazole 125mg tablets
- Metronidazole 375mg capsules
- Minocycline ER tablets (Minolira™)
- Minocycline ER tablets (Solodyn®)
- Nitrofurantoin 50mg/5mL suspension

Lastly, based on the 2024 American College of Gastroenterology (ACG) guideline updates, the College of Pharmacy recommends updating the Tetracycline 250mg and 500mg Capsule and Tablet Approval Criteria to remove the prior authorization requirement from tetracycline 250mg and 500mg capsules for the diagnosis of *Helicobacter pylori* (*H. pylori*) infection (changes shown in red):

Tetracycline 250mg and 500mg Capsule and Tablet Approval Criteria:

~~1. Approval requires a patient-specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).~~

2. For the capsule formulation, a quantity of 56 capsules for 14 days is available without a prior authorization for a diagnosis of *Helicobacter pylori* (*H. pylori*) infection; or
3. For the tablet formulation, approval ~~also~~ requires a patient-specific, clinically significant reason why the member requires the tablet formulation and cannot use the capsule formulation, which is available without prior authorization; and
4. A quantity limit of 56 capsules or tablets per 14 days will apply; and
    a. A quantity limit override for longer durations of therapy for indications other than for the eradication of *H. pylori* infection will require a patient specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).

Recommendation 7: Vote to Prior Authorize Tramadol 75mg Tablet and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications

MOTION CARRIED by unanimous approval.

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

1. Adding tramadol 75mg tablet to the Special PA Tier with the following additional criteria; and
2. Moving oxycodone tablet (RoxyBond™) to the Special PA Tier with the following additional criteria; and
3. Making hydrocodone ER capsule (Hysingla® ER) brand preferred; and
4. Moving tramadol ER tablet (Ultram® ER) to Tier 1.

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

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

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Actiq® and Fentora® are approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
    a. Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use of these products despite the medication being contraindicated for the member's age; or
    b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.
5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; or
    b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; and
    c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
6. Levorphanol Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
7. Methadone Oral Solution Approval Criteria:
    a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or

b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.

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

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

1. Removing the prior authorization of Subutex® (buprenorphine SL tablet) based on net cost and to increase access and decrease barriers to opioid use disorder (OUD) treatment; and
2. Updating the Brixadi® (buprenorphine ER injection) and Sublocade® (buprenorphine ER injection) approval criteria based on the FDA label expansion of Sublocade®.

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

1. Generic buprenorphine/naloxone SL tablet and buprenorphine SL tablet ~~is~~ are the preferred products. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why ~~generic buprenorphine/naloxone SL tablets~~ the preferred SL tablets are not appropriate.
~~2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and~~
3. Member must have an FDA approved diagnosis of opioid abuse/ dependence [i.e., opioid use disorder (OUD)]; and
4. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
5. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
6. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 60 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg: A quantity limit of 60 SL tablets per 30 days will apply.
    i. Zubsolv® 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

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

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder (OUD); and
2. ~~For Sublocade®, member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; or~~
3. ~~For Brixadi®,~~ Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
4. Concomitant treatment with opioids (including tramadol) will be denied; and
5. Medication should only be prepared and administered by a health care provider; and
6. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual (SL) tablets or buprenorphine SL tablets) must be provided; and
7. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
8. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
9. ~~A quantity limit of 1 monthly dose per 28 days or 4 weekly doses per 28 days will apply.~~
10. The following quantity limits will apply:
    a. Brixadi® 8mg/0.16mL, 16mg/0.32mL, 24mg/0.48mL, and 32mg/0.64mL: 4 weekly doses per 28 days
    b. Brixadi® 64mg/0.18mL, 96mg/0.27mL, and 128mg/0.36mL: 1 monthly dose per 28 days
    c. Sublocade® 100mg/0.5mL and 300mg/1.5mL: 1 monthly dose per 28 days
        i. A quantity limit override will be approved for initial dosing for members who need the second injection 1 week after the first injection when requested.

Recommendation 8: Vote to Update the Approval Criteria for the Topical Corticosteroids

MOTION CARRIED by unanimous approval.

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

1. Ultra-High to High Potency:
    a. Move amcinonide 0.1% cream from Tier-2 to Tier-3; and

b. Move augmented betamethasone dipropionate 0.05% (Diprolene®) lotion from Tier-2 to Tier-1; and

2. Medium-High to Medium Potency:
   a. Move hydrocortisone valerate 0.2% (Westcort®) ointment from Tier-3 to Tier-2.

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,**L,**O	~~**amcinonide 0.1%**~~	~~**C**~~	**amcinonide 0.1%**	**C**
betamethasone dipropionate 0.05% (Diprosone®)	C,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G~~,L~~	clobetasol propionate 0.025% (Impoyz®)	C
clobetasol propionate 0.05% (Olux®)	F	clobetasol propionate 0.05% (Clobex®)	L,Sh,Spr	clobetasol propionate 0.05% (Olux-E®, Tovet®)	F
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	desoximetasone 0.25% (Topicort®)	Spr
desoximetasone 0.25% (Topicort®)	C,O	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
fluocinonide 0.05%	C,O,So	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon E®)	C
fluocinonide 0.1% (Vanos®)	C	halobetasol propionate 0.05% (Ultravate®)	L	halcinonide 0.1% (Halog®)	C,So
halobetasol propionate 0.05% (Ultravate®)	C,O			halobetasol propionate 0.01% (Bryhali®)	L
				halobetasol propionate 0.05%	F
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone valerate 0.12% (Luxiq®)	F	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)	O,Sus
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.1% (Beta-Val®)	L	clocortolone pivalate 0.1% (Cloderm®)	C

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluticasone propionate 0.005% (Cutivate®)	O	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F	desoximetasone 0.05% (Topicort LP®)	C,O
fluticasone propionate 0.05% (Cutivate®)	C	fluocinolone acetonide 0.025% (Synalar®)	C,O	flurandrenolide 0.05%	L
hydrocortisone valerate 0.2% (Westcort®)	C	fluocinonide emollient 0.05% (Lidex E®)	C	fluticasone propionate 0.05% (Cutivate®)	L
mometasone furoate 0.1% (Elocon®)	C,L,O, So	hydrocortisone butyrate 0.1%	O, So	hydrocortisone butyrate 0.1%	C,L
triamcinolone acetonide 0.025%	O	hydrocortisone probutate 0.1% (Pandel®)	C	~~**hydrocortisone valerate 0.2% (Westcort®)**~~	~~**O**~~
triamcinolone acetonide 0.1%	C,L,O	**hydrocortisone valerate 0.2% (Westcort®)**	**O**	triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr
triamcinolone acetonide 0.5%	C,O	triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,O	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	fluocinolone acetonide 0.01% (Synalar®)	C	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O				
triamcinolone acetonide 0.025%	C,L				

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
C = cream; F = foam; G = gel; L= lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

Additionally, the College of Pharmacy recommends removing the prior authorization of Cortifoam® (hydrocortisone acetate 10% rectal foam) and recommends the prior authorization of Proctofoam® HC (hydrocortisone/ pramoxine 1%/1% rectal foam) based on net costs (changes shown in red):

~~**Cortifoam® (Hydrocortisone Acetate 10% Rectal Foam) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason why the member cannot use other strengths and rectal formulations of hydrocortisone must be provided.~~

Proctofoam® HC (Hydrocortisone/Pramoxine 1%/1% Rectal Foam) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Epifoam® (hydrocortisone/pramoxine 1%/1% rectal foam) or other rectal formulations of hydrocortisone available without a prior authorization must be provided.

Recommendation 9: Vote to Prior Authorize Ryoncil® (Remestemcel-L-rknd) and Update the Approval Criteria for the Miscellaneous Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Ryoncil® (remestemcel-l-rknd) with the following criteria (shown in red):

Ryoncil® (Remestemcel-L-rknd) Approval Criteria [Acute Graft Versus Host Disease (aGVHD) Diagnosis]:

1. Diagnosis of aGVHD; and
2. Disease is steroid refractory; and
3. Member is 2 months of age to younger than 18 years of age; and
4. Member is an allogeneic hematopoietic stem cell transplant (HSCT) recipient; and
5. Initial approvals will be for a maximum of 8 infusions; and
6. Subsequent approvals for additional infusions will require repeat authorization and clinical documentation must be submitted to support the need for additional infusions; and
    a. All requests for subsequent approvals will require review by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician.

Additionally, the College of Pharmacy recommends updating the Loqtorzi® (toripalimab-tpzi) approval criteria based on National Comprehensive Cancer Network (NCCN) recommendations with the following changes (shown in red):

Loqtorzi® (Toripalimab-tpzi) Approval Criteria [Anal Carcinoma, Colorectal Cancer (CRC), and Small Bowel Adenocarcinoma Diagnosis]:

1. Diagnosis of anal carcinoma, CRC, or small bowel adenocarcinoma; and
2. Disease is locally unresectable, medically inoperable, advanced, or metastatic; and
3. Must meet 1 of the following:

a. Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H); or
b. Polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]; and

4. No prior treatment with a checkpoint inhibitor; and
5. Used as a single agent; and
6. Dose as follows:
    a. 3mg/kg every 2 weeks.

Recommendation 10: Fiscal Year 2025 Annual Review of Camzyos® (Mavacamten)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Camzyos® (mavacamten) approval criteria based on the FDA-approved updates to the package labeling and Risk Evaluation and Mitigation Strategy (REMS) program (changes shown in red):

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or nondihydropyridine calcium channel blockers; and
~~7. Member must not be taking concurrent moderate to strong CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole, fluvoxamine), strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir), moderate to strong CYP2C19 inducers (e.g., rifampicin, carbamazepine), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and~~
8. Member must not be taking concurrent strong CYP2C19 inhibitors (e.g., fluvoxamine, fluconazole), moderate to strong CYP2C19 inducers (e.g., rifampin), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and
9. If the member is taking moderate to strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or weak to moderate CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole), the prescriber

must verify that the Camzyos® dose will be adjusted according to the package labeling; and

10. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos®; and
11. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 4 months after the final dose of Camzyos®; and
12. Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
13. 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; and
14. Subsequent approvals will be for the duration of 1 year.

Recommendation 11: Fiscal Year 2025 Annual Review of Synagis® (Palivizumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Synagis® (palivizumab) approval criteria to be more consistent with current AAP recommendations for RSV prophylaxis with the following changes (shown in red):

Prior authorization is required for all members who receive palivizumab in an outpatient setting. Palivizumab is approved for members who meet the established prior authorization criteria, which is based on the American Academy of Pediatrics (AAP) 2014 guidelines for palivizumab prophylaxis and AAP's updated *Red Book 2024-2027* recommendations for RSV monoclonal antibody prophylaxis.

Synagis® (Palivizumab) Approval Criteria:

A. Member Selection:
   1. Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:
      a. Born before 29 weeks, 0 days gestation; or
      b. Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or
      c. Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or
      d. May be considered for:

i. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or
ii. Infants who undergo cardiac transplantation during RSV season; or
iii. Infants who are profoundly immunocompromised during RSV season; or
iv. Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised; or

2. Infants 12 ~~to 24~~ through 19 months of age at the start of RSV season:
   a. Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) during the 6 months before the start of the RSV season; or
   b. May be considered for:
      i. Infants who undergo cardiac transplantation during RSV season; or
      ii. Infants who are profoundly immunocompromised during RSV season; or
      iii. Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.

B. Product Selection: A patient-specific, clinically significant reason why the member cannot receive Beyfortus® (nirsevimab-alip) and Enflonsia™ (clesrovimab-cfor), as recommended by the CDC, must be provided. Per AAP recommendations, palivizumab is not recommended for routine use. Additionally, the prescriber must confirm the member has not already received Beyfortus® or Enflonsia™ for the current RSV season. Concomitant use with Beyfortus® or Enflonsia™ will not be approved.

C. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. Initial and subsequent approvals will be for the duration of 1 month until RSV season ends. A separate prior authorization request will be required for consideration of initial

approval and for each subsequent approval. Members initially approved for palivizumab will require a patient-specific, clinically significant reason why the member still cannot receive Beyfortus® and Enflonsia™.

D. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. Doses are to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.
E. Dose-Pooling: To avoid unnecessary risk to the member, multiple members are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Recommendation 12: Fiscal Year 2025 Annual Review of Jynarque® (Tolvaptan)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Jynarque® (tolvaptan) approval criteria based on the new FDA approved label update, Kidney Disease Improving Global Outcomes (KDIGO) guideline updates, and net costs (changes shown in red):

Jynarque® (Tolvaptan) Approval Criteria:

1. An FDA approved indication to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD); and
2. Member must be 18 years of age or older; and
3. Member must have a baseline (prior to treatment with tolvaptan) estimated glomerular filtration rate (eGFR) of ≥25mL/min/1.73m^2; and
4. Member is not currently receiving renal replacement therapy (i.e., dialysis, kidney transplant); and
5. Member must not have any contraindications to taking Jynarque® including the following:
    a. Taking any concomitant strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. History of signs or symptoms of significant liver impairment or injury (does not include uncomplicated polycystic liver disease); and
    c. Uncorrected abnormal blood sodium concentrations; and
    d. Unable to sense or respond to thirst; and
    e. Hypovolemia; and
    f. Hypersensitivity to tolvaptan or any of its components; and

g. Uncorrected urinary outflow obstruction; and
h. Anuria; and

6. Member must not be taking any of the following medications concomitantly with Jynarque®:
   a. Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
   b. Strong CYP3A inducers (e.g., rifampin); and
   ~~c. OATP1B1/3 and OAT3 transporter substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and~~
   ~~d. BCRP transporter substrates (e.g., rosuvastatin); and~~
   e. V2-receptor agonists (e.g., desmopressin); and
7. Jynarque® must be prescribed by a nephrologist or specialist with expertise in the treatment of ADPKD (or an advanced care practitioner with a supervising physician who is a nephrologist or specialist with expertise in the treatment of ADPKD); and
8. Prescriber must agree to assess ALT, AST, and bilirubin prior to initiation of Jynarque®, at 2 weeks and 4 weeks after initiation, then monthly for 18 months, and every 3 months thereafter; and
9. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
10. Jynarque® is brand preferred. Requests for generic tolvaptan will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
11. Prescriber, pharmacy, and member must be enrolled in the Jynarque® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

Recommendation 13: Fiscal Year 2025 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Datroway® (Datopotamab Deruxtecan-dlnk) and Itovebi™ (Inavolisib)

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

Recommendation 14: 30-Day Notice to Prior Authorize Encelto™ (Revakinagene Taroretcel-lwey)

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

Recommendation 15: Fiscal Year 2025 Annual Review of Hyperphosphatemia Medications and 30-Day Notice to Prior Authorize Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet

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

Recommendation 16: Fiscal Year 2025 Annual Review of Cystic Fibrosis (CF) Medications and 30-Day Notice to Prior Authorize Alyftrek™ (Vanzacaftor/Tezacaftor/Deutivicaftor)

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

Recommendation 17: Fiscal Year 2025 Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Attruby™ (Acoramidis)

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

Recommendation 18: 30-Day Notice to Prior Authorize Photrexa®/ Photrexa® Viscous (Riboflavin 5'-Phosphate)

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

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

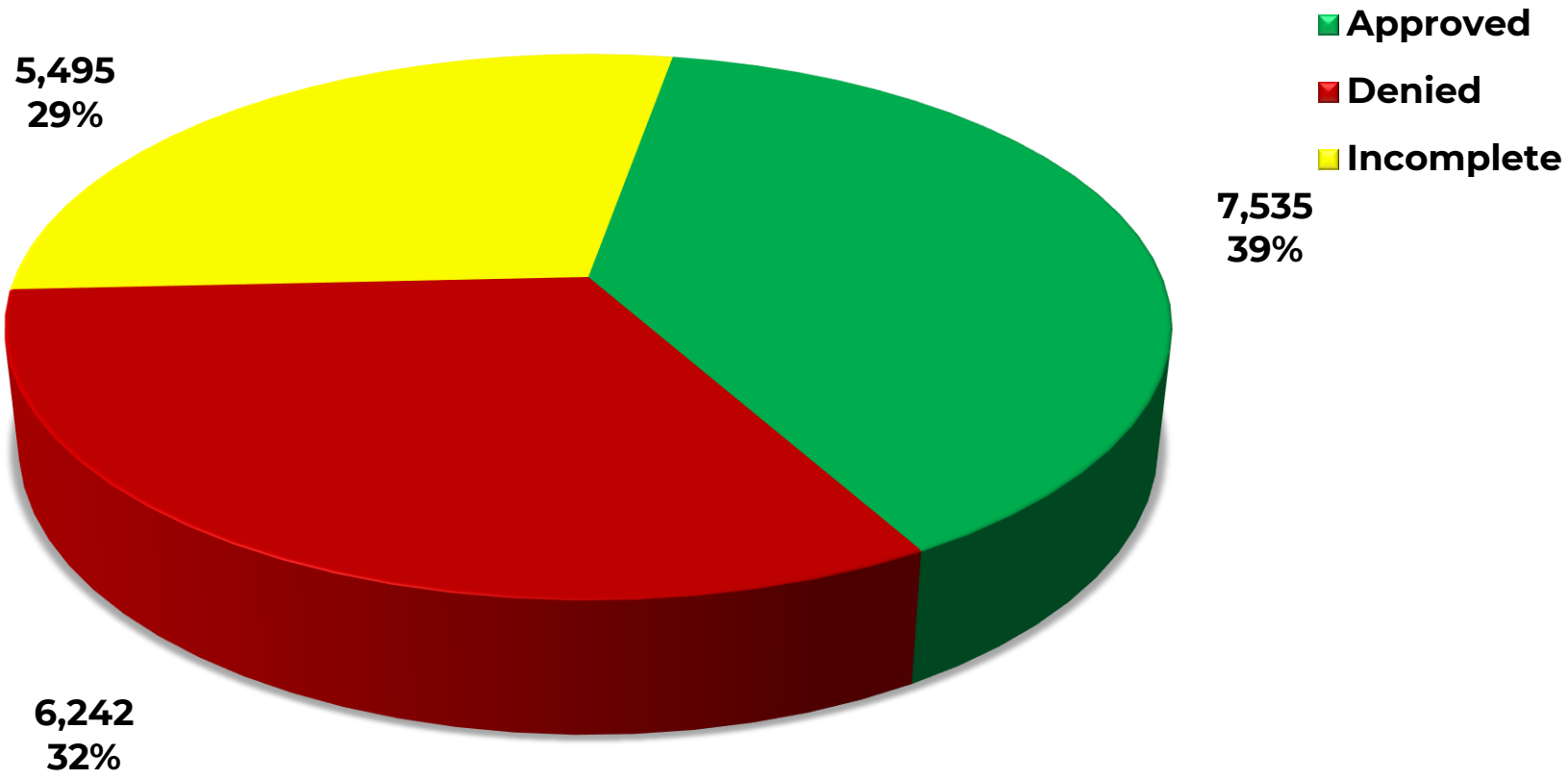
NO ACTION REQUIRED.

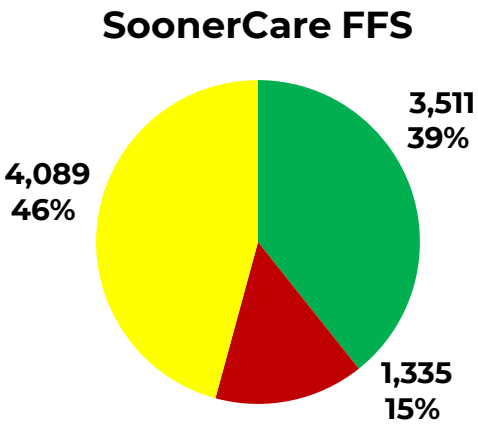
Recommendations 20: Future Business

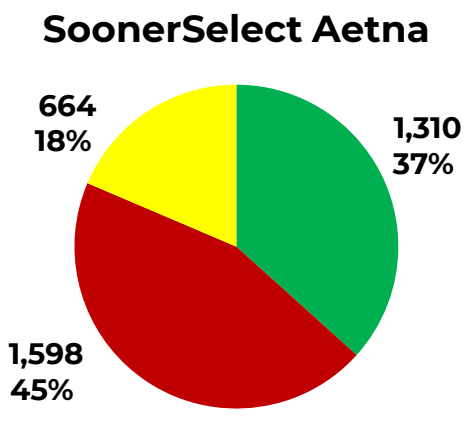
NO ACTION REQUIRED.

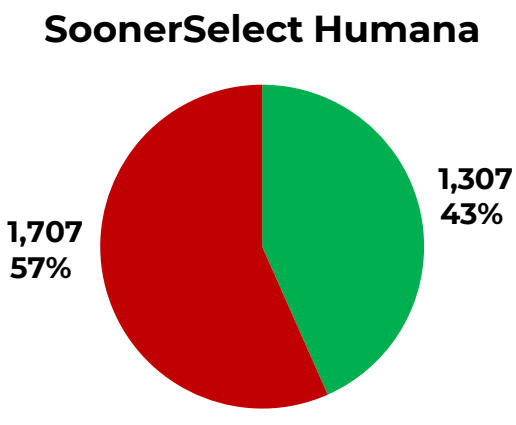
Appendix B

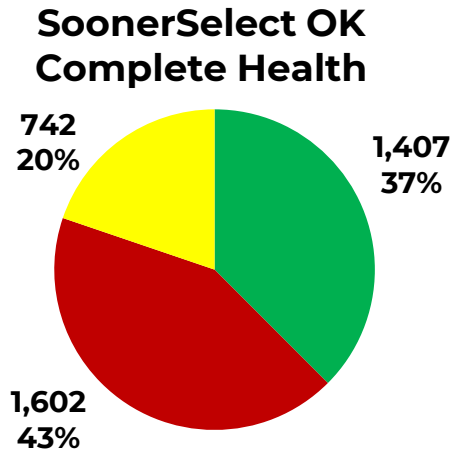
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: SEPTEMBER 2025





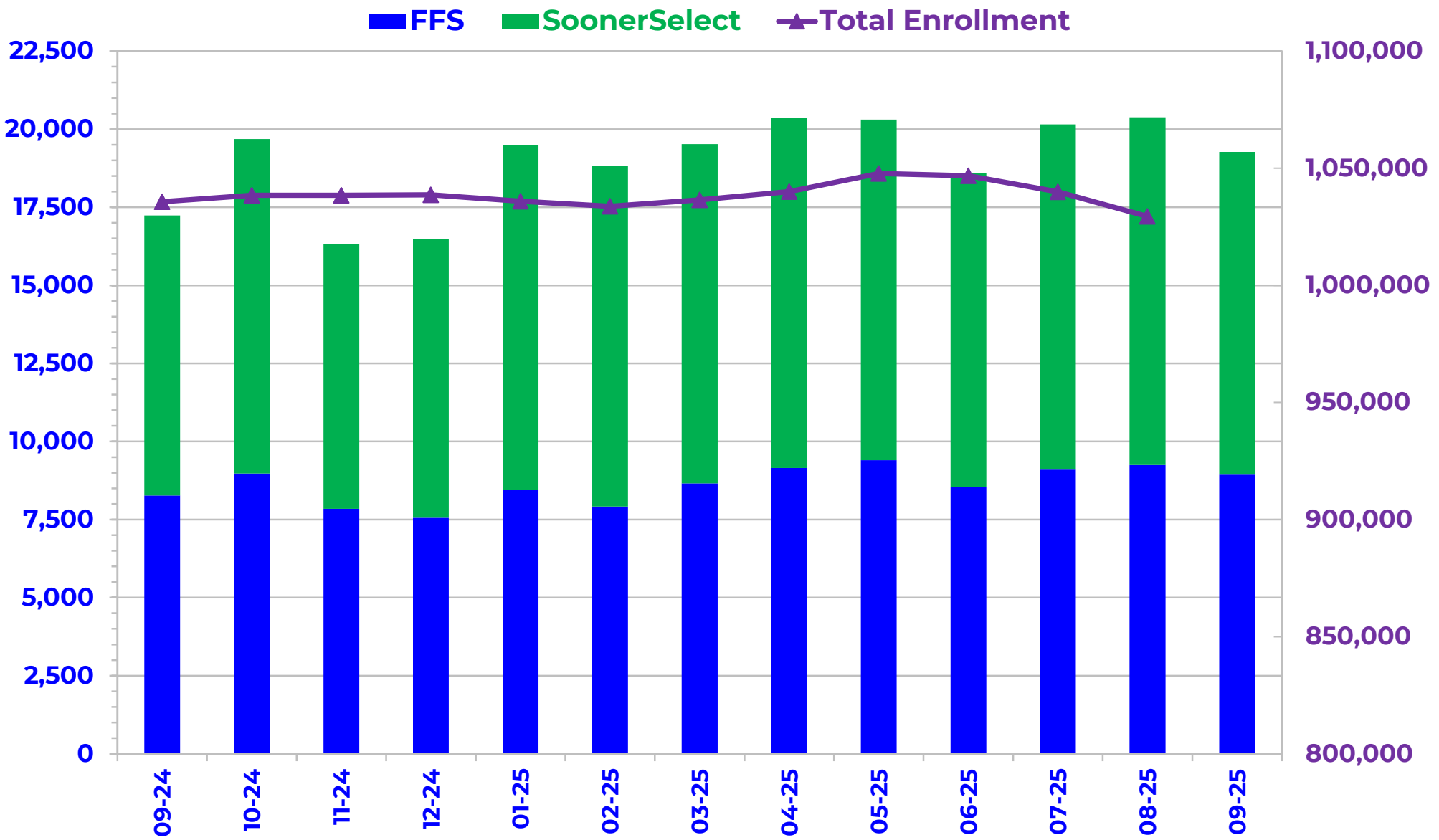






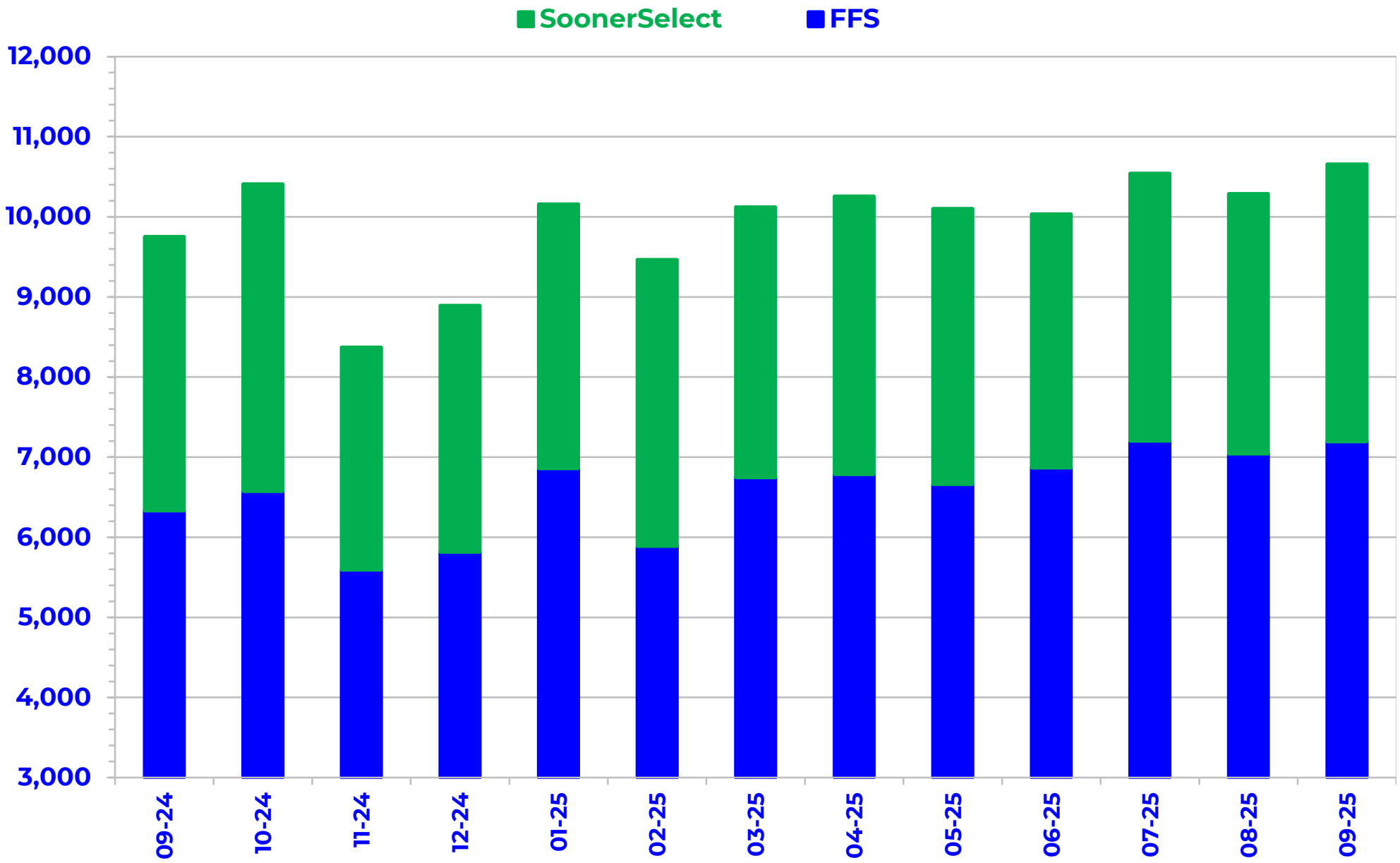
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: SEPTEMBER 2024 – SEPTEMBER 2025



SoonerCare FFS Prior Authorization Activity

9/1/2025 Through 9/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amebicides	2	0	0	2	0
Amphetamines	999	475	84	440	357
Analgesics - Anti-Inflammatory	212	83	27	102	310
Analgesics - Nonnarcotic	8	0	0	8	0
Analgesics - Opioid	341	140	40	161	127
Androgens - Anabolic	70	22	12	36	356
Anorectal and Related Products	4	1	1	2	46
Anorexiants Non-Amphetamine	1	0	1	0	0
Antacids	1	1	0	0	360
Anthelmintics	17	6	2	9	19
Anti-infective Agents - Misc.	23	6	4	13	246
Anti-obesity Agents	91	5	72	14	26
Antianginal Agents	1	0	0	1	0
Antianxiety Agents	14	4	2	8	302
Antiarrhythmics	1	1	0	0	361
Antiasthmatic and Bronchodilator Agents	515	106	106	303	321
Antibiotics	27	11	5	11	327
Anticoagulants	12	1	1	10	360
Anticonvulsants	211	108	9	94	332
Antidepressants	247	78	41	128	251
Antidiabetics	1,297	399	243	655	356
Antidiarrheal/Probiotic Agents	1	0	1	0	0
Antidotes and Specific Antagonists	5	1	2	2	360
Antiemetics	11	1	0	10	179
Antifungals	7	1	0	6	47
Antihistamines	19	7	4	8	359
Antihyperlipidemics	55	15	14	26	292
Antihypertensives	11	3	2	6	359
Antimalarials	1	1	0	0	86
Antineoplastics and Adjunctive Therapies	199	136	9	54	178
Antiparkinson and Related Therapy Agents	8	3	0	5	360
Antipsychotics/Antimanic Agents	287	123	36	128	349
Antivirals	27	8	3	16	6
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	226	149	19	58	344
Beta Blockers	8	3	2	3	359
Calcium Channel Blockers	2	0	1	1	0
Cardiovascular Agents - Misc.	100	44	10	46	319
Chemicals	1	0	0	1	0
Contraceptives	36	14	5	17	335
Corticosteroids	23	3	10	10	212
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	439	132	96	211	234
Diagnostic Products	37	13	3	21	190
Dietary Products/Dietary Management Products	3	0	1	2	0
Digestive Aids	6	4	0	2	357
Diuretics	13	7	0	6	306
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	195	87	26	82	223
Estrogens	4	0	0	4	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents - Misc.	299	90	66	143	250
Genitourinary Agents - Misc.	6	2	0	4	361
Gout Agents	8	2	0	6	356
Hematological Agents - Misc.	10	4	1	5	357
Hematopoietic Agents	33	15	6	12	208
Hypnotics/Sedatives/Sleep Disorder Agents	70	6	15	49	314
Laxatives	19	7	3	9	218
Medical Devices and Supplies	277	48	52	177	285
Migraine Products	378	92	80	206	256
Minerals and Electrolytes	7	3	1	3	359
Miscellaneous Therapeutic Classes	67	20	11	36	322
Mouth/Throat/Dental Agents	1	0	0	1	0
Multivitamins	5	3	0	2	359
Musculoskeletal Therapy Agents	38	6	5	27	268
Nasal Agents - Systemic and Topical	13	2	4	7	359
Neuromuscular Agents	79	39	19	21	350
Ophthalmic Agents	68	14	13	41	143
Other*	33	17	0	16	145
Otic Agents	31	13	1	17	13
Passive Immunizing and Treatment Agents	5	0	0	5	0
Progestins	9	1	2	6	360
Psychotherapeutic and Neurological Agents - Misc.	203	71	34	98	226
Respiratory Agents - Misc.	25	15	0	10	309
Stimulants - Misc.	218	109	12	97	358
Thyroid Agents	16	4	3	9	359
Ulcer Drugs/Antispasmodics/Anticholinergics	66	22	15	29	232
Urinary Antispasmodics	59	10	18	31	359
Vaginal and Related Products	2	1	0	1	4
Vasopressors	1	0	0	1	0
Vitamins	38	3	23	12	207
Total	**7,903**	**2,821**	**1,278**	**3,804**	

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	31	15	4	12	242
Compound	8	5	0	3	89
Dosage Change	169	160	1	8	16
High Dose	5	4	0	1	358
IHS-Brand	1	1	0	0	360
Ingredient Duplication	5	3	0	2	12
Lost/Broken Rx	33	30	3	0	15
MAT Override	6	2	2	2	85
NDC vs Age	152	92	22	38	312
NDC vs Sex	17	13	0	4	235
Nursing Home Issue	63	58	0	5	13
Opioid MME Limit	92	19	3	70	130
Opioid Quantity	21	13	3	5	177
Other	34	29	1	4	19
Prescriber Temp Unlock	3	2	0	1	360
Quantity vs Days Supply	332	210	18	104	271

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
STBS/STBSM	8	5	0	3	96
Step Therapy Exception	4	2	0	2	360
Stolen	2	2	0	0	189
Third Brand Request	46	25	0	21	16
Overrides Total	**1,032**	**690**	**57**	**285**	
Total Regular PAs + Overrides	**8,935**	**3,511**	**1,335**	**4,089**	

Denial Reasons	
Unable to verify required trials.	3,580
Does not meet established criteria.	1,359
Lack required information to process request.	479
Other PA Activity	
Duplicate Requests	1,041
Letters	41,512
No Process	2
Helpdesk Initiated Prior Authorizations	314
PAs Missing Information	326
Pharmacotherapy	82
Changes to Existing PAs	601

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

SoonerSelect Aetna Prior Authorization Activity

9/1/2025 Through 9/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	301	183	98	20	363
Analgesics - Anti-Inflammatory	100	68	21	11	341
Analgesics - Nonnarcotic	13	7	4	2	90
Analgesics - Opioid	161	80	47	34	212
Androgens - Anabolic	64	15	47	2	334
Antacids	1	1	0	0	365
Anthelmintics	3	1	2	0	7
Antianxiety Agents	31	16	4	11	309
Antiasthmatic and Bronchodilator Agents	153	39	76	38	279
Antibiotics	15	2	5	8	189
Anticoagulants	4	3	0	1	181
Anticonvulsants	56	24	14	18	327
Antidepressants	215	49	100	66	321
Antidiabetics	598	174	323	101	315
Antiemetics	17	1	14	2	365
Antifungals	2	2	0	0	61
Antihistamines	22	6	16	0	365
Antihyperlipidemics	29	2	8	19	273
Antihypertensives	19	0	0	19	0
Anti-Infective Agents - Misc.	12	6	5	1	219
Antineoplastics and Adjunctive Therapies	36	10	13	13	307
Anti-Obesity Agents	72	7	59	6	28
Antiparkinson and Related Therapy Agents	5	1	2	2	365
Antipsychotics/Antimanic Agents	139	48	55	36	360
Antivirals	3	1	2	0	200
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	89	67	17	5	365
Beta Blockers	22	1	2	19	309
Calcium Channel Blockers	8	1	1	6	365
Cardiovascular Agents - Misc.	33	14	14	5	331
Contraceptives	10	1	7	2	365
Corticosteroids	26	18	4	4	180
Dermatologicals	287	111	132	44	234
Diagnostic Products	45	26	8	11	348
Digestive Aids	3	2	0	1	365
Diuretics	21	2	3	16	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	53	27	23	3	227
Estrogens	9	1	7	1	365
Gastrointestinal Agents - Misc.	84	29	51	4	231
Genitourinary Agents - Misc.	4	0	3	1	0
Gout Agents	2	1	0	1	181
Hematological Agents - Misc.	1	1	0	0	91
Hematopoietic Agents	3	1	1	1	365
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	30	3	12	15	242
Laxatives	15	5	7	3	209
Medical Devices and Supplies	80	32	34	14	340
Migraine Products	219	66	145	8	248
Minerals and Electrolytes	13	5	2	6	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
Miscellaneous Therapeutic Classes	45	35	6	4	341
Multivitamins	3	0	3	0	0
Musculoskeletal Therapy Agents	41	3	10	28	81
Nasal Agents - Systemic and Topical	27	1	19	7	365
Neuromuscular Agents	4	2	2	0	365
Nutrients	8	1	7	0	365
Ophthalmic Agents	26	4	15	7	255
Other	1	0	0	1	0
Otic Agents	24	1	22	1	15
Passive Immunizing and Treatment Agents	2	1	1	0	180
Progestins	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	32	11	16	5	191
Respiratory Agents - Misc.	2	2	0	0	365
Stimulants - Misc.	85	64	18	3	344
Thyroid Agents	2	1	1	0	365
Ulcer Drugs/Antispasmodics/Anticholinergics	76	15	35	26	265
Urinary Antispasmodics	14	4	9	1	365
Vaccines	2	1	1	0	365
Vitamins	46	3	43	0	365
****Total**	**3,572**	**1,310**	**1,598**	**664**	

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

Overrides					
Brand	1	1	0	0	365
Other	663	0	0	663	0
Quantity Level Limit	33	33	0	0	343
Step Therapy Met	1	1	0	0	365
Overrides Total	**698**	**35**	**0**	**663**	

Denial Reason	
Benefit	79
Experimental/Investigational	148
Medical Necessity	1233
Request did not have enough information to determine medical necessity	137
Other	1
Other PA Activity	
Duplicate Requests	12
Letters	4493
No Process	257
Changes to existing PAs	0
Helpdesk initiated PA	4
PAs missing info	5

*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

9/1/2025 Through 9/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	1	1	0	0	365
Analgesics - Anti-Inflammatory	56	48	8	0	339
Analgesics - Opioid	58	33	25	0	188
Androgens - Anabolic	37	11	26	0	234
Anthelmintics	6	4	2	0	365
Antiasthmatic and Bronchodilator Agents	101	35	66	0	202
Antibiotics	6	2	4	0	365
Anticonvulsants	6	3	3	0	365
Antidepressants	36	12	24	0	229
Antidiabetics	227	94	133	0	228
Antiemetics	2	1	1	0	365
Antifungals	1	1	0	0	365
Antihyperlipidemics	17	4	13	0	125
Anti-Infective Agents - Misc.	5	4	1	0	365
Antineoplastics and Adjunctive Therapies	49	46	3	0	231
Anti-Obesity Agents	55	7	48	0	76
Antiparkinson and Related Therapy Agents	1	1	0	0	365
Antipsychotics/Antimanic Agents	5	3	2	0	219
Antivirals	5	2	3	0	35
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	6	5	1	0	365
Beta Blockers	3	1	2	0	365
Cardiovascular Agents - Misc.	33	10	23	0	376
Chemicals	1	0	1	0	0
Contraceptives	48	35	13	0	334
Corticosteroids	1	1	0	0	365
Dermatologicals	132	47	85	0	247
Diagnostic Products	14	11	3	0	319
Diuretics	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	32	20	12	0	241
Estrogens	9	2	7	0	91
Gastrointestinal Agents - Misc.	69	29	40	0	212
Gout Agents	5	3	2	0	136
Hematological Agents - Misc.	3	3	0	0	91
Hematopoietic Agents	5	3	2	0	280
Hypnotics/Sedatives/Sleep Disorder Agents	9	0	9	0	0
Laxatives	5	1	4	0	183
Medical Devices and Supplies	65	60	5	0	383
Migraine Products	103	58	45	0	165
Minerals and Electrolytes	3	0	3	0	0
Miscellaneous Therapeutic Classes	5	4	1	0	273
Musculoskeletal Therapy Agents	21	15	6	0	313
Nasal Agents - Systemic and Topical	2	0	2	0	0
Neuromuscular Agents	19	13	6	0	300
Ophthalmic Agents	19	5	14	0	405
Other	2	1	1	0	365
Otic Agents	5	0	5	0	0
Psychotherapeutic and Neurological Agents - Misc.	32	22	10	0	218
Respiratory Agents - Misc.	1	1	0	0	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
Stimulants - Misc.	11	6	5	0	319
Thyroid Agents	4	0	4	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	21	4	17	0	210
Urinary Antispasmodics	6	1	5	0	365
Vaginal and Related Products	1	0	1	0	0
Vitamins	30	2	28	0	191
Total	**1,400**	**675**	**725**	**0**	
Overrides					
Compound	3	3	0	0	365
Dosage Change	14	13	1	0	5
High Dose	2	1	1	0	183
Ingredient Duplication	137	77	60	0	190
NDC vs Age	335	207	128	0	225
Opioid MME Limit	6	3	3	0	287
Opioid Quantity	2	2	0	0	237
Other	146	53	93	0	109
Quantity vs Days Supply	189	111	78	0	229
STBS/STBSM	431	15	416	0	13
Step Therapy Exception	349	147	202	0	159
Overrides Total	**1,614**	**632**	**982**	**0**	
Total Regular PAs + Overrides	**3,014**	**1,307**	**1,707**	**0**	
Denial Reasons					
Benefit					768
Medical Necessity					939

*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

9/1/2025 Through 9/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	3	0	2	1	0
Amebicides	1	0	0	1	0
Amphetamines	297	125	93	79	305
Analgesics - Anti-Inflammatory	99	44	29	26	352
Analgesics - Nonnarcotic	8	0	7	1	0
Analgesics - Opioid	337	103	168	66	178
Androgens - Anabolic	97	11	73	13	338
Antacids	1	0	0	1	0
Anthelmintics	4	1	3	0	366
Antianxiety Agents	27	3	23	1	199
Antiasthmatic and Bronchodilator Agents	219	52	128	39	235
Antibiotics	13	4	7	2	190
Anticoagulants	1	1	0	0	120
Anticonvulsants	49	21	20	8	315
Antidepressants	128	49	65	14	306
Antidiabetics	616	249	271	96	320
Antiemetics	18	6	6	6	221
Antifungals	2	1	0	1	99
Antihistamines	25	8	11	6	314
Antihyperlipidemics	21	5	14	2	365
Antihypertensives	5	0	2	3	0
Anti-Infective Agents - Misc.	12	3	6	3	277
Antimyasthenic/Cholinergic Agents	1	0	1	0	0
Antineoplastics and Adjunctive Therapies	63	40	11	12	235
Anti-Obesity Agents	78	1	39	38	28
Antiparkinson and Related Therapy Agents	4	3	1	0	365
Antipsychotics/Antimanic Agents	91	44	30	17	324
Antivirals	8	5	1	2	180
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	101	52	39	10	311
Beta Blockers	5	2	1	2	119
Calcium Channel Blockers	5	3	2	0	365
Cardiovascular Agents - Misc.	27	13	4	10	328
Contraceptives	15	7	7	1	259
Corticosteroids	5	1	1	3	365
Cough/Cold/Allergy	6	2	0	4	365
Dermatologicals	305	108	127	70	250
Diagnostic Products	71	37	26	8	262
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	1	0	0	1	0
Diuretics	1	1	0	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	46	19	23	4	273
Estrogens	13	5	5	3	339
Gastrointestinal Agents - Misc.	82	24	50	8	299
Genitourinary Agents - Misc.	3	0	3	0	0
Gout Agents	6	1	4	1	365
Hematological Agents - Misc.	14	6	4	4	223
Hematopoietic Agents	18	6	6	6	197
Hypnotics/Sedatives/Sleep Disorder Agents	26	8	14	4	187

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Laxatives	12	2	8	2	232
Medical Devices and Supplies	134	83	20	31	323
Migraine Products	144	33	94	17	300
Minerals and Electrolytes	1	1	0	0	180
Miscellaneous Therapeutic Classes	25	17	4	4	284
Mouth/Throat/Dental Agents	1	1	0	0	120
Multivitamins	3	0	3	0	0
Musculoskeletal Therapy Agents	19	1	11	7	180
Nasal Agents - Systemic and Topical	12	1	7	4	365
Neuromuscular Agents	12	10	0	2	206
Nutrients	1	1	0	0	365
Ophthalmic Agents	33	6	17	10	274
Other	33	12	1	20	245
Otic Agents	14	0	12	2	0
Passive Immunizing and Treatment Agents	1	0	0	1	0
Progestins	9	2	6	1	235
Psychotherapeutic and Neurological Agents - Misc.	47	14	25	8	265
Respiratory Agents - Misc.	5	2	2	1	365
Stimulants - Misc.	183	115	31	37	272
Thyroid Agents	31	19	6	6	238
Ulcer Drugs/Antispasmodics/Anticholinergics	31	8	14	9	329
Urinary Antispasmodics	17	5	10	2	113
Vaccines	1	0	1	0	0
Vaginal and Related Products	2	0	2	0	0
****Total**	**3,751**	**1,407**	**1,602**	**742**	

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

Denial Reasons	
Medical Necessity	1,602

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

Appendix C

Fall 2025 Pipeline Update

Oklahoma Health Care Authority
October 2025

Introduction

The following report is a pipeline review compiled by the University of Oklahoma College of Pharmacy: Pharmacy Management Consultants. Information in this report is focused on medications not yet approved by the U.S. Food and Drug Administration (FDA). The pipeline report is not an all-inclusive list, and medications expected to be highly utilized or have a particular impact in the SoonerCare population have been included for review. Pipeline data is collected from a variety of sources and is subject to change; dates listed are projections and all data presented are for informational purposes only. Costs listed in the following report do not reflect rebated prices or net costs.

Sibeprenlimab[1,2,3,4]

Anticipated Indication(s): Treatment of immunoglobulin A nephropathy (IgAN)

Clinical Trial(s): In May 2025, the FDA accepted the biologics license application (BLA) for sibeprenlimab. The efficacy of sibeprenlimab for the treatment of IgAN was studied in the Phase 2 ENVISION clinical trial and the Phase 3 VISIONARY clinical trial. The Phase 2 ENVISION clinical trial was a multi-center, double-blind, randomized, placebo-controlled, parallel group clinical trial in 155 adults with IgAN who were at high risk for disease progression, despite standard of care treatment, who were randomized to 4 groups to receive either sibeprenlimab at 2mg/kg, 4mg/kg, 8mg/kg of body weight or placebo once monthly for 12 months in addition to standard of care treatment [i.e., highest dose tolerated of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blockers (ARBs)]. The primary endpoint was the change from baseline in the 24-hour urinary protein-to-creatinine ratio (UPCR) at month 12. The patients in the sibeprenlimab groups had a greater reduction in 24-hour UPCR from baseline than the placebo group. The Phase 3 VISIONARY clinical trial was a multicenter, randomized, double-blind, placebo-controlled trial in 510 adult patients with IgAN who were receiving standard of care therapy who were randomized to receive sibeprenlimab 400mg administered subcutaneously (sub-Q) every 4 weeks compared to placebo. The primary efficacy endpoint was the change in the 24-hour UPCR at 9 months compared to baseline. The patients in the

sibeprenlimab group achieved a 51.2% (P<0.001) reduction in proteinuria (measured by 24-hour UPCR) at 9 months of treatment compared to placebo.

Place in Therapy: Sibeprenlimab is a monoclonal antibody that selectively inhibits the activity of APRIL (A PRoliferation-Inducing Ligand) in adults with IgAN. The pathogenesis of IgAN includes the production of galactose-deficient IgA1 (Gd-IgA1) which results in the development of autoantibodies against Gd-IgA1 leading to the formation of immune complexes that deposit in the kidney triggering an inflammatory response, complement activation, and a dysregulated proliferative response leading to worsening kidney function. APRIL is a member of the tumor necrosis factor alpha superfamily and regulates the B-mediated immune response including IgA production. Blocking APRIL is a potential method to reduce Gd-IgA1 from circulating and to decrease the associated immune response. Sibeprenlimab would be the first medication to target APRIL and would be another therapy to help manage the IgAN-specific drivers of nephron loss. If approved, sibeprenlimab will be available in a single-dose prefilled syringe for sub-Q injection that can be self-administered. Other medications that are currently FDA approved for IgAN include Tarpeyo® (budesonide DR capsule), Fabhalta® (iptacopan), Filspari® (sparsentan), and Vanrafia® (atrasentan).

Projected FDA Decision: 11/28/2025

SoonerCare Impact: During fiscal year 2025 (07/01/2024 to 06/30/2025), there were 23 paid claims for IgAN medications for 8 unique members, which accounted for a total cost of $317,561.35 and an average cost per claim of $13,807.02.

Lerodalcibep[5,6,7,8,9,10]

Anticipated Indication(s): To reduce low-density lipoprotein cholesterol (LDL-C) for the treatment of patients with atherosclerotic cardiovascular disease (ASCVD), or who are at very high or high risk of ASCVD, and primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) and those 10 years of age and older with homozygous familial hypercholesterolemia (HoFH)

Clinical Trial(s): In February 2025, the FDA accepted the BLA for lerodalcibep to lower LDL-C. The safety and efficacy of lerodalcibep were studied in the LIBerate program that included 5 global Phase 3 trials, which included over 2,300 patients on maximally tolerated statin therapy and other oral agents (i.e., ezetimibe) who required additional LDL-C reduction. The results of a pooled analysis of 3 of the Phase 3 trials (LIBerate-HR, LIBerate-CVD, and LIBerate-HeFH) showed -58.6% LDL-C change at week 24 and -59.0% LDL-C change at week 52. Additionally, 83% of the patients treated with lerodalcibep at week 24 and 90% at week 52 achieved both recommended targets of a

≥50% LDL-C reduction from baseline and achieved their target LDL-C level (<55mg/dL). Lerodalcibep had similar adverse effects to the placebo group other than mild injection site reactions. The LIBerate-VI trial compared the safety and efficacy of lerodalcibep to inclisiran in 160 patients who were randomized 1:1 to receive treatment with either product. The results, after 9 months, showed that LDL-C decreased by 53% in the lerodalcibep group compared to 45.3% in the inclisiran group. Additionally, 58% of patients on lerodalcibep and 42% on inclisiran met both recommended targets of a ≥50% LDL-C reduction from baseline and achieved their target LDL-C level (<55mg/dL).

Place in Therapy: Lerodalcibep is an investigational third-generation proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. It is dosed once monthly via a single sub-Q injection that does not require refrigeration. The currently approved PCSK9 inhibitors, Repatha® (evolocumab) and Praluent® (alirocumab), require multiple injections for the monthly dosing, and they require refrigeration. Leqvio® (inclisiran), a small interfering RNA product targeting PCSK9, is administered by a health care provider via sub-Q injection every 6 months. The products seem to have similar LDL-C lowering effects. Repatha® and Praluent® have an additional indication to reduce the risk of major cardiovascular events.

Projected FDA Decision: 12/12/2025

SoonerCare Impact: During fiscal year 2025, there were 926 paid claims for PCSK9 inhibitors (i.e., Repatha® and Praluent®) for 195 unique members, which accounted for a total cost of $511,789.90 and an average cost per claim of $552.69.

Depemokimab[11,12,13,14,15,16]

Anticipated Indication(s):

- Add-on maintenance treatment of asthma in adult and pediatric patients aged 12 years and older with type 2 inflammation characterized by an eosinophilic phenotype
- Add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

Clinical Trial(s): In March 2025, the FDA accepted the BLA for depemokimab. 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 inhaled corticosteroids. Patients were randomized 2:1 to receive a 100mg dose of depemokimab or placebo at weeks 0 and 26, plus standard of

care treatment. 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. The adverse events were similar between the depemokimab and placebo groups in all the trials.

Place in Therapy: Depemokimab is a monoclonal antibody that targets interleukin (IL)-5. IL-5 is a key cytokine in type 2 inflammation and is typically identified by blood eosinophil counts. Type 2 inflammation is typically present in patients with both severe asthma and uncontrolled CRSwNP. Currently, there are 3 other IL-5 inhibitors on the market including Cinqair® (reslizumab), Fasenra® (benralizumab), and Nucala® (mepolizumab), which are all indicated in severe asthma with an eosinophilic phenotype. Nucala® is also indicated for CRSwNP. The main difference between depemokimab and the products currently on the market is the dosing frequency. Depemokimab is dosed every 6 months versus the other options, which are dosed every 4 to 8 weeks. Fasenra® and Nucala® both can be administered by a health care provider (HCP) or can be self-administered after training, while Cinqair® requires administration by a HCP.

Projected FDA Decision: 12/16/2025

SoonerCare Impact: During fiscal year 2025, there were 615 paid pharmacy claims for the other IL-5 inhibitors (i.e., Fasenra® and Nucala®) for 135 unique members, which accounted for a total cost of $2,956,479.14 and an average cost per claim of $4,807.28.

Pipeline Table[17,18,19,20]

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
ataluren	PTC	DMD	PO	NDA; Fst Trk; OD	07/2025-09/2025
bentracimab	SFJ Pharmaceuticals	Antiplatelet drug toxicity	IV	BLA; Brk Thru	07/2025-09/2025
sodium pyruvate	EmphyCorp	IPF	IN	NDA	09/2025
carbidopa/ levodopa	Mitsubishi Tanabe	Parkinson's disease motor fluctuations	sub-Q	505(b)(2) NDA	10/2025-12/2025
pegzilarginase	Immedica	ARG1-D	IV, sub-Q	BLA; Brk Thru; Fst Trk; OD	10/2025-12/2025
semaglutide 25mg tablet	Novo Nordisk	Reduce the risk of MACE in adults with obesity/ overweight and established CVD	PO	NDA	10/2025-12/2025
nerandomilast	Boehringer Ingelheim	IPF	PO	NDA	10/2025-12/2025
sodium chlorite	Neuvivo	ALS	IV	NDA; OD	10/07/2025
valacyclovir oral suspension	Hyloris	Herpes Zoster	PO	505(b)(2) NDA	10/12/2025
atropine	Sydnexis	Myopia (pediatric)	OPH	505(b)(2) NDA	10/23/2025
remibrutinib	Novartis	Chronic spontaneous urticaria	PO	NDA	11/2025
elinzanetant	Bayer	VMS associated with menopause	PO	NDA	11/09/2025
etuvetidigene autotemcel (OTL-103)	Fondazione Telethon	Wiskott-Aldrich syndrome	IV	BLA; OD	11/11/2025
troriluzole	Biohaven	Spinocerebellar ataxia	PO	505(b)(2) NDA; Fst Trk; OD	11/11/2025
plozasiran	Arrowhead	FCS	sub-Q	NDA; Brk Thru; Fst Trk; OD	11/18/2025
navepegritide	Ascendis	Achondroplasia (children)	sub-Q	NDA; OD	11/28/2025
sibeprenlimab	Otsuka	IgA nephropathy	sub-Q	BLA; Brk Thru	11/28/2025
lerodalcibep	LIB Therapeutics	HCH	sub-Q	BLA	12/12/2025

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
etripamil (Cardamyst)	Milestone	Paroxysmal supraventricular tachycardia	IN	NDA	12/13/2025
zoliflodacin	Innoviva	Gonorrhea (uncomplicated, ages ≥ 12 years)	PO	NDA; Fst Trk	12/15/2025
depemokimab	GSK	Asthma (ages ≥ 12 years, type 2 inflammation); chronic rhinosinusitis	sub-Q	BLA	12/16/2025
reproxalap	Aldeyra	DED	OPH	NDA	12/16/2025
aficamten	Cytokinetics	Obstructive hypertrophic cardiomyopathy	PO	NDA; Brk Thru; OD	12/26/2025
narsoplimab	Omeros	TA-TMA	IV, sub-Q	BLA; OD	12/26/2025
fibrinogen	Grifols	Fibrinogen deficiency (acquired and congenital)	IV	BLA	12/27/2025
tolebrutinib	Sanofi	Multiple sclerosis	PO	NDA	12/28/2025
relacorilant	Corcept	Cushing's syndrome	PO	NDA; OD	12/30/2025
tradipitant	Vanda, Eli Lilly	Motion sickness	PO	NDA	12/30/2025
tividenofusp alfa	Denali	MPSII	IV	BLA; Brk Thru; Fst Trk; OD	01/05/2026
tabelecleucel	Atara Biotherapeutics	Lympho-proliferative disorder	IV	BLA	01/10/2026
brimonidine/ carbachol	Visus, Tenpoint	Presbyopia	OPH	505(b)(2) NDA	01/28/2026
epinephrine	Aquestive	Anaphylaxis	SL	505(b)(2) NDA; Fst Trk	01/31/2026
clemidsogene lanparvovec (RGX-121)	Nippon Shinyaku, Regenxbio	MPSII	IC	BLA; OD; Fst Trk	02/08/2026
milsaperidone	Vanda	Bipolar I disorder; schizophrenia	PO	NDA	02/21/2026
desmopressin oral solution	Eton	CDI	IN	505(b)(2) NDA	02/25/2026
linerixibat	GSK	Cholestatic pruritus	PO	NDA; OD	03/24/2026

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
doravirine/ islatravir	Merck	HIV-1 infection treatment	PO	NDA	04/28/2026
nimodipine	Grace	Subarachnoid hemorrhage	IV	505(b)(2) NDA; Fst Trk; OD	06/25/2026
icotrokinra	Janssen	Plaque psoriasis	PO	NDA	07/21/2026
cytisinicline	Achieve	Smoking cessation (nicotine dependence)	PO	NDA; Brk Thru	07/26/2026
dexmethyl-phenidate	Cingulate	ADHD	PO	NDA	08/06/2026

*Most biosimilars and oncology medications are excluded from the table. Medications known to have received a Complete Response Letter (CRL) from the FDA that have not resubmitted were also excluded.
ADHD = attention deficit hyperactivity disorder; Admin = administration; ALS = amyotrophic lateral sclerosis; ARG1-D = arginase 1 deficiency; BLA = biologic license application; Brk Thru = breakthrough; CDI = central diabetes insipidus; CVD = cardiovascular disease; DED = dry eye disease; DMD = Duchenne muscular dystrophy; FCS = familial chylomicronemia syndrome; Fst Trk = fast track; GSK = GlaxoSmithKline; HCH = hypercholesteremia; HIV = Human Immunodeficiency Virus; IC = intracisternal; IgA = immunoglobulin A; IN = intranasal; IPF = idiopathic pulmonary fibrosis; IV = intravenous; MACE = major adverse cardiovascular events; MPSII = mucopolysaccharidosis II; NDA = new drug application; OD = orphan drug; OPH = ophthalmic; PO = by mouth; sub-Q = subcutaneous; SL = sublingual; SMA = spinal muscular atrophy; TA-TMA = transplant associated thrombotic microangiopathy; TD = transdermal; VMS = vasomotor symptoms

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Appendix D

Vote to Prior Authorize Attruby™ (Acoramidis) and Update the Prior Authorization Criteria for the Amyloidosis Medications

Oklahoma Health Care Authority
October 2025

Market News and Updates[1,2]

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

- **November 2024:** The FDA approved Attruby™ (acoramidis), an oral transthyretin stabilizer, for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) death and CV-related hospitalization.
- **May 2025:** Amvuttra® (vutrisiran) received FDA expanded approval for the treatment of the ATTR-CM with wild-type or variant transthyretin genotypes to reduce CV death and CV-related hospitalization. Amvuttra® is currently the only product FDA approved for the treatment of both ATTR-CM and the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN).

Attruby™ (Acoramidis) Product Summary[1]

Therapeutic Class: Transthyretin stabilizer

Indication(s): Treatment of wild-type or variant ATTR-CM in adults to reduce CV death and CV-related hospitalization

How Supplied: 356mg film-coated tablets

Dosing and Administration: 712mg (2 tablets) orally twice daily

Efficacy: Attruby™ was evaluated in a multicenter, international, randomized, double-blind, placebo-controlled study in 611 patients.

- Key Inclusion Criteria:
  - Diagnosis of ATTR-CM with either wild-type or variant transthyretin genotype
  - History of heart failure with New York Heart Association (NYHA) Class I-III symptoms due to ATTR-CM
  - On stable CV medical therapy

- Key Exclusion Criteria:
  - History of acute myocardial infarction, acute coronary syndrome, coronary revascularization or experienced a stroke or transient ischemic attack within the 90 days prior to screening
  - Confirmed diagnosis of primary (light chain) amyloidosis
  - Current treatment with any FDA approved or experimental drug for ATTR-CM
- Intervention(s):
  - Attruby™ 712mg orally twice daily vs. placebo tablet orally twice daily
- Primary Endpoint(s):
  - Composite endpoint of all-cause mortality and cumulative frequency of CV-related hospitalizations (CVH) over 30 months
- Results:
  - A statistically significant reduction in the composite endpoint (P=0.018) was seen in the Attruby™ arm (n=409) vs. the placebo arm (n=202).
  - All-cause mortality was reported in 19% of patients in the Attruby™ arm vs. 26% of patients the placebo arm.
  - The mean number of CVH events was 0.3 vs. 0.6 per year.

Cost Comparison:

Product	Cost Per Tablet	Cost Per Year*
Attruby™ (acoramidis) 356 mg tablet	**$167.49**	**$241,185.60**
Vyndamax® (tafamidis) 61mg tablet	$744.41	$267,987.60
Vyndaqel® (tafamidis meglumine) 20mg tablet	$186.10	$267,984.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per year is based on the FDA recommended dosing of Attruby™ 712mg twice daily, Vyndamax® 61mg once daily, and Vyndaqel® 80mg once daily.

Recommendations

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.

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[1] Attruby™ (Acoramidis) Prescribing Information. BridgeBio Pharma. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216540s000lbl.pdf. Last revised 11/2024. Last accessed 09/24/2025.

[2] Alnylam® Pharmaceuticals. Alnylam Announces FDA Approval of Amvuttra® (Vutrisiran), the First RNAi Therapeutic to Reduce Cardiovascular Death, Hospitalizations and Urgent Heart Failure Visits in Adults with ATTR Amyloidosis with Cardiomyopathy (ATTR-CM). Available online at: https://investors.alnylam.com/press-release?id=28831. Issued 03/20/2025. Last accessed 09/24/2025.

Appendix E

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

Oklahoma Health Care Authority
October 2025

Market News and Updates[1,2,3]

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

- **December 2024:** The FDA approved Alyftrek® (vanzacaftor/tezacaftor/ deutivacaftor) for the treatment of CF in patients 6 years of age and older who have at least 1 *F508del* mutation or another mutation in the CF transmembrane conductance regulator (*CFTR*) gene that is responsive to Alyftrek®.
- **December 2024:** The FDA approved a label expansion for Trikafta® (elexacaftor/tezacaftor/ivacaftor) to include patients with a mutation that is responsive to Trikafta® based on clinical and/or *in vitro* data, allowing 94 additional non-*F508del CFTR* mutations to be added to the Trikafta® label. This label expansion allows approximately 300 additional CF patients to be eligible for CFTR modulator therapy. Additionally, the safety information on liver injury and liver failure has been updated from *Warnings and Precautions* to a *Boxed Warning*.

Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor) Product Summary[4,5]

Therapeutic Class: Combination CFTR potentiator (deutivacaftor) and CFTR correctors (vanzacaftor and tezacaftor)

Indication(s): Treatment of CF in patients 6 years of age and older who have at least 1 *F508del* mutation or another responsive mutation in the *CFTR* gene

- If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least 1 indicated mutation.

How Supplied: Alyftrek® is supplied as fixed dose combination tablets in the following strengths:

- Vanzacaftor/tezacaftor/deutivacaftor 4/20/50mg
- Vanzacaftor/tezacaftor/deutivacaftor 10/50/125mg

Dosing and Administration:

Age	Weight	Once Daily Dose
6 to <12 years	<40kg	3 tablets of vanzacaftor/tezacaftor/ deutivacaftor 4/20/50mg
	≥40kg	2 tablets of vanzacaftor/tezacaftor/ deutivacaftor 10/50/125mg
≥12 years	Any weight	

- Prior to initiating Alyftrek®, liver function tests [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and bilirubin] should be obtained in all patients and should be monitored every month during the first 6 months of treatment, then every 3 months during the next 12 months, then at least annually thereafter.
- Alyftek® should not be used in patients with severe hepatic impairment or in patients with moderate hepatic impairment unless the benefit outweighs the risk. If used, no dose adjustment is recommended. Liver function tests should be closely monitored.
- See the full *Prescribing Information* for dosage modifications for concomitant use with strong or moderate CYP3A inhibitors and a list of *CFTR* gene mutations responsive to Alyftrek®.

Efficacy: Alyftrek® was studied in 2 randomized, double-blind, active-controlled trials, SKYLINE 102 and SKYLINE 103, comparing Alyftrek® to elexacaftor, tezacaftor, and ivacaftor (ELX/TEZ/IVA) for 971 patients who were 12 years of age or older with CF.

- Key Inclusion Criteria:
  - SKYLINE 102:
    - Heterozygous for *F508del* and a minimal function mutation
    - Forced expiratory volume in 1 second (FEV_1) ≥40% and ≤90% of predicted mean for age, sex, and height for participants currently receiving ELX/TEZ/IVA
    - FEV_1 ≥40% and ≤80% for participants not currently receiving ELX/TEZ/IVA
  - SKYLINE 103:
    - ≥1 of the following genotypes: homozygous for the *F508del* mutation, heterozygous for the *F508del* mutation and either a gating or a residual function mutation, or at least 1 mutation responsive to ELX/TEZ/IVA with no *F508del* mutation
    - FEV_1 ≥40% and ≤90% of predicted mean for age, sex, and height for participants currently receiving CFTR modulator therapy
    - FEV_1 ≥40% and ≤80% for participants not currently receiving therapy with a CFTR modulator

- Key Exclusion criteria:
  - History of intolerance to ELX/TEZ/IVA
- Intervention(s): Patients were randomized 1:1 to receive Alyftrek® or ELX/TEZ/IVA for 52 weeks.
  - To establish a reliable on-treatment baseline, all study participants received ELX/TEZ/IVA during a 4-week run-in period, and the baseline values for all endpoints were measured at the end of the ELX/TEZ/IVA run-in.
- Endpoint(s):
  - Primary: Non-inferiority in mean absolute change in percent predicted FEV_1 ($ppFEV_1$) from baseline through week 24
    - Both trials included a prespecified non-inferiority margin of -3.0%.
  - Key Secondary Endpoint: Mean absolute change from baseline in SwCl through week 24
- Results:
  - Primary Endpoint:
    - SKYLINE 102: Absolute change in $ppFEV_1$ was 0.5% for those on Alyftrek® vs. 0.3% for those on ELX/TEZ/IVA [treatment difference: 0.2%; 95% confidence interval (CI): -0.7, 1.1; P<0.001]
    - SKYLINE 103: Absolute change in $ppFEV_1$ was 0.2% for those on Alyftrek® vs. 0.0% for those on ELX/TEZ/IVA (treatment difference: 0.2%; 95% CI: -0.5, 0.9; P<0.001)
  - Secondary Endpoint:
    - SKYLINE 102: Absolute change in SwCl was -7.5mmol/L for those on Alyftrek® vs. 0.9mmol/L for those on ELX/TEZ/IVA (treatment difference: -8.4mmol/L; 95% CI: -10.5, -6.3; P<0.0001)
    - SKYLINE 103: Absolute change in SwCl was -5.1mmol/L for those on Alyftrek® vs. -2.3mmol/L for those on ELX/TEZ/IVA (treatment difference: -2.8mmol/L; 95% CI: -4.7, -0.9; P=0.0034)

Cost Comparison:

Product	Cost Per Tablet	Cost Per 28 Days	Cost Per Year
Alyftrek® (vanz/teza/deut) 10/50/125mg	**$507.22**	**$28,404.32***	**$369,256.16**
Trikafta® (elx/teza/iva and iva) 100/50/75mg	$338.15	$28,404.60⁺	$369,259.80

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).
deut = deutivacaftor; elx = elexacaftor; iva = ivacaftor; teza = tezacaftor; vanz = vanzacaftor
*Cost per 28 days based on the maximum FDA approved dosing of 2 tablets once daily.
⁺Cost per 28 days is based on the maximum FDA approved dosing of 2 tablets in the morning and 1 tablet of ivacaftor in the evening.

Recommendations

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 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.

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[1] Vertex Pharmaceuticals. Vertex Announces US FDA Approval of Alyftrek™, a Once-Daily Next-in-Class CFTR Modulator for the Treatment of Cystic Fibrosis. Available online at: https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-us-fda-approval-alyftrektm-once-daily-next. Issued 12/20/2024. Last accessed 09/22/2025.

[2] Vertex Pharmaceuticals. Vertex Announces U.S. FDA Approval for Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) to Include Additional Non-*F508del* Trikafta®-Responsive Variants. Available online at: https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-us-fda-approval-trikafta. Issued 12/20/2024. Last accessed 09/22/2025.

[3] Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor; Ivacaftor) – Updated Label, Boxed Warning Added. *OptumRx*®. Available online at: https://professionals.optumrx.com/content/dam/noindex-resources/business/support-documents/clinical-updates/clinicalupdate_trikafta_2024-1223.pdf. Issued 12/20/2024. Last accessed 09/22/2025.

[4] Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor) Prescribing Information. Vertex Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218730s000lbl.pdf. Last revised 12/2024. Last accessed 09/22/2025.

[5] Keating C, Yonker L, Vermeulen F, et.al. Vanzacaftor–Tezacaftor–Deutivacaftor Versus Elexacaftor–Tezacaftor–Ivacaftor in Individuals With Cystic Fibrosis Aged 12 Years and Older (SKYLINE Trials VX20-121-102 and VX20-121-103): Results From Two Randomised, Active-Controlled, Phase 3 Trials. *Lancet Respir Med* 2025; 13:256-71. doi: 10.1016/2213-2600(24)00411-9.

Appendix F

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

Oklahoma Health Care Authority
October 2025

Encelto™ (Revakinagene Taroretcel-lwey) Product Summary[1,2,3]

Therapeutic Class: Allogenic encapsulated cell-based gene therapy

Indication(s): Treatment of adults with idiopathic macular telangiectasia (MacTel) type 2

How Supplied: Sterile, single-dose implant that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (rhCNTF) (NTC-201-6A cell line)

Dosing and Administration:

- Encelto™ is administered by a single surgical intravitreal procedure performed by a qualified ophthalmologist.
- The recommended dose is 1 Encelto™ implant per affected eye.
- The provider should carefully inspect Encelto™ prior to use and refer to the *Instructions for Use* in the *Prescribing Information* when preparing for and performing surgical placement or removal of Encelto™.
- Encelto™ implant should be removed if vitrectomy with a complete gas fill or silicone oil fill is required or if infectious endophthalmitis occurs.

Efficacy: The safety and efficacy of Encelto™ were studied in 2 identically designed, randomized, multicenter, sham-controlled studies in adult patients.

- Key Inclusion Criteria:
  - At least 1 study eye with a diagnosis of MacTel type 2 with evidence of fluorescein leakage and at least 1 of the other features including the following:
    - Hyperpigmentation that is outside of a 500-micron radius from the center of the fovea
    - Retinal opacification
    - Crystalline deposits
    - Right-angle vessels
    - Inner/outer lamellar cavities
  - 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-ODT)

    - Best corrected visual acuity (BCVA) or 54-letter score or better (20/80 or better Snellen equivalent) measured by Early Treatment Diabetic Retinopathy Study (ETDRS) chart at screening
- Key Exclusion Criteria:
    - Neovascular MacTel type 2
- Intervention: Randomized to receive either Encelto™ intravitreal implant or sham procedure under standard operative procedures
- Primary Outcome: Rate of change in the area EZ loss (IS/OS macular PR loss) over 24 months as measured by SD-OCT
- Primary Outcome Results:
    - Study 1: 0.075mm^2 [95% confidence interval (CI): 0.05, 0.10] in the Encelto™ group vs. 0.166mm^2 (95% CI: 0.14, 0.19) in the sham group; treatment difference: -0.091mm^2 (95% CI: -0.13, -0.06; P<0.0001)
    - Study 2: 0.111mm^2 (95% CI: 0.08, 0.14) in the Encelto™ group vs. 0.160mm^2 (95% CI: 0.13, 0.19) in the sham group; treatment difference: -0.049mm^2 (95% CI: -0.089, -0.008; P=0.0186)

Cost: The Wholesale Acquisition Cost (WAC) of Encelto™ is $250,000 per implant.

Recommendations

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.

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[1] Encelto™ (Revakinagene Taroretcel-lwey) Prescribing Information. Neurotech Pharmaceuticals, Inc. Available online: https://www.fda.gov/media/185726/download?attachment. Last revised 03/2025. Last accessed 09/15/2025.
[2] A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 – Protocol A. *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT03316300. Last revised 09/24/2024. Last accessed 09/15/2025.
[3] A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 – Protocol B. *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT03319849. Last revised 09/24/2024. Last accessed 09/15/2025.

Appendix G

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

Oklahoma Health Care Authority
October 2025

Cost Comparison: Lanthanum Carbonate Products

Product	Cost Per Unit	Cost Per Day*
Fosrenol® (lanthanum carbonate) 750mg packet	**$12.01**	**$48.04**
Fosrenol® (lanthanum carbonate) 1,000mg packet	**$12.01**	**$36.03**
Fosrenol® (lanthanum carbonate) 750mg chewable tablet	$12.01	$48.04
Fosrenol® (lanthanum carbonate) 1,000mg chewable tablet	$12.01	$36.03
lanthanum carbonate 750mg chewable tablet (generic)	$3.63	$14.52
lanthanum carbonate 1,000mg chewable tablet (generic)	$3.15	$9.45

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day is based on the typical maximum daily dose of 3,000mg.
Unit = packet or tablet

Recommendations

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®) 1000mg chewable tablet, PhosLo® (calcium acetate gel capsule), and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Appendix H

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

Oklahoma Health Care Authority
October 2025

Photrexa®/Photrexa® Viscous (Riboflavin 5'-phosphate) Product Summary[1]

Therapeutic Class: Photo-enhancers

Indication(s): For use with the KXL® System in corneal cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery

How Supplied:

- Photrexa® Viscous is supplied in a 3mL glass syringe containing sterile 1.56mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution.
- Photrexa® is supplied in a 3mL glass syringe containing sterile 1.46mg/mL riboflavin 5'-phosphate ophthalmic solution.

Dosing and Administration:

- See *Prescribing Information* for full dosing and administration.
- For topical ophthalmic use. Do not inject.
- For single use only. Discard syringe(s) after use.
- Photrexa® Viscous and Photrexa® are for use with the KXL® System only.

Efficacy: The safety and efficacy of Photrexa®/Photrexa® Viscous with the KXL® system were studied in 3 prospective, randomized, parallel-group, open-label, sham-controlled trials.

- Key Inclusion Criteria:
  - Study 1: Patients with a diagnosis of progressive keratoconus or corneal ectasia following refractive surgery
  - Study 2: Patients with a diagnosis of progressive keratoconus only
  - Study 3: Patients with a diagnosis of corneal ectasia following refractive surgery only
- Intervention: In each study, 1 eye was designated as the study eye and was randomized to receive 1 of 2 study treatments (Photrexa®/ Photrexa® Viscous with the KXL® system or sham) at the baseline visit. The patients were evaluated at day 1, week 1, and at months 1, 3, 6, and 12. At month 3 or later, patients had the option of receiving treatment in both the sham study eye and non-study eye and were followed for 12 months from the time of receiving treatment.
- Primary Outcome: The maximum corneal curvature (K_{max}) was assessed at baseline and at months 1, 3, and 12.

- Results: The treated eyes showed increasing improvement in K_{max} from month 3 to month 12.
  - Progressive keratoconus patients had an average K_{max} reduction of 1.4 diopters in Study 1 and 1.7 diopters in Study 2 at month 12 in the treated eyes, while the sham eyes had an average increase of 0.5 diopter in Study 1 and 0.6 diopter in Study 2 at month 12.
    - The treatment differences [95% confidence interval (CI)] between the groups were -1.9 (-3.4, -0.3) diopters in Study 1 and -2.3 (-3.5, -1.0) in Study 2.
  - Corneal ectasia patients had an average K_{max} reduction of 1.0 diopter in Study 1 and 0.5 diopter in Study 3 at 12 months in the treated eyes, while the sham eyes had an average increase of 1.0 diopter in Study 1 and 0.5 diopter in Study 3.
    - The treatment difference (95% CI) between the groups were -2.0 (-3.0, -1.1) diopters in Study 1 and -1.1 (-1.9, -0.3) diopters in Study 3.

Cost: The Wholesale Acquisition Cost (WAC) of Photrexa®/Photrexa® Viscous is $4,560 per kit; therefore, to treat both eyes, the medication cost would be $9,120.

Recommendations

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.

[1] Photrexa® Viscous and Photrexa® Prescribing Information. Glaukos Company. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/203324s010lbl.pdf. Last revised 02/2025. Last accessed 09/15/2025.

Appendix I

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

Oklahoma Health Care Authority
October 2025

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

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

- **October 2024:** The FDA approved Itovebi™ (inavolisib), in combination with palbociclib and fulvestrant, for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.
- **January 2025:** The FDA approved Datroway® (datopotamab deruxtecan-dlnk) for the treatment of adult patients with unresectable or metastatic, HR-positive, HER2-negative immunohistochemistry (IHC) 0, IHC 1+, or IHC 2+/in situ hybridization (ISH)-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.
- **January 2025:** The FDA approved Enhertu® (fam-trastuzumab deruxtecan-nxki) for a new indication for the treatment of HR-positive, HER2-low (IHC 1+ or IHC 2+/ISH-negative) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on 1 or more endocrine therapies in the metastatic setting.
- **April 2025:** The FDA approved Ibrance® (palbociclib) for a new indication, in combination with inavolisib and fulvestrant, for the treatment of adult patients with endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.
- **June 2025:** The FDA granted accelerated approval to Datroway® for a new indication for the treatment of adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.

News:

- **October 2024:** Gilead, the manufacturer of Trodelvy® (sacituzumab govitecan-hziy), announced plans to voluntarily withdraw the previous accelerated approval for Trodelvy® for the treatment of adults with locally advanced or metastatic urothelial cancer who have received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. The required confirmatory trial for this indication did not meet the primary endpoint of overall survival (OS) in the intent-to-treat (ITT) population. In November 2024, the FDA announced that the withdrawal of this indication has been completed.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for central nervous system cancers allow for the use of neratinib in combination with ado-trastuzumab emtansine in patients with breast cancer and brain metastases.

Datroway® (Datopotamab Deruxtecan-dlnk) Product Summary[9]

Therapeutic Class: Trop-2-directed antibody and topoisomerase inhibitor conjugate

Indication(s):

- Treatment of adult patients with unresectable or metastatic, HR-positive, HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-negative) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease
- Treatment of adult patients with locally advanced or metastatic EGFR-mutated NSCLC who have received prior EGFR-directed therapy and platinum-based chemotherapy
    - This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

How Supplied: 100mg lyophilized powder in a single-dose vial (SDV)

Dosing and Administration:

- The recommended dose is 6mg/kg (up to a maximum of 540mg for patients ≥90kg) as an intravenous (IV) infusion every 3 weeks.
- Datroway® should be continued until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) of Datroway® is $4,891.07 per SDV. For a member weighing 80kg, this would result in an estimated cost of $24,455.35 per dose or $440,196.30 per year based on recommended dosing.

Itovebi™ (Inavolisib) Product Summary[10]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment, in combination with palbociclib and fulvestrant, of adults with endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy

How Supplied: 3mg and 9mg oral tablets

Dosing and Administration:

- The recommended dose is 9mg orally once daily, with or without food, until disease progression or unacceptable toxicity.
- Itovebi™ should be administered in combination with palbociclib and fulvestrant.

Cost: The WAC of Itovebi™ is $816.68 per 9mg tablet. This would result in an estimated cost of $22,867.04 per 28 days or $297,271.52 per year based on recommended dosing.

Cost Comparison: Trastuzumab Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Herzuma® (trastuzumab-pkrb) 150mg vial	$77.49	$3,487.05	$62,766.90
Herceptin® (trastuzumab) 150mg vial	$76.18	$3,428.10	$61,705.80
Hercessi™ (trastuzumab-strf) 150mg vial	$76.18	$3,428.10	$61,705.80
Ogivri® (trastuzumab-dkst) 150mg vial	$44.59	$2,006.55	$36,117.90
Kanjinti® (trastuzumab-anns) 150mg vial	$43.28	$1,947.60	$35,056.80
Trazimera® (trastuzumab-qyyp) 150mg vial	$28.62	$1,287.90	$23,182.20
Ontruzant® (trastuzumab-dttb) 150mg vial	$21.99	$989.55	$17,811.90

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 21 days based on use of (3) 150mg vials per dose (6mg/kg every 3 weeks for a 75kg member)

Recommendations

The College of Pharmacy recommends the prior authorization of 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 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.

[1] U.S. Food and Drug Administration (FDA). FDA Approves Inavolisib with Palbociclib and Fulvestrant for Endocrine-Resistant, PIK3CA-Mutated, HR-Positive, HER2-Negative, Advanced Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-inavolisib-palbociclib-and-fulvestrant-endocrine-resistant-pik3ca-mutated-hr-positive. Issued 10/10/2024. Last accessed 09/23/2025.
[2] U.S. FDA. FDA Approves Datopotamab Deruxtecan-dlnk for Unresectable or Metastatic, HR-Positive, HER2-Negative Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-datopotamab-deruxtecan-dlnk-unresectable-or-metastatic-hr-positive-her2-negative-breast. Issued 01/17/2025. Last accessed 09/23/2025.
[3] U.S. FDA. FDA Approves Fam-Trastuzumab Deruxtecan-nxki for Unresectable or Metastatic HR-Positive, HER2-Low or HER2-Ultralow Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-hr-positive-her2-low-or-her2. Issued 01/27/2025. Last accessed 09/23/2025.
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[5] U.S. FDA. FDA Grants Accelerated Approval to Datopotamab Deruxtecan-dlnk for EGFR-Mutated Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-datopotamab-deruxtecan-dlnk-egfr-mutated-non-small-cell-lung-cancer. Issued 06/23/2025. Last accessed 09/23/2025.
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[9] Datroway® (Datopotamab Deruxtecan-dlnk) Prescribing Information. Daiichi Sankyo, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761464s000lbl.pdf. Last revised 06/2025. Last accessed 09/23/2025.
[10] Itovebi™ (Inavolisib) Prescribing Information. Genentech USA, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219249s000lbl.pdf. Last revised 10/2024. Last accessed 09/23/2025.

Appendix J

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

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

Utilization data for Reblozyl® (luspatercept-aamt) and approval criteria for indications other than MPN can be found in the October 2025 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the anemia medications.

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

1. Diagnosis of PV; and
2. Used as a single agent.

Elzonris® (Tagraxofusp-erzs) Approval Criteria [Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) Diagnosis]:

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

Inrebic® (Fedratinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of MF in adult members; and
2. Intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia); and
3. In combination with prophylactic thiamine 100mg daily.

Jakafi® (Ruxolitinib) Approval Criteria [Graft-Versus-Host Disease (GVHD) Diagnosis]:

1. Diagnosis of acute or chronic GVHD; and
2. Failure of at least 1 prior line of systemic therapy; and
3. Member must be 12 years of age or older.

Jakafi® (Ruxolitinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of MF; and
2. Used in 1 of the following settings:
    a. Symptomatic lower-risk MF with no response or loss of response to peginterferon alfa-2a or hydroxyurea; or
    b. Intermediate to high-risk MF; and
3. Member must be 18 years of age or older.

Jakafi® (Ruxolitinib) Approval Criteria [Polycythemia Vera (PV) Diagnosis]:

1. Diagnosis of PV; and
2. Inadequate response or loss of response to hydroxyurea or peginterferon alfa-2a therapy; and
3. Member must be 18 years of age or older.

Ojjaara (Momelotinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of intermediate or high-risk disease (including MF, polycythemia vera, or post-essential thrombocythemia); and
2. Presence of anemia.

Reblozyl® (Luspatercept-aamt) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. An FDA approved indication of 1 of the following:
    a. Treatment of adult members with very low-to-intermediate risk MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with anemia failing an erythropoiesis stimulating agent (ESA) and requiring ≥2 red blood cell (RBC) units over 8 weeks; or
    b. Treatment of adult members with very low-to-intermediate risk MDS with anemia who are ESA-naive and who required ≥2 RBS units within the last 8 weeks; and
2. For MDS-RS or MDS/MPN-RS-T:
    a. Member must have had an inadequate response to prior treatment with an ESA, be intolerant of ESAs, or have a serum erythropoietin level >200U/L; and
    b. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
    c. Prescriber must verify the member does not have deletion 5q (del 5q); and
3. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
4. Reblozyl® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in treatment of MDS (or an advanced care practitioner with a supervising physician who is a hematologist, oncologist, or specialist with expertise in treating MDS); and
5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
6. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and

7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 6 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Vonjo® (Pacritinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of intermediate or high-risk primary or secondary MF; and
2. Platelet count $<50 \times 10^9/L$.

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.

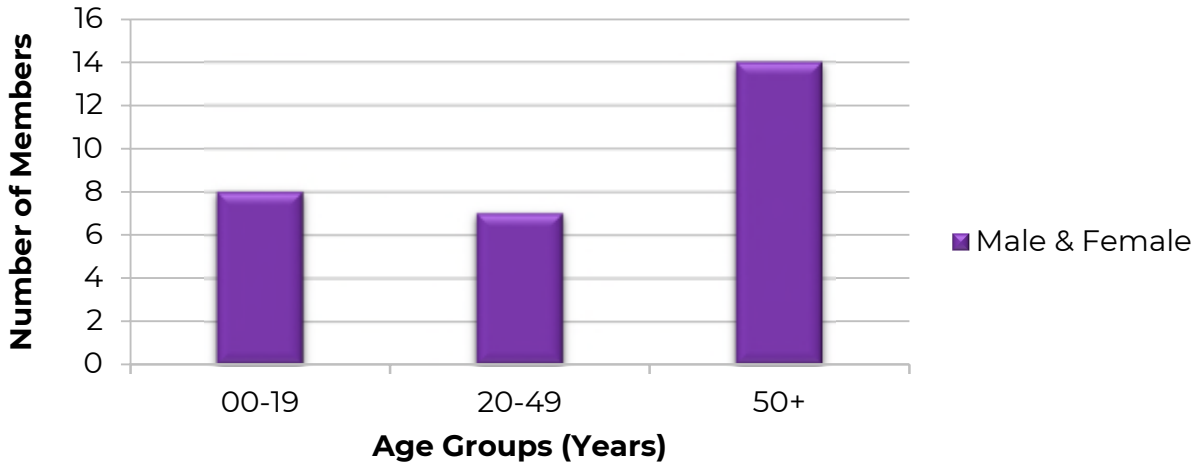
Utilization of MPN Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

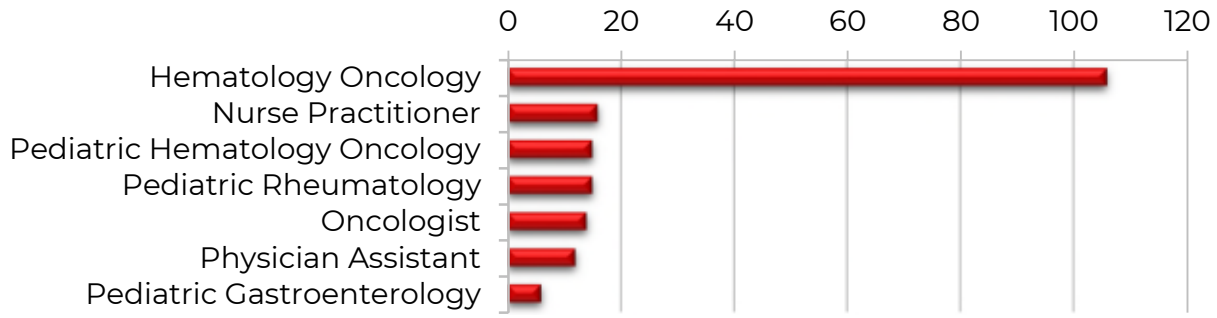
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	22	135	$2,120,188.85	$15,705.10	$517.75	7,500	4,095
Aetna	2	4	$68,645.64	$17,161.41	$572.05	240	120
Humana	4	8	$154,441.28	$19,305.16	$643.51	540	240
OCH	2	6	$102,968.46	$17,161.41	$572.05	360	180
2024 Total	**22**	**153**	**$2,446,244.23**	**$15,988.52**	**$527.78**	**8,640**	**4,635**
Fiscal Year 2025							
FFS	16	90	$1,542,605.08	$17,140.06	$575.81	5,583	2,679
Aetna	5	39	$561,357.49	$14,393.78	$501.66	1,929	1,119
Humana	5	32	$510,837.90	$15,963.68	$532.12	1,620	960
OCH	5	23	$394,087.09	$17,134.22	$597.10	1,380	660
2025 Total	**29**	**184**	**$3,008,887.56**	**$16,352.65**	**$555.35**	**10,512**	**5,418**
% Change	**31.80%**	**20.30%**	**23.00%**	**2.30%**	**5.20%**	**21.70%**	**16.90%**
Change	**7**	**31**	**$562,643.33**	**$364.13**	**$27.57**	**1,872**	**783**

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 MPN Medications (All Plans)



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



Prior Authorization of MPN Medications

There were 51 prior authorization requests submitted for MPN 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	28	67%	13	31%	1	2%	**42**
Aetna	2	50%	2	50%	0	0%	**4**
Humana	1	100%	0	0%	0	0%	**1**
OCH	3	75%	1	25%	0	0%	**4**
Total	**34**	**67%**	**16**	**31%**	**1**	**2%**	**51**

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

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Jakafi® (ruxolitinib): December 2028
- Vonjo® (pacritinib): March 2030
- Inrebic® (fedratinib): September 2039

- Ojjaara (momelotinib): December 2040

Recommendations

The College of Pharmacy does not recommend any changes to the current MPN medications prior authorization criteria at this time.

Utilization Details of MPN Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RUXOLITINIB PRODUCTS						
JAKAFI TAB 20MG	68	12	$1,091,362.88	$16,049.45	5.67	36.27%
JAKAFI TAB 5MG	51	9	$781,081.41	$15,315.32	5.67	25.96%
JAKAFI TAB 25MG	25	3	$332,052.75	$13,282.11	8.33	11.04%
JAKAFI TAB 15MG	13	6	$226,723.83	$17,440.29	2.17	7.54%
JAKAFI TAB 10MG	13	5	$207,764.83	$15,981.91	2.6	6.91%
SUBTOTAL	**170**	**35**	**$2,638,985.70**	**$15,523.45**	**4.86**	**87.71%**
FEDRATINIB PRODUCTS						
INREBIC CAP 100MG	12	2	$312,146.26	$26,012.19	6	10.37%
SUBTOTAL	**12**	**2**	**$312,146.26**	**$26,012.19**	**6**	**10.37%**
MOMELOTINIB PRODUCTS						
OJJAARA TAB 200MG	2	1	$57,755.60	$28,877.80	2	1.92%
SUBTOTAL	**2**	**1**	**$57,755.60**	**$28,877.80**	**2**	**1.92%**
TOTAL	**184**	**29***	**$3,008,887.56**	**$16,352.65**	**6.34**	**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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 09/2025. Last accessed 09/15/2025.

Appendix K

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

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

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 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.

Utilization of *C. difficile* Medications: Fiscal Year 2025

Fiscal Year 2025 Utilization: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	1	1	$18,561.41	$18,561.41	$6,187.14	12	3
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**1**	**1**	**$18,561.41**	**$18,561.41**	**$6,187.14**	**12**	**3**
Fiscal Year 2025							
FFS	1	1	$19,117.91	$19,117.91	$6,372.64	12	3
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
2025 Total	**1**	**1**	**$19,117.91**	**$19,117.91**	**$6,372.64**	**12**	**3**
% Change	**0.00%**	**0.00%**	**3.00%**	**3.00%**	**3.00%**	**0.00%**	**0.00%**
Change	**0**	**0**	**$556.50**	**$556.50**	**$185.50**	**0**	**0**

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	3	3	$7,812.95	$2,604.32	1
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**3**	**3**	**$7,812.95**	**$2,604.32**	**1**
Fiscal Year 2025					
FFS	2	2	$6,579.90	$3,289.95	1
Aetna	0	0	$0.00	$0.00	0
Humana	1	1	$2,949.64	$2,949.64	1
OCH	2	2	$13,578.50	$6,789.25	1
2025 Total	**5**	**5**	**$23,108.04**	**$4,621.61**	**1**
% Change	**66.67%**	**66.67%**	**195.77%**	**77.46%**	**0.00%**
Change	**2**	**2**	**$15,295.09**	**$2,017.29**	**0**

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 *C. difficile* Medications: Pharmacy Claims (All Plans)

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

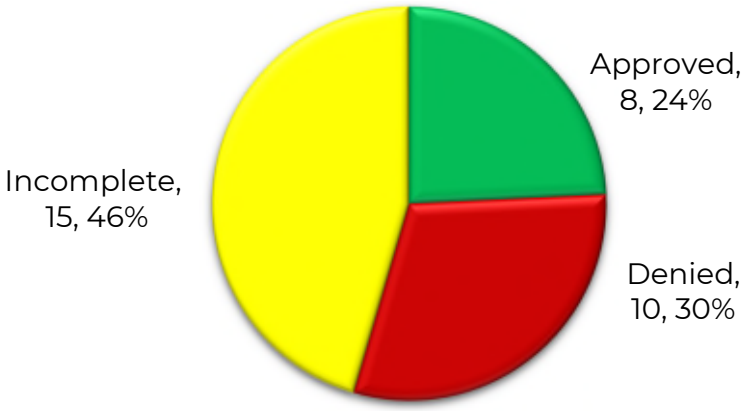
Top Prescriber Specialties of *C. difficile* Medications by Number of Claims: Pharmacy Claims (All Plans)

- There was 1 pharmacy claim for *C. difficile* medications during fiscal year 2025, which was prescribed by a nurse practitioner supervised by an infectious disease specialist.

Prior Authorization of *C. difficile* Medications

There were 33 prior authorization requests submitted for *C. difficile* 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	5	25%	9	45%	6	30%	**20**
Aetna	0	0%	3	100%	0	0%	**3**
Humana	1	50%	0	0%	1	50%	**2**
OCH	2	25%	3	38%	3	38%	**8**
Total	**8**	**24%**	**15**	**46%**	**10**	**30%**	**33**

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

Market News and Updates[1,2,3]

News:

- **January 2025:** The FDA announced Zinplava™ (bezlotoxumab) would be discontinued on January 31, 2025. Merck, the manufacturer of Zinplava™, did not provide a reason for the discontinuation.

Pipeline:

- **LMN-201:** LMN-201 contains 4 therapeutic proteins that work together to neutralize both the *C. difficile* bacterium and the toxin that causes its virulence directly in the patient's gastrointestinal (GI) tract. In April 2025, results from the preliminary cohort (Part A) of the RePreve trial were announced, which showed that all patients [21/21; 95% confidence interval (CI): 85%, 100%; P<0.001] achieved initial clinical cure compared to an 80% initial clinical cure rate (625/781; 95% CI: 77, 83%) observed in the active arm of the MODIFY I and II trials. Additionally, the LMN-201 treated patients showed a sustained clinical cure rate on day 28 with 95.2% (20/21; 95% CI: 77, 100%) achieving this measure. Part B of the RePreve trial has begun, which is a randomized, double-blind, placebo-controlled trial that will include 350 patients randomized 1:1 to receive LMN-201 or placebo, alongside standard antibiotic therapy, with the

primary endpoint being sustained clinical cure (initial clinical cure plus no recurrence at 12 weeks) compared to placebo.

Recommendations

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.

Utilization Details of *C. difficile* Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VOWST CAP	1	1	$19,117.91	$19,117.91	1	100%
TOTAL	**1**	**1***	**$19,117.91**	**$19,117.91**	**1**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
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
J0565 BEZLOTOXUMAB INJ	4	4	$13,518.54	$3,379.64	1
J1440 FECAL MICROBIOTA JSLM	1	1	$9,589.50	$9,589.50	1
TOTAL	**5⁺**	**5***	**$23,108.04**	**$4,621.61**	**1**

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

[1] Ernst D. *C. Difficile* Prevention Therapy Zinplava™ Discontinued. Available online at: https://www.empr.com/news/c-difficile-prevention-therapy-zinplava-discontinued/. Issued 01/07/2025. Last accessed 09/16/2025.
[2] Cosdon N. LMN-201 Fast Tracked by FDA as a Potential Breakthrough Treatment for C diff Infection. Available online: https://www.contagionlive.com/view/lmn-201-fast-tracked-by-fda-as-a-potential-breakthrough-treatment-for-c-diff-infection. Issued 05/17/2023. Last accessed 09/16/2025.
[3] Lumen Bioscience. LMN-201 Achieves 100% Initial *C. difficile* Clinical Cure in Preliminary Cohort of RePreve Trial. Available online at: https://www.lumen.bio/2025/04/02/lmn-201-preliminary-cohort-repreve-trial/. Issued 04/03/2025. Last accessed 09/16/2025.

Appendix L

Fiscal Year 2025 Annual Review of Allergen Immunotherapies

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

Grastek® (Timothy Grass Pollen Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test (labs required) or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies for Timothy grass or cross-reactive grass pollen (cool season grasses); 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 during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of the grass pollen season (November 15th) and continue throughout the season; and
7. 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
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. 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
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

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

1. Member must be 12 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.

Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to 1 of the 5 grass pollens contained in Oralair®; 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 during a previous season; and

b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥16 weeks prior to the start of the grass pollen season (October 15th) and continue throughout the season; and
7. 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
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 16 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. 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
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

Palforzia® (Peanut Allergen Powder-dnfp) Approval Criteria:

1. Member must be 1 to 17 years of age to initiate initial dose escalation (maintenance dosing may be continued for members 1 year of age and older); and
2. Member must have a diagnosis of peanut allergy confirmed by a positive skin test, positive *in vitro* test for peanut-specific immunoglobulin E (IgE), or positive clinician-supervised oral food challenge; and
3. Prescriber must confirm member will use Palforzia® with a peanut-avoidant diet; and
4. Member must not have severe uncontrolled asthma; and
5. Member must not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
6. Member must not have had severe or life-threatening anaphylaxis within the previous 60 days; and
7. Member or caregiver 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. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
9. Prescriber, health care setting, and pharmacy must be certified in the Palforzia® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Palforzia® REMS program; and

11. Palforzia must be administered under the direct observation of a health care provider in a REMS certified health care setting with observation duration in accordance with the prescribing information; and
12. After successful completion of initial dose escalation and all levels of up-dosing as documented by the prescriber, initial approvals of maintenance dosing will be for 6 months. For continued approval, member must be compliant, and prescriber must verify member is responding well to treatment.

Ragwitek® (Short Ragweed Pollen Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis symptoms; 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 during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of ragweed pollen season (May 15th) and continue throughout the season; and
7. 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
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. 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
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

Utilization of Allergen Immunotherapies: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

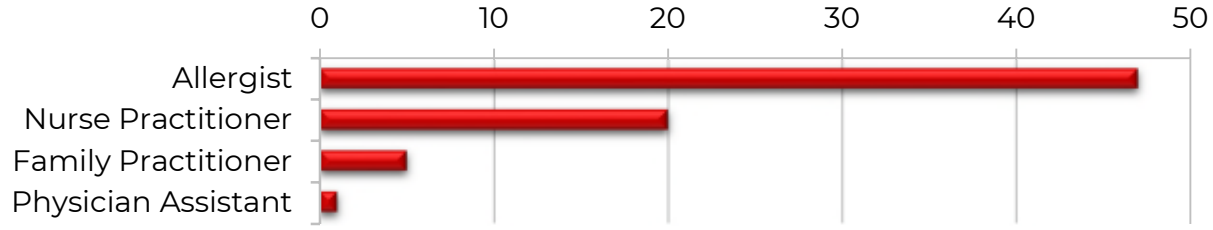
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	6	19	$6,077.29	$319.86	$10.66	570	570
Aetna	5	12	$5,311.01	$442.58	$20.75	478	256
Humana	4	6	$2,074.17	$345.69	$11.52	180	180
OCH	4	7	$2,403.90	$343.41	$11.45	210	210
2024 Total	**18**	**44**	**$15,866.37**	**$360.60**	**$13.05**	**1,438**	**1,216**
Fiscal Year 2025							
FFS	4	15	$5,245.51	$349.70	$11.66	450	450
Aetna	8	33	$13,046.62	$395.35	$14.26	1,050	915
Humana	8	20	$6,967.83	$348.39	$11.61	600	600
OCH	4	5	$1,769.96	$353.99	$11.80	150	150
2025 Total	**23**	**73**	**$27,029.92**	**$370.27**	**$12.78**	**2,250**	**2,115**
% Change	**27.80%**	**65.90%**	**70.40%**	**2.70%**	**-2.10%**	**56.50%**	**73.90%**
Change	**5**	**29**	**$11,163.55**	**$9.67**	**-$0.27**	**812**	**899**

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 Allergen Immunotherapies: Pharmacy Claims (All Plans)

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

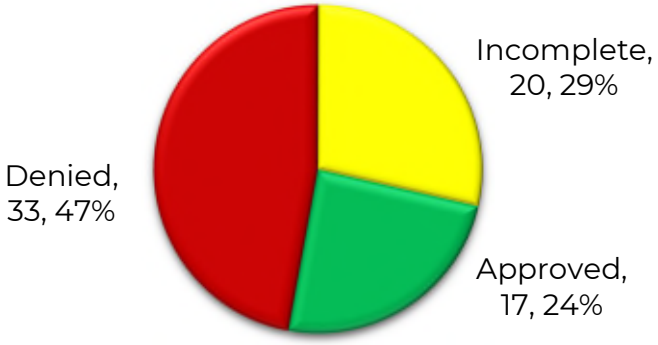
Top Prescriber Specialties of Allergen Immunotherapies by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Allergen Immunotherapies

There were 70 prior authorization requests submitted for allergen immunotherapies during fiscal year 2025. The following chart shows 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	5	19%	12	46%	9	35%	**26**
Aetna	5	26%	5	26%	9	47%	**19**
Humana	6	40%	0	0%	9	60%	**15**
OCH	1	10%	3	30%	6	60%	**10**
Total	**17**	**24%**	**20**	**29%**	**33**	**47%**	**70**

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

Market News and Updates[1,2]

U.S. Food and Drug Administration (FDA) Label Update(s):

- **February 2025:** The FDA approved an age expansion for Odactra® (house dust mite allergen extract) to include patients 5 to 11 years of age.

Pipeline:

- **PQ Grass [Grass Modified Allergy Tyrosine Adsorbed (MATA) Monophosphoryl Lipid-A (MPL)]:** Phase 3 trial results have been published for Allergy Therapeutic's PQ Grass (grass MATA MPL), a subcutaneously administered allergen extract of 12 grass pollens from *Pooideae spp*. The trial was stopped for success at a pre-defined interim analysis as PQ Grass demonstrated superiority over placebo for the primary endpoint of European Academy of Allergy and Clinical Immunology Combined Symptom and Medication Score (EAACI-CSMS) during the peak grass pollen season [difference: -0.27 points; 95% confidence interval (CI): -0.42, -0.12; P=0.0005].

Recommendations

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.

Utilization Details of Allergen Immunotherapies: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ODACTRA 12 SQ-HDM SUB TAB	38	14	$13,270.29	$349.22	2.71	49.09%
GRASTEK 2800 BAU SUB TAB	15	6	$5,271.15	$351.41	2.5	19.50%
RAGWITEK 12 AMB A 1-U SUB TAB	15	6	$5,232.63	$348.84	2.5	19.36%
PALFORZIA PACK 120MG DOSE	2	1	$1,302.34	$651.17	2	4.82%
PALFORZIA PACK 160MG DOSE	1	1	$651.17	$651.17	1	2.41%
PALFORZIA PACK 40MG DOSE	1	1	$651.17	$651.17	1	2.41%
PALFORZIA PACK 80MG DOSE	1	1	$651.17	$651.17	1	2.41%
TOTAL	**73**	**23***	**$27,029.92**	**$370.27**	**3.17**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BAU = bioequivalent allergy units; SQ-HDM = standardized quality-house dust mite; SUB = sublingual; TAB = tablet; U = unit

[1] ALK. FDA Approves Odactra® for the Treatment of House Dust Mite Allergy in Young Children. *Globe Newswire*. Available online at: https://ml-eu.globenewswire.com/Resource/Download/07b0f635-e0da-4468-82d1-12c9afec9280. Issued 02/27/2025. Last accessed 09/24/2025.
[2] Zielen S, Berstein JA, Strum GJ, et al. Six Injections of Modified Adjuvanted PQ Grass Is Effective and Well-tolerated in a Pivotal Phase 3 Trial. *Allergy*. 2025; 80(7):1982-1994. doi: 10.1111/all.16491.

Appendix M

Fiscal Year 2025 Annual Review of Cushing's Syndrome Medications

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

Isturisa® (Osilodrostat) Approval Criteria:

1. An FDA approved indication for the treatment of adult members with Cushing's 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.

Korlym® (Mifepristone) Approval Criteria:

1. An FDA approved indication to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus (T2DM) or glucose intolerance; and
2. Member must have failed surgery intended to correct the cause of endogenous Cushing's syndrome or not be a candidate for surgery that is expected to correct the cause of endogenous Cushing's syndrome; and
3. Member must be 18 years of age or older; and
4. Korlym® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
6. Female members of reproductive potential must use a non-hormonal, medically acceptable method of contraception (unless member has undergone surgical sterilization) during treatment with Korlym® and for at least 1 month after discontinuing treatment; and
7. Member must not have any contraindications to taking Korlym® including the following:
    a. Taking drugs metabolized by CYP3A (e.g., simvastatin, lovastatin) and CYP3A substrates with narrow therapeutic ranges (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus); and
    b. Receiving systemic corticosteroids for lifesaving purposes (e.g., immunosuppression after organ transplantation); and
    c. Female members must not have a history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma; and
    d. Known hypersensitivity to mifepristone or to any of the product components; and
8. Authorizations will be for the duration of 12 months; and
9. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Recorlev® (Levoketoconazole) Approval Criteria:

1. An FDA approved indication for the treatment of adult members with Cushing's 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.

Utilization of Cushing's Syndrome Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

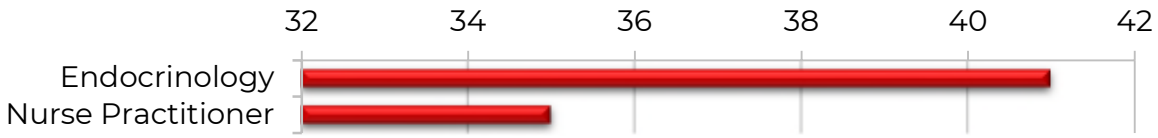
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	7	39	$1,634,032.82	$41,898.28	$1,452.47	2,680	1,125
Aetna	1	3	$56,475.93	$18,825.31	$672.33	84	84
Humana	2	5	$363,891.25	$72,778.25	$2,492.41	526	146
OCH	1	1	$20,762.41	$20,762.41	$692.08	30	30
2024 Total	**9**	**48**	**$2,075,162.41**	**$43,232.55**	**$1,498.31**	**3,320**	**1,385**
Fiscal Year 2025							
FFS	4	14	$662,586.03	$47,327.57	$1,681.69	958	394
Aetna	2	7	$179,632.05	$25,661.72	$855.39	270	210
Humana	8	42	$1,312,170.29	$31,242.15	$1,046.39	2,052	1,254
OCH	3	13	$481,800.19	$37,061.55	$1,295.16	702	372
2025 Total	**16**	**76**	**$2,636,188.56**	**$34,686.69**	**$1,182.15**	**3,982**	**2,230**
% Change	**77.80%**	**58.30%**	**27.00%**	**-19.80%**	**-21.10%**	**19.90%**	**61.00%**
Change	**7**	**28**	**$561,026.15**	**-$8,545.86**	**-$316.16**	**662**	**845**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = OK 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 Cushing's Syndrome Medications (All Plans)

- There were 16 unique members utilizing Cushing's syndrome medications during fiscal year 2025. Due to the limited number of utilizing members, detailed demographic information could not be provided.

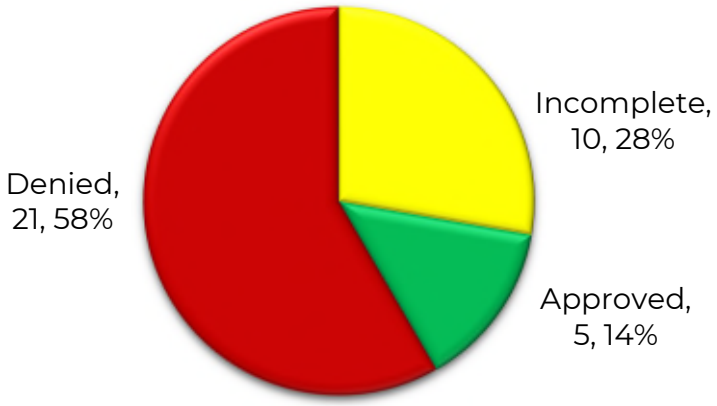
Top Prescriber Specialties of Cushing's Syndrome Medications by Number of Claims (All Plans)



Prior Authorization of Cushing's Syndrome Medications

There were 36 prior authorization requests submitted for Cushing's syndrome 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	3	27%	5	45%	3	27%	**11**
Aetna	1	33%	2	67%	0	0%	**3**
Humana	1	7%	0	0%	14	93%	**15**
OCH	0	0%	3	43%	4	57%	**7**
Total	**5**	**14%**	**10**	**28%**	**21**	**58%**	**36**

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

Market News and Updates[1, 2, 3]

Anticipated Patent Expiration(s):

- Isturisa® (osilodrostat): October 2035
- Recorlev® (levoketoconazole): March 2040
- Korlym® (mifepristone tablet): August 2038

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

- **April 2025:** The FDA approved a supplemental New Drug Application (sNDA) for Isturisa® (osilodrostat) for the treatment of endogenous hypercortisolemia in adults with Cushing's syndrome for whom surgery is not an option or has not been curative. Previously, Isturisa® was approved for the treatment of patients with Cushing's disease, which is a sub-type of Cushing's syndrome. The Isturisa® sNDA was supported by the Isturisa® extensive clinical development program that included over 350 patients with Cushing's disease or Cushing's syndrome.

Pipeline:

- **Relacorilant:** Relacorilant is an investigational, selective cortisol modulator that is being studied in 2 Phase 3 trials, GRACE and GRADIENT, for the treatment of endogenous hypercortisolism,

Cushing's syndrome. In both trials patients on relacorilant experienced improvements in an array of hypercortisolism signs and symptoms. Relacorilant was well tolerated in clinical trials with no adverse effects of adrenal insufficiency, hypokalemia, or QT prolongation. A New Drug Application (NDA) has been submitted to the FDA and a Prescription Drug User Fee Act (PDUFA) date has been set for December 30, 2025.

Recommendations

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.

Utilization Details of Cushing's Syndrome Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MIFEPRISTONE PRODUCTS						
KORLYM TAB 300MG	69	12	$2,477,487.22	$35,905.61	5.75	93.98%
MIFEPRISTONE TAB 300MG	2	2	$46,271.19	$23,135.60	1	1.76%
SUBTOTAL	**71**	**14**	**$2,523,758.41**	**$35,545.89**	**5.07**	**95.74%**
LEVOKETOCONAZOLE PRODUCTS						
RECORLEV TAB 150MG	5	2	$112,430.15	$22,486.03	2.5	4.26%
SUBTOTAL	**5**	**2**	**$112,430.15**	**$22,486.03**	**2.5**	**4.26%**
TOTAL	**76**	**16***	**$2,636,188.56**	**$34,686.69**	**4.75**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 09/2025. Last accessed 09/15/2025.
[2] Recordati. Recordati: FDA Grants Isturisa® (Osilodrostat) Expanded Indication for the Treatment of Endogenous Hypercortisolemia in Patients with Cushing's Syndrome. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2025/04/16/3062342/0/en/RECORDATI-FDA-GRANTS-ISTURISA-OSILODROSTAT-EXPANDED-INDICATION-FOR-THE-TREATMENT-OF-ENDOGENOUS-HYPERCORTISOLEMIA-IN-PATIENTS-WITH-CUSHING-S-SYNDROME.html. Issued 04/16/2025. Last accessed 09/15/2025.
[3] Corecept Therapeutics. FDA Files Corcept's New Drug Application for Relacorilant as Treatment for Patients With Hypercortisolism. *Businesswire*. Available online at: https://www.businesswire.com/news/home/20250303227690/en/FDA-Files-Corcepts-New-Drug-Application-for-Relacorilant-as-Treatment-for-Patients-With-Hypercortisolism. Issued 03/03/2025. Last accessed 09/15/2025.

Appendix N

Fiscal Year 2025 Annual Review of Ophthalmic Anti-Inflammatory Products

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone 0.1% sus (Maxidex®)	fluorometholone 0.25% sus (FML Forte®)
dexamethasone sodium phosphate 0.1% sol	loteprednol 1% sus (Inveltys®)
difluprednate 0.05% emu (Durezol®) – **Brand Preferred**	loteprednol 0.38% gel (Lotemax® SM)
fluorometholone 0.1% sus (Flarex®)	prednisolone acetate 1% sus (Pred Forte®)
fluorometholone 0.1% sus (FML Liquifilm®)	
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

Ophthalmic Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic corticosteroids (from different product lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower-tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic corticosteroids lack.

Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria (Medical Only):

1. An FDA approved indication for the treatment of ocular inflammation and pain following ophthalmic surgery; and
2. Prescriber must verify that Dextenza® will be placed by a physician immediately following ophthalmic surgery; and
3. Date of ophthalmic surgery must be provided; and
4. A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used following ophthalmic surgery are not appropriate for the member must be provided; and
5. A quantity limit of 1 insert per eye every 30 days will apply.

Iluvien® (Fluocinolone Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved diagnosis of diabetic macular edema in members who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure; 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.

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 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.

Ozurdex® (Dexamethasone Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved indication for 1 of the following:
    a. Treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); or
    b. Treatment of non-infectious uveitis affecting the posterior segment of the eye; or
    c. Treatment of diabetic macular edema; and
2. Ozurdex® must be administered by an ophthalmologist; and

3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Ozurdex® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A quantity limit of 1 implant per eye every 3 months will apply.

Retisert® (Fluocinolone Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved diagnosis of chronic non-infectious posterior uveitis; and
2. Retisert® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Retisert® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A patient-specific, clinically significant reason why the member requires Retisert® in place of Ozurdex® or Yutiq® must be provided; and
7. A quantity limit of 1 implant per eye every 30 months will apply.

Xipere® (Triamcinolone Acetonide Injection) Approval Criteria (Medical Only):

1. An FDA approved indication for the treatment of macular edema associated with non-infectious uveitis; and
2. Member must be 18 years of age or older; and
3. Xipere® must be administered by an ophthalmologist; and
4. Prescriber must confirm that the member does not have an active ocular or periocular infection; and
5. Prescriber must confirm member does not have untreated ocular hypertension or uncontrolled glaucoma; and
6. A patient-specific, clinically significant reason why the member cannot use corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
7. A patient-specific, clinically significant reason the member cannot use Triesence® (triamcinolone acetonide injection) must be provided; and
8. Initial authorization will be for 12 weeks, with an additional dose approved at or after 12 weeks if the prescriber documents improvement from baseline in visual acuity.

Yutiq® (Fluocinolone Acetonide Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved diagnosis of chronic, non-infectious uveitis affecting the posterior segment of the eye; and
2. Yutiq® 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 Yutiq® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A patient-specific, clinically significant reason why the member requires Yutiq® in place of Ozurdex® must be provided; and
6. A quantity limit of 1 implant per eye every 36 months will apply.

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
Tier-1	**Tier-2**
diclofenac 0.1% sol (Voltaren®)	bromfenac 0.09% sol (Bromday®)
flurbiprofen 0.03% sol[Δ] (Ocufen®)	bromfenac 0.075% sol (BromSite®)
ketorolac 0.5% sol (Acular®)	bromfenac 0.07% sol (Prolensa®)
	ketorolac 0.4% sol (Acular LS®)
	ketorolac 0.45% sol (Acuvail®)
	nepafenac 0.1% sus (Nevanac®)
	nepafenac 0.3% sus (Ilevro®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
sol = solution; sus = suspension
[Δ]Not a required Tier-1 trial; does not have to be attempted for approval of a Tier-2 medication.

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic NSAIDs (from different medication lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic NSAIDs lack.

Utilization of Ophthalmic Anti-Inflammatory Products: Fiscal Year 2025

Comparison of Fiscal Years: Ophthalmic Corticosteroids Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	3,856	5,391	$308,815.25	$57.28	$2.14	34,991	144,248
Aetna	332	378	$23,278.64	$61.58	$3.37	2,299	6,917
Humana	358	460	$29,513.60	$64.16	$2.88	2,742	10,247
OCH	284	329	$16,533.10	$50.25	$2.25	2,013	7,359
2024 Total	**4,620**	**6,558**	**$378,140.59**	**$57.66**	**$2.24**	**42,044**	**168,771**
Fiscal Year 2025							
FFS	2,341	3,283	$174,710.05	$53.22	$2.25	20,610	77,533
Aetna	1,308	1,728	$99,250.89	$57.44	$3.15	10,312	31,492
Humana	1,408	1,925	$104,717.91	$54.40	$2.69	11,746	38,862
OCH	1,438	1,982	$96,752.43	$48.82	$2.44	11,801	39,587
2025 Total	**6,357**	**8,918**	**$475,431.28**	**$53.31**	**$2.54**	**54,469**	**187,474**
% Change	**37.60%**	**36.00%**	**25.70%**	**-7.50%**	**13.40%**	**29.60%**	**11.10%**
Change	**1,737**	**2,360**	**$97,290.69**	**-$4.35**	**$0.30**	**12,425**	**18,703**

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: Ophthalmic Corticosteroids Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	11	20	$60,588.74	$3,029.44	1.82
Aetna	0	0	$0.00	$0.00	0
Humana	1	1	$1,439.27	$1,439.27	1
OCH	0	0	$0.00	$0.00	0
2024 Total	**12**	**21**	**$62,588.74**	**$2,980.42**	**1.75**
Fiscal Year 2025					
FFS	4	7	$16,781.56	$2,397.37	1.75
Aetna	1	2	$2,878.26	$1,439.13	2
Humana	5	8	$5,756.52	$719.57	1.6
OCH	1	1	$2,878.68	$2,878.68	1
2025 Total	**11**	**18**	**$28,295.02**	**$1,571.95**	**1.64**
% Change	**-8.33%**	**-14.29%**	**-54.79%**	**-47.26%**	**-6.29%**
Change	**-1**	**-3**	**-$34,293.72**	**-$1,408.47**	**-0.11**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = OK Complete Health
Fiscal Year 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: Oxervate® (Cenegermin-bkbj) Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	2	3	$106,107.35	$35,369.12	$2,526.37	56	42
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	1	1	$27,510.87	$27,510.87	$1,965.06	14	14
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**3**	**4**	**$133,618.22**	**$33,404.56**	**$2,386.04**	**70**	**56**
Fiscal Year 2025							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	1	4	$115,433.40	$28,858.35	$2,061.31	56	56
Humana	5	16	$442,102.20	$27,631.39	$1,973.67	224	224
OCH	2	8	$346,254.56	$43,281.82	$3,091.56	168	112
2025 Total	**8**	**28**	**$903,790.16**	**$32,278.22**	**$2,305.59**	**448**	**392**
% Change	**166.70%**	**600.00%**	**576.40%**	**-3.40%**	**-3.40%**	**540.00%**	**600.00%**
Change	**5**	**24**	**$770,171.94**	**-$1,126.34**	**-$80.45**	**378**	**336**

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.

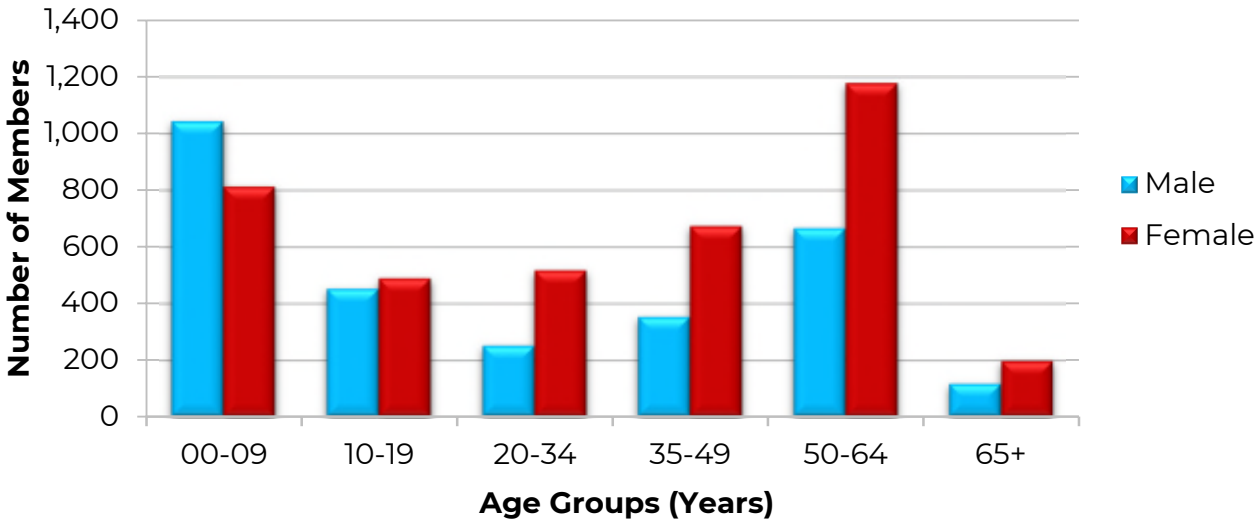
Comparison of Fiscal Years: Ophthalmic NSAIDs Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	1,179	1,513	$27,504.96	$18.18	$0.72	8,767	38,242
Aetna	82	94	$3,391.32	$36.08	$1.71	507	1,986
Humana	125	155	$6,365.60	$41.07	$1.77	849	3,597
OCH	80	96	$3,010.31	$31.36	$1.32	500	2,287
2024 Total	**1,428**	**1,858**	**$40,272.19**	**$21.68**	**$0.87**	**10,623**	**46,112**
Fiscal Year 2025							
FFS	646	865	$15,333.48	$17.73	$0.71	4,850	21,730
Aetna	233	323	$6,279.49	$19.44	$0.90	1,753	6,961
Humana	333	495	$12,708.19	$25.67	$1.07	2,761	11,842
OCH	268	370	$9,577.01	$25.88	$1.08	2,092	8,895
2025 Total	**1,457**	**2,053**	**$43,898.17**	**$21.38**	**$0.89**	**11,456**	**49,428**
% Change	**2.00%**	**10.50%**	**9.00%**	**-1.40%**	**2.30%**	**7.80%**	**7.20%**
Change	**29**	**195**	**$3,625.98**	**-$0.30**	**$0.02**	**833**	**3,316**

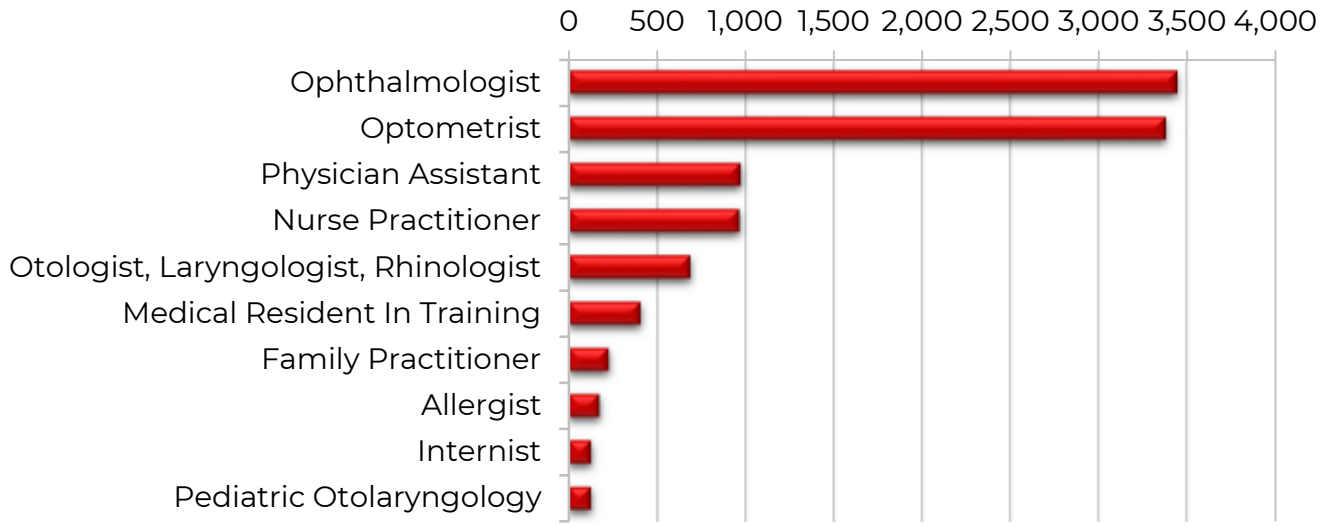
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective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

- Aggregate drug rebates collected during fiscal year 2024 for the ophthalmic anti-inflammatory products totaled $251,857.43.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2024 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2025 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Ophthalmic Anti-Inflammatory Products (All Plans)



Top Prescriber Specialties of Ophthalmic Anti-Inflammatory Products by Number of Claims (All Plans)



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

Prior Authorization of Ophthalmic Anti-Inflammatory Products

There were 197 prior authorization requests submitted for ophthalmic anti-inflammatory products 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	35	33%	61	57%	11	10%	**107**
Aetna	0	0%	7	58%	5	42%	**12**
Humana	2	11%	0	0%	16	89%	**18**
OCH	20	33%	23	38%	17	28%	**60**
Total	**57**	**29%**	**91**	**46%**	**49**	**25%**	**197**

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

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

Anticipated Patent Expiration(s):

- Nevanac® (nepafenac 0.1% ophthalmic suspension): January 2027
- Acular LS® (ketorolac 0.4% ophthalmic solution): November 2027
- Yutiq® (fluocinolone intravitreal implant): January 2028
- Iluvien® (fluocinolone intravitreal implant): November 2028
- Acuvail® (ketorolac 0.45% ophthalmic solution): August 2029
- BromSite® (bromfenac 0.075% ophthalmic solution): March 2029
- Ilevro® (nepafenac 0.3% ophthalmic suspension): March 2032
- Inveltys® (loteprednol 1% ophthalmic suspension): May 2033
- Prolensa® (bromfenac 0.07% ophthalmic solution): November 2033
- Xipere® (triamcinolone acetonide injectable suspension): May 2034
- Lotemax® SM (loteprednol 0.38% ophthalmic gel): December 2036
- Dextenza® (dexamethasone ophthalmic insert): April 2041

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

- **October 2021:** The FDA approved a supplemental New Drug Application (sNDA) for Dextenza® (dexamethasone ophthalmic insert)

for the treatment of ocular itching associated with allergic conjunctivitis. The efficacy for this indication was supported by 3 randomized, multicenter, double-masked, parallel group, vehicle-controlled trials where patients who received Dextenza® had a lower mean ocular itching score compared with the vehicle-controlled group at all time points throughout the 1-month study.

- **March 2025:** The FDA approved Iluvien® (fluocinolone acetonide intravitreal implant) for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. It was previously only indicated for the treatment of diabetic macular edema. The approval was based on the efficacy data from 2 randomized, double-masked, parallel group, Phase 3 trials which showed that patients treated with Iluvien® had fewer recurrence of uveitis at 6 months compared with the sham group.
- **April 2025:** The FDA expanded the approval of Dextenza® to include pediatric patients based on evidence from the adult clinical trials as well as safety data from 1 active-controlled trial in patients from birth to 5 years of age. Dextenza® is now indicated to treat ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients and to treat itching associated with allergic conjunctivitis in adults and pediatric patients 2 years of age and older. However, the use of Dextenza® for the treatment of ocular itching is not recommended in pediatric patients who require sedation for the insertion procedure.

News:

- **February 2014:** Bausch + Lomb announced that they will no longer supply brand name Lotemax® (loteprednol) suspension, and after the current supply is exhausted, it will no longer be available. This decision was based on the anticipated launch of the generic formulations.

Pipeline:

- **OCS-01:** OCS-01 is a once daily, preservative-free high concentration dexamethasone product that is being studied for inflammation and pain following cataract surgery and for diabetic macular edema (DME). OCS-01 uses a proprietary OPTIREACH® technology that improves the solubility of lipophilic drugs; therefore, increasing the time on the surface of the eye. In September 2025, the results of Stage 1 of the DIAbetic Macular edema patients ON a Drop (DIAMOND)-1 and DIAMOND-2 were presented at the European Society of Retina Specialists, which showed 100 patients receiving OCS-01 gained a mean of 7.2 letters on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at week 6 compared with 3.1 letters for 48 patients in the vehicle group. Additionally, the proportion of patients achieving ≥15-letter improvement was higher with the OCS-01 treated group (25.3%

vs. 9.8% at week 6, P=0.007). Stage 2 of the DIAMOND Phase 3 clinical trial is ongoing.

Recommendations

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

Utilization Details of Ophthalmic Corticosteroids: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
PREDNISOLONE PRODUCTS						
PREDNISOLONE SUS 1% OP	5,109	3,456	$188,725.05	$36.94	1.48	39.70%
PRED MILD SUS 0.12% OP	24	15	$4,436.28	$184.85	1.6	0.93%
PRED SOD PHO SOL 1% OP	13	12	$661.73	$50.90	1.08	0.14%
SUBTOTAL	**5,146**	**3,483**	**$193,823.06**	**$37.66**	**1.48**	**40.77%**
DEXAMETHASONE PRODUCTS						
DEXAMETH PHO SOL 0.1% OP	2,730	2,286	$122,032.49	$44.70	1.19	25.67%
MAXIDEX SUS 0.1% OP	201	177	$18,175.49	$90.43	1.14	3.82%
SUBTOTAL	**2,931**	**2,463**	**$140,207.98**	**$47.84**	**1.19**	**29.49%**
FLUOROMETHOLONE PRODUCTS						
FLUOROMETHOLONE SUS 0.1% OP	409	311	$30,248.97	$73.96	1.32	6.36%
FLAREX SUS 0.1% OP	28	17	$3,784.82	$135.17	1.65	0.80%
SUBTOTAL	**437**	**328**	**$34,033.79**	**$77.88**	**1.33**	**7.16%**
LOTEPREDNOL PRODUCTS						
LOTEMAX SUS 0.5%	124	93	$45,153.67	$364.14	1.33	9.50%
LOTEMAX GEL 0.5%	49	33	$12,570.17	$256.53	1.48	2.64%
LOTEMAX OIN 0.5%	18	12	$6,458.11	$358.78	1.5	1.36%
LOTEPREDNOL SUS 0.5%	9	8	$973.95	$108.22	1.13	0.20%
LOTEPREDNOL GEL 0.5% OP	7	6	$780.51	$111.50	1.17	0.16%
SUBTOTAL	**207**	**152**	**$65,936.41**	**$318.53**	**1.36**	**13.87%**
DIFLUPREDONATE PRODUCTS						
DUREZOL EMU 0.05%	154	91	$35,070.93	$227.73	1.69	7.38%
DIFLUPREDNATE EMU 0.05%	28	12	$2,417.38	$86.34	2.33	0.51%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**182**	**103**	**$37,488.31**	**$205.98**	**1.77**	**7.89%**
TIER-1 SUBTOTAL	**8,903**	**6,529**	**$471,489.55**	**$52.96**	**1.36**	**99.17%**
TIER-2 UTILIZATION						
LOTEPREDNOL PRODUCTS						
LOTEMAX SM GEL 0.38%	13	9	$3,340.10	$256.93	1.44	0.70%
INVELTYS SUS 1%	2	1	$601.63	$300.82	2	0.13%
TIER-2 SUBTOTAL	**15**	**10**	**$3,941.73**	**$262.78**	**1.5**	**0.83%**
TOTAL	**8,918**	**6,357***	**$475,431.28**	**$53.31**	**1.4**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DEXAMETH = dexamethasone; EMU = emulsion; OIN = ointment; OP = ophthalmic; PHO = phosphate; PRED = prednisolone; SOD = sodium; SOL = solution; SUS = suspension
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
OZURDEX (J7312)	15	9	$17,267.32	$1,151.15	1.67
XIPERE (J3299)	2	1	$1,742.40	$871.20	2
ILUVIEN (J7313)	1	1	$9,285.30	$9,285.30	1
TOTAL	**18**	**11**	**$28,295.02**	**$1,571.95**	**1.64**

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

Utilization Details of Oxervate® (Cenegermin-bkbj): Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OXERVATE SOL 20MCG/ML	28	8	$903,790.16	$32,278.22	3.5	100%
TOTAL	**28**	**8***	**$903,790.16**	**$32,278.22**	**3.5**	**100%**

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

Utilization Details of Ophthalmic NSAIDs: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
KETOROLAC SOL 0.5% OP	1,904	1,359	$34,837.70	$18.30	1.4	79.36%
DICLOFENAC SOL 0.1% OP	90	66	$1,693.57	$18.82	1.36	3.86%
FLURBIPROFEN SOL 0.03% OP	30	19	$1,043.62	$34.79	1.58	2.38%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 SUBTOTAL	**2,024**	**1,444**	**$37,574.89**	**$18.56**	**1.4**	**85.60%**
TIER-2 UTILIZATION						
BROMFENAC DRO 0.07% OP	7	6	$729.52	$104.22	1.17	1.66%
KETOROLAC SOL 0.4% OP	6	6	$395.92	$65.99	1	0.90%
ILEVRO DRO 0.3% OP	6	4	$2,256.36	$376.06	1.5	5.14%
PROLENSA DRO 0.07% OP	5	4	$1,775.67	$355.13	1.25	4.04%
BROMSITE DRO 0.075%OP	3	2	$779.93	$259.98	1.5	1.78%
ACUVAIL SOL 0.45% OP	1	1	$333.51	$333.51	1	0.76%
BROMFENAC DRO 0.09% OP	1	1	$52.37	$52.37	1	0.12%
TIER-2 SUBTOTAL	**29**	**24**	**$6,323.28**	**$218.04**	**1.21**	**14.40%**
TOTAL	**2,053**	**1,457***	**$43,898.17**	**$21.38**	**1.41**	**100.00**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
DRO = drops; OP = ophthalmic; SOL = solution
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[9] DIAMOND Data from Euretina Supports OCS-01 Efficacy in DME. *Ophthalmology Management*. Available online at: https://ophthalmologymanagement.com/news/2025/positive-data-reported-for-patients-with-dme/. Issued 09/05/2025. Last accessed 09/15/2025.

Appendix O

Fiscal Year 2025 Annual Review of Hyperoxaluria Medications

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

Oxlumo® (Lumasiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma 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. Oxlumo® must be prescribed by a nephrologist, geneticist, urologist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a nephrologist, geneticist, urologist, or other specialist with expertise in the treatment of PH1); and
3. Member must not have a history of liver transplant; and
4. Prescriber must verify that Oxlumo® will be administered by a health care professional; and
5. For members 9 years of age or older, a patient-specific, clinically significant reason why the member cannot use Rivfloza® (nedosiran) must be provided; and
6. Oxlumo® will not be approved for concomitant use with Rivfloza® (nedosiran); and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion or plasma oxalate levels.

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 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.

Utilization of Hyperoxaluria Medications: Fiscal Year 2025

There was no SoonerCare utilization of hyperoxaluria medications during fiscal year 2025 (07/01/2024 to 06/30/2025).

Prior Authorization of Hyperoxaluria Medications: Fiscal Year 2025

There were no prior authorization requests submitted for hyperoxaluria medications during fiscal year 2025.

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Rivfloza® (nedosiran): October 2038
- Oxlumo® (lumasiran): November 2038

U.S. Food and Drug Administration (FDA) Label Update(s):

- **March 2025:** The FDA approved an age expansion for Rivfloza® (nedosiran) to include children 2 years of age and older for its approved indication to lower urinary oxalate levels.

Recommendations

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.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 09/2025. Last accessed 09/23/2025.
[2] Rivfloza® (Nedosiran) Prescribing Information. Novo Nordisk. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215842s002lbl.pdf. Last revised 03/27/2025. Last accessed 09/23/2025.

Appendix P

Fiscal Year 2025 Annual Review of Anemia Medications

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

Adakveo® (Crizanlizumab-tmca) Approval Criteria:

1. An FDA approved indication to reduce the frequency of vaso-occlusive crises (VOCs) in adult members and in pediatric members 16 years of age and older with sickle cell disease (SCD); and
2. Member must have a history of VOCs; and
3. Adakveo® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and
4. Prescriber must verify Adakveo® will be administered by a trained health care provider. The prior authorization request must indicate how Adakveo® will be administered; and
    a. Adakveo® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Adakveo® must be shipped via cold chain supply to the member's home and administer by a home health provider, and the member's caregiver must be trained on the proper storage of Adakveo®; and
5. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Approval quantities will be dependent on the member's weight and will include loading doses at week 0 and 2, then subsequent doses every 4 weeks in accordance with package labeling; and
7. Initial approvals will be for the duration of 3 months. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Aranesp® (Darbepoetin Alfa) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of anemia due to chemotherapy in members with non-myeloid malignancies; or
    b. Treatment of anemia associated with chronic renal failure; and
        i. For the diagnosis of anemia associated with chronic renal failure: member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis

payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

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

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

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

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

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

13. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy®; and
14. Member will not be approved for treatment with Reblozyl® (luspatercept-aamt) following Casgevy® infusion (current authorizations for luspatercept-aamt will be discontinued upon Casgevy® approval); and
15. Casgevy® must be administered at a Casgevy® authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy® dose from receipt to storage to administration; and
16. Approvals will be for 1 dose per member per lifetime.

Endari® (L-Glutamine) Approval Criteria:

1. An FDA approved diagnosis of sickle cell disease (SCD); and
2. Member must be 5 years of age or older; and
3. A trial of hydroxyurea or documentation why hydroxyurea is not appropriate for the member must be provided; and
4. Endari® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or in consultation with an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and
5. Endari® (L-glutamine) is brand preferred. Use of generic L-glutamine will require a patient specific, clinically significant reason why the member cannot use the brand formulation; 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 package labeling; and
7. Initial approvals will be for a duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Enjaymo® (Sutimlimab-jome) Approval Criteria:

1. An FDA approved diagnosis of primary cold agglutin disease confirmed by the following:
    a. Chronic hemolysis; and
    b. Positive direct antiglobulin (Coombs) test for C3d; and
    c. Cold agglutin titer of ≥64 at 4° Celsius; and
2. Member must have 1 or more symptoms associated with cold agglutinin disease (i.e., symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, a major adverse vascular event); and
3. Member has a hemoglobin (Hgb) level ≤10g/dL; and
4. Member has a bilirubin level above the normal reference range; and
5. Enjaymo® must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and

6. Member has not received rituximab within 3 months of initiation and will not be using rituximab concomitantly with Enjaymo®; and
7. Prescriber must verify the member has been vaccinated against encapsulated bacteria (e.g., *Neisseria meningitides, Streptococcus pneumoniae, Haemophilus influenzae*) at least 2 weeks prior to initiation of treatment; and
8. Enjaymo® must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
9. The prescriber must agree to monitor the member for at least 2 hours following the initial infusion for signs or symptoms of an infusion and/or hypersensitivity reaction and for 1 hour following completion of subsequent infusions; and
10. Prescriber must verify the member has no chronic systemic infections [e.g., hepatitis B, hepatitis C, human immunodeficiency virus (HIV)]; and
11. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to therapy, as confirmed by at least 1 of the following:
    a. Member has an increase in Hgb level of ≥2g/dL from baseline; or
    b. Member has had normalization of Hgb level to ≥12g/dL; or
    c. Member has had a decreased number of RBC transfusions since initiation of therapy.

Epogen® (Epoetin Alfa), Procrit® (Epoetin Alfa), and Retacrit® (Epoetin Alfa-epbx) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of anemia due to chemotherapy in members with non-myeloid malignancies; or
    b. Treatment of anemia in zidovudine-treated human immunodeficiency virus (HIV)-infected members; or
    c. Reduction of allogeneic blood transfusion(s) in members undergoing surgery; or
    d. Treatment of anemia associated with chronic renal failure; and
        i. For the diagnosis of anemia associated with chronic renal failure: member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and

further approval may be granted if the member's recent hemoglobin level is <11g/dL.

Lyfgenia® (Lovotibeglogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of sickle cell disease (SCD) with a history of vaso-occlusive events (VOEs); and
2. Member must be 12 years of age or older; and
3. Member must have evidence of severe disease as demonstrated by ≥4 severe VOEs in the last 2 years; and
4. Member must not have >2 α-globin gene deletions; and
5. Lyfgenia® must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Lyfgenia®; and
6. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and
7. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
8. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
9. Member must not have previously received treatment with Casgevy® (exagamglogene autotemcel); and
10. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
11. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Lyfgenia®); and
12. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
13. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
14. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lyfgenia® administration; and
15. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lyfgenia®; and
16. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member; and
17. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Lyfgenia®; and
18. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential)

performed at month 6 and month 12 after treatment with Lyfgenia®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
19. Lyfgenia® must be administered at a Lyfgenia® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Lyfgenia® dose from receipt to storage to administration; and
20. A patient-specific, clinically significant reason why the member cannot use Casgevy® (exagamglogene autotemcel) must be provided; and
21. Approvals will be for 1 dose per member per lifetime.

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. 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
7. 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.

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

1. An FDA approved indication for the treatment of adult members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must require regular RBC transfusions (no transfusion-free period >35 days during the prior 6 month period); and

3. Member must not have previously received treatment with Zynteglo® (betibeglogene autotemcel) or Casgevy® (exagamglogene autotemcel); and
4. Reblozyl® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of beta thalassemia (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating beta thalassemia); and
5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
6. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and
7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 4 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.25mg/kg (allows for initial dosing of 6 weeks at 1mg/kg). Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Reblozyl® (Luspatercept-aamt) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. An FDA approved indication of 1 of the following:
    a. Treatment of adult members with very low-to-intermediate risk MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with anemia failing an erythropoiesis stimulating agent (ESA) and requiring ≥2 red blood cell (RBC) units over 8 weeks; or
    b. Treatment of adult members with very low-to-intermediate risk MDS with anemia who are ESA-naive and who required ≥2 RBS units within the last 8 weeks; and
2. For MDS-RS or MDS/MPN-RS-T:
    a. Member must have had an inadequate response to prior treatment with an ESA, be intolerant of ESAs, or have a serum erythropoietin level >200U/L; and
    b. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
    c. Prescriber must verify the member does not have deletion 5q (del 5q); and

3. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
4. Reblozyl® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in treatment of MDS (or an advanced care practitioner with a supervising physician who is a hematologist, oncologist, or specialist with expertise in treating MDS); and
5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
6. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and
7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 6 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Siklos® (Hydroxyurea Tablets) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Member must be 2 years of age or older; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. A trial of hydroxyurea capsules or a patient-specific, clinically significant reason why hydroxyurea capsules are not appropriate for the member must be provided; and
5. Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and
6. Prescriber must agree to monitor the member for the development of secondary malignancies; and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Siklos® for at least 6 months after therapy; and
9. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Vafseo® (Vadadustat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia due to chronic kidney disease (CKD) in adults; and
2. Member must currently be on dialysis and must have been receiving dialysis for ≥3 months; and
3. Prescriber must verify that member does not have uncontrolled hypertension; and
4. Prescriber must verify that member does not have an active malignancy; and
5. Prescriber must verify that liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Vafseo® treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
6. Member's pre-treatment hemoglobin (Hgb) must be <11g/dL. Recent Hgb levels must be provided; and
7. Member must be hyporesponsive to an erythropoiesis-stimulating agent (ESA) (or have a contraindication to use), defined as:
    a. No increase in Hgb after 1 month of weight-based dosing; or
    b. 2 increases in ESA dose up to 50% more than previous dose to maintain current Hgb level; and
8. Prescriber must verify that member will not use Vafseo® concomitantly with an ESA or another hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor; and
9. Initial and subsequent approvals will be for the duration of 12 weeks of treatment. Subsequent approvals will be granted if the member meets 1 of the following:
    a. Member has achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL and the member's Hgb level is <12g/dL; or
    b. If the member has not achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL, then all of the following will be required:
        i. The dose will be increased as tolerated to a maximum of 600mg per day; and
        ii. The member has not received 600mg per day for >12 weeks without achieving a clinically meaningful increase in hemoglobin of ≥1g/dL; and
        iii. The member's Hgb is <12g/dL; and
10. Vafseo® should be discontinued in members who do not show evidence of a clinically meaningful increase in Hgb by 24 weeks.

Xromi® (Hydroxyurea Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Xromi® will not require a prior authorization for members 6 years of age and younger. For members 7 years of age and older, a patient-specific,

clinically significant reason why the member cannot use hydroxyurea capsules or tablets must be provided; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and
5. Prescriber must agree to monitor the member for the development of secondary malignancies; and
6. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
7. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Xromi® for at least 6 months after therapy; and
8. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Zynteglo® (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must be 4 years of age or older; and
3. Member must weigh ≥6kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
    a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
    b. ≥8 transfusions of packed RBCs per year in the last 2 years; and
5. Zynteglo® must be prescribed by a hematologist or transplant specialist with expertise in the treatment of beta thalassemia and the administration of Zynteglo®; and
6. Member must not have a known and available human leukocyte antigen (HLA) fully-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Casgevy® (exagamglogene autotemcel) for the transfusion-dependent beta thalassemia (TDT) indication; and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Zynteglo®); and

11. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo® administration; and
12. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6months after administration of Zynteglo®; and
13. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member; and
14. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo®; and
15. Member will not be approved for treatment with Reblozyl® (luspatercept-aamt) following Zynteglo® infusion (current authorizations for luspatercept-aamt will be discontinued upon Zynteglo® approval); and
16. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Zynteglo™, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
17. Zynteglo® must be administered at a Zynteglo® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zynteglo® dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Utilization of Anemia 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	230	1,107	$1,936,394.27	$1,749.23	$54.63	69,541	35,444
Aetna	25	52	$29,083.94	$559.31	$19.80	3,280	1,469
Humana	29	59	$154,813.32	$2,623.95	$88.62	3,330	1,747
OCH	28	62	$10,500.20	$169.36	$7.07	3,029	1,485
2024 Total	**244**	**1,280**	**$2,130,791.73**	**$1,664.68**	**$53.08**	**79,179**	**40,145**
Fiscal Year 2025							
FFS	147	604	$375,625.04	$621.90	$18.87	34,729	19,906
Aetna	42	161	$35,432.04	$220.07	$7.24	10,602	4,896
Humana	37	178	$113,170.36	$635.79	$18.59	11,357	6,089
OCH	50	216	$65,289.11	$302.26	$10.50	15,238	6,217
2025 Total	**250**	**1,159**	**$589,516.55**	**$508.64**	**$15.89**	**71,927**	**37,108**
% Change	**2.50%**	**-9.50%**	**-72.30%**	**-69.40%**	**-70.10%**	**-9.20%**	**-7.60%**
Change	**6**	**-121**	**-$1,541,275.18**	**-$1,156.04**	**-$37.19**	**-7,252**	**-3,037**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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.

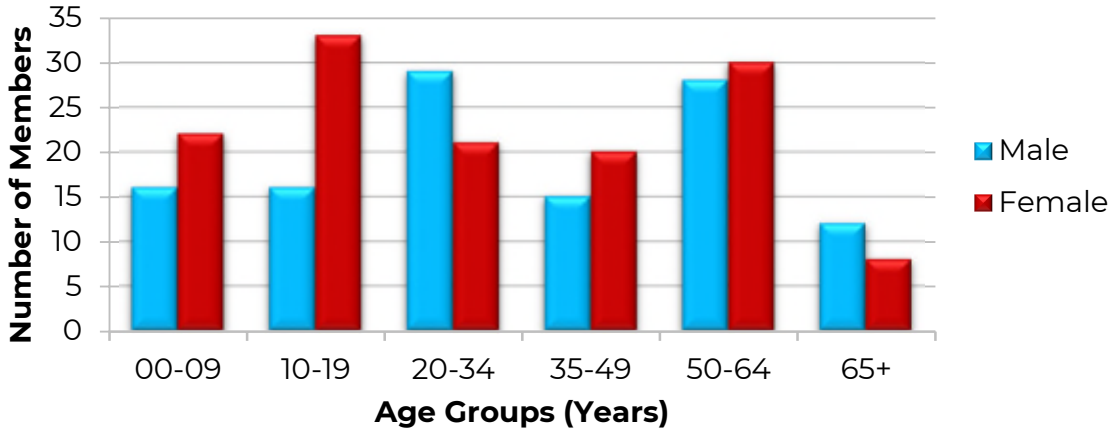
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	61	326	$1,622,471.24	$4,976.91	5.34
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	2	3	$20,336.00	$6,778.67	1.5
2024 Total	**62**	**329**	**$1,642,807.24**	**$4,993.34**	**5.31**
Fiscal Year 2025					
FFS	29	158	$859,664.84	$5,440.92	5.45
Aetna	4	5	14002.4	$2,800.48	1.25
Humana	3	10	2949.48	$294.95	3.33
OCH	6	18	25853.2	$1,436.29	3
2025 Total	**38**	**191**	**$902,469.92**	**$4,724.97**	**5.03**
% Change	**-38.71%**	**-41.95%**	**-45.07%**	**-5.37%**	**-5.28%**
Change	**-24**	**-138**	**-$740,337.32**	**-$268.36**	**-0.28**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
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 2024 for anemia medications totaled $559,811.07.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2024 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2025 (7/1/2024 to 6/30/2025) are still being collected at this time. The costs included in this report do not reflect net costs.

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



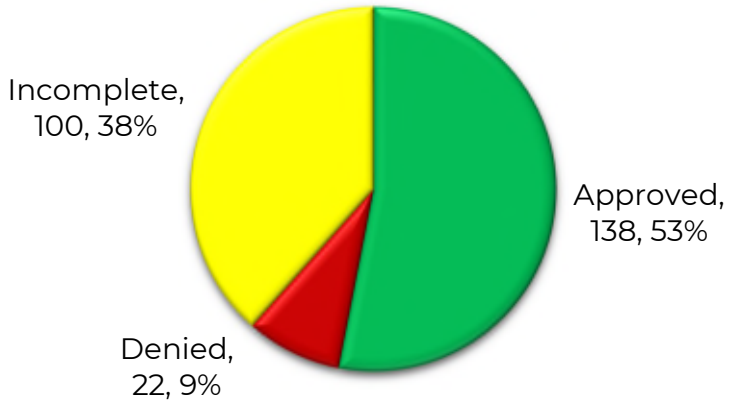
Top Prescriber Specialties of Anemia Medications by Number of Claims: Pharmacy Claims (All Plans)

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

Prior Authorization of Anemia Medications

There were 260 prior authorization requests submitted for anemia 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	107	50%	92	43%	17	8%	**216**
Aetna	8	67%	2	17%	2	17%	**12**
Humana	9	90%	0	0%	1	10%	**10**
OCH	14	64%	6	27%	2	9%	**22**
Total	**138**	**53%**	**100**	**38%**	**22**	**9%**	**260**

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

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

Anticipated Patent Expiration(s):

- Vafseo® (vadadustat tablets): March 2036
- Pyrukynd® (mitapivat tablets) July 2041

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

- **January 2025:** The FDA approved a label update for Pyrukynd® (mitapivat) to include new safety information regarding the risk of hepatocellular injury. Based on this update, the *Warnings and Precautions* section of the package labeling now includes hepatocellular injury in another condition. It is recommended that liver tests be obtained prior to initiation of Pyrukynd®, monthly for the first 6 months, and as clinically indicated thereafter. If clinically significant increases in liver tests are observed or alanine aminotransferase is >5 times the upper limit of normal, treatment should be interrupted and

treatment should be discontinued if hepatic injury due to Pyrukynd® is suspected.

News:

- **December 2024:** GSK announced the voluntary withdrawal of Jesduvroq® (daprodustat) from the market due to business reasons and not due to any safety or efficacy issues. It is recommended that health care providers work with their patients to identify alternative treatment options.

Pipeline:

- **Pyrukynd® (Mitapivat):** Mitapivat is an oral pyruvate kinase (PK) activator that is being studied for the treatment of non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia. The FDA accepted a supplemental New Drug Application (sNDA) for this indication based on results from the ENERGIZE and ENERGIZE-T Phase 3 trials and a Prescription Drug User Fee Act (PDUFA) date was set for September 7, 2025. On September 4, 2025, Agios announced that the FDA extended the PDUFA date to December 7, 2025 following an additional information request from the FDA. Agios submitted a proposed Risk Evaluation and Mitigation Strategy (REMS) to mitigate the risk of hepatocellular injury that was described in the original sNDA and stated that the extension is not due to any new or additional safety or efficacy data. Mitapivat is also being studied in multiple other trials for other indications such as sickle cell disease and pediatric PK deficiency.
- **Wayrilz™ (Rilzabrutinib):** Rilzabrutinib is an oral, reversible Bruton's tyrosine kinase (BTK) inhibitor that is being studied for various immune-mediated diseases. The FDA granted Orphan Drug designation to rilzabrutinib for warm autoimmune hemolytic anemia (wAIHA) and IgG4-related disease. Rilzabrutinib for wAIHA showed clinically meaningful outcomes on response rate and disease markers in a Phase 2b study that is still ongoing. On August 29, 2025, rilzabrutinib was approved by the FDA for adults with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Recommendations

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.

Utilization Details of Anemia Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYUREA PRODUCTS						
HYDROXYUREA CAP 500MG	933	214	$21,708.04	$23.27	4.36	3.68%
DROXIA CAP 200MG	38	9	$2,183.80	$57.47	4.22	0.37%
DROXIA CAP 400MG	28	14	$1,474.40	$52.66	2	0.25%
DROXIA CAP 300MG	20	7	$954.70	$47.74	2.86	0.16%
SIKLOS TAB 1,000MG	11	2	$6,465.55	$587.78	5.5	1.10%
XROMI SOL 100MG/ML	1	1	$370.87	$370.87	1	0.06%
SUBTOTAL	**1,031**	**247**	**$33,157.36**	**$32.16**	**4.17**	**5.62%**
EPOETIN ALFA PRODUCTS						
PROCRIT INJ 20,000U/ML	16	4	$21,947.75	$1,371.73	4	3.72%
EPOGEN INJ 10,000U/ML	12	5	$12,678.24	$1,056.52	2.4	2.15%
PROCRIT INJ 10,000U/ML	6	1	$6,482.46	$1,080.41	6	1.10%
EPOGEN INJ 20,000U/ML	5	2	$2,709.85	$541.97	2.5	0.46%
EPOGEN INJ 4,000U/ML	5	2	$1,358.85	$271.77	2.5	0.23%
PROCRIT INJ 40,000U/ML	3	1	$12,469.00	$4,156.33	3	2.12%
RETACRIT INJ 10,000U/ML	3	2	$521.44	$173.81	1.5	0.09%
RETACRIT INJ 20,000U/ML	2	1	$456.02	$228.01	2	0.08%
EPOGEN INJ 2,000U/ML	1	1	$43.76	$43.76	1	0.01%
SUBTOTAL	**53**	**19**	**$58,667.37**	**$1,106.93**	**2.79**	**9.95%**
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ 40MCG/0.4ML	12	2	$13,203.04	$1,100.25	6	2.24%
ARANESP INJ 100MCG/0.5ML	8	2	$22,921.26	$2,865.16	4	3.89%
ARANESP INJ 25MCG/0.42ML	7	1	$5,321.21	$760.17	7	0.90%
ARANESP INJ 60MCG/0.3ML	5	2	$8,057.68	$1,611.54	2.5	1.37%
ARANESP INJ 150MCG/0.3ML	3	1	$13,966.23	$4,655.41	3	2.37%
ARANESP INJ 10MCG/0.4ML	2	1	$642.02	$321.01	2	0.11%
SUBTOTAL	**37**	**9**	**$64,111.44**	**$1,732.74**	**4.11**	**10.88%**
VOXELOTOR PRODUCTS						
OXBRYTA TAB SUSP 300MG	22	8	$279,567.32	$12,707.61	2.75	47.42%
OXBRYTA TAB 500MG	11	7	$133,502.31	$12,136.57	1.57	22.65%
SUBTOTAL	**33**	**15**	**$413,069.63**	**$12,517.26**	**2.2**	**70.07%**
L-GLUTAMINE PRODUCTS						
ENDARI POW 5GM	4	1	$17,090.80	$4,272.70	4	2.90%
L-GLUTAMINE POW 5GM	1	1	$3,419.95	$3,419.95	1	0.58%
SUBTOTAL	**5**	**2**	**$20,510.75**	**$4,102.15**	**2.5**	**3.48%**
TOTAL	**1,159**	**250***	**$589,516.55**	**$508.64**	**4.64**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; POW = powder; SUSP = suspension; TAB = tablet; U = unit
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
ADAKVEO INJ J0791	77	13	$557,348.60	$7,238.29	5.92
ARANESP INJ J0881	54	15	$30,900.80	$572.24	3.6
PROCRIT INJ J0885	33	10	$8,046.52	$243.83	3.3
REBLOZYL INJ J0896	27	2	$306,174.00	$11,339.78	13.5
TOTAL	**191**	**38**	**$902,469.92**	**$4,724.97**	**5.03**

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

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Appendix Q

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)

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

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-aacf (Idacio®)±
azathioprine	adalimumab-aqvh (Yusimry®)⁺±	certolizumab pegol (Cimzia®)	adalimumab-aaty (Yuflyma®)±
hydroxychloroquine	adalimumab-bwwd (Hadlima™)⁺±	deucravacitinib (Sotyktu®)	adalimumab-adaz (Hyrimoz®)±
leflunomide	anakinra (Kineret®)	golimumab (Simponi®, Simponi Aria®)	adalimumab-adbm (Cyltezo®)±
mesalamine	apremilast (Otezla®)ß	infliximab (Remicade®)±	adalimumab-afzb (Abrilada™)±
methotrexate	etanercept (Enbrel®)±	infliximab-abda (Renflexis®)±	adalimumab-atto (Amjevita®)±
minocycline	infliximab-dyyb (Inflectra®)±	infliximab-axxq (Avsola®)±	adalimumab-fkjp (Hulio®)±
NSAIDs	rituximab (Rituxan®)~±	sarilumab (Kevzara®)§	adalimumab-ryvk (Simlandi®)±
oral corticosteroids	rituximab-abbs (Truxima®)±	tocilizumab-aazg (Tyenne®)±	anifrolumab-fnia (Saphnelo®)**
sulfasalazine	rituximab-arrx (Riabni®)±	tofacitinib (Xeljanz®, Xeljanz® XR, Xeljanz® oral solution)**	avacopan (Tavneos®)**
topical corticosteroids	rituximab-pvvr (Ruxience®)±	vedolizumab intravenous (IV) (Entyvio®)**	baricitinib (Olumiant®)€
			belimumab (Benlysta®)**

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
			bimekizumab-bkzx (Bimzelx®)
			brodalumab (Siliq®)**
			canakinumab (Ilaris®)¥
			deuruxolitinib (Leqselvi™)€
			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-bavi (Tofidence™)±
			upadacitinib (Rinvoq®, Rinvoq® LQ)#
			ustekinumab (Stelara®)±
			ustekinumab-aauz (Otulfi®)±
			ustekinumab-aekn (Selarsdi™)±
			ustekinumab-auub (Wezlana™)±
			ustekinumab-ttwe (Pyzchiva®)±
			vedolizumab subcutaneous (sub-Q) (Entyvio®)**
			voclosporin (Lupkynis®)**

DMARDs = disease modifying anti-rheumatic drugs; 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).
[π]Unique 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 a diagnosis of atopic dermatitis (AD).
[€]Unique criteria applies for a diagnosis of alopecia areata.
[§]Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).
[Δ]Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS).
[**]Unique criteria applies to this medication for approval.

Targeted Immunomodulator Agents Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. A trial of at least 1 Tier-1 medication (appropriate to the member's disease state) in the last 90 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-2 medication documented within the last 100 days.

Targeted Immunomodulator Agents Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state) and at least 2 Tier-2 medications (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-3 medication documented within the last 100 days; or

5. A unique FDA-approved indication not covered by Tier-2 medications (unique approval criteria may apply).

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

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state), at least 2 Tier-2 medications (appropriate to the member's disease state), and 1 Tier-3 medication (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Special PA medication documented within the last 100 days; or
5. A unique FDA-approved indication not covered by lower-tiered medications (unique approval criteria may apply).

Abrilada™ (Adalimumab-afzb), Amjevita® (Adalimumab-atto), Cyltezo® (Adalimumab-adbm), Hulio® (Adalimumab-fkjp), Hyrimoz® (Adalimumab-adaz), Idacio® (Adalimumab-aacf), Simlandi® (Adalimumab-ryvk), and Yuflyma® (Adalimumab-aaty) 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 Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry® (adalimumab-aqvh) 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) and Tofidence™ (Tocilizumab-bavi) 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 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) 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.

Actemra® (Tocilizumab), 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® or Tofidence™ will require a patient-specific, clinically significant reason why the member cannot use 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).

Actemra® (Tocilizumab) Approval Criteria [Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Diagnosis]:

1. An FDA approved diagnosis SSc-ILD; and
2. Member must be 18 years of age or older; and
3. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
4. Approvals will be for subcutaneous administration using the FDA approved dosing of 162mg once weekly.

Arcalyst® (Rilonacept) Approval Criteria [Cryopyrin-Associated Periodic Syndromes (CAPS) Diagnosis]:

1. An FDA approved indication of CAPS verified by genetic testing. This includes familial cold auto-inflammatory syndrome (FCAS) and Muckle-

Wells syndrome (MWS) in adults and children 12 years of age and older; and
2. A patient-specific, clinically significant reason the member cannot utilize Kineret® (anakinra) or Ilaris® (canakinumab) must be provided. Tier structure rules apply; and
3. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst®; and
4. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
5. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for members 18 years of age and older:
        i. Initial treatment: Loading dose of 320mg delivered as (2) 2mL subcutaneous (sub-Q) injections of 160mg each given on the same day at 2 different injection sites; and
        ii. Continued treatment: (1) 160mg injection given once weekly; or
    c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member's recent weight in kilograms):
        i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
        ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and
6. Approvals will be for the duration of 1 year.

Arcalyst® (Rilonacept) Approval Criteria [Deficiency of Interleukin-1 Receptor Antagonist (DIRA) Diagnosis]:

1. An FDA approved indication of maintenance of remission of DIRA verified by genetic testing; and
2. Member must weigh ≥10kg; and
3. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst®; and
4. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
5. Arcalyst® will be used for maintenance of remission following treatment with Kineret® (anakinra); and

6. A patient-specific, clinically significant reason the member cannot continue to utilize Kineret® (anakinra) instead of switching to Arcalyst® must be provided; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for adults and pediatric members weighing ≥10kg is 4.4mg/kg up to a maximum of 320mg, delivered as 1 or 2 injections (2mL/injection) once weekly; and
9. Approvals will be for the duration of 1 year.

Arcalyst® (Rilonacept) Approval Criteria [Recurrent Pericarditis Diagnosis]:

1. An FDA approved indication of recurrent pericarditis and reduction in risk of recurrence in members 12 years of age and older; and
2. Member has had at least 2 episodes of pericarditis; and
3. Member has had failure with colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroids defined as symptomatic pericarditis recurrence; and
4. A patient-specific, clinically significant reason the member cannot utilize Kineret® (anakinra) must be provided; and
5. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst®; and
6. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling for members 12 to 17 years of age; and
8. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for members 18 years of age and older:
        i. Initial treatment: Loading dose of 320mg delivered as (2) 2mL subcutaneous (sub-Q) injections of 160mg each given on the same day at 2 different injection sites; and
        ii. Continued treatment: (1) 160mg injection given once weekly; or
    c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member's recent weight in kilograms):
        i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with

a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
   ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and
9. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by decreased recurrence of pericarditis or improvement in signs and symptoms of recurrent pericarditis (e.g., C-reactive protein, pericarditic chest pain, pericardial effusion). Subsequent approvals will be granted for the duration of 1 year.

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

Benlysta® (Belimumab) Approval Criteria:

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

6. Benlysta® will not be approved for concomitant use with IV cyclophosphamide (exception for induction treatment with IV cyclophosphamide for members with a diagnosis of LN).

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) or Dupixent® (dupilumab) that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. 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
7. 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
8. 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
9. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
10. For Rinvoq®, the maximum approvable dose for AD is 30mg once daily.

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

1. A diagnosis of moderate-to-severe HS; and

2. Hurley Stage II or III disease; and
3. Member must have at least 5 abscesses or inflammatory nodules; 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) for at least 12 weeks at recommended dosing (or documented intolerance).

Entyvio® (Vedolizumab) Approval Criteria:

1. An FDA approved diagnosis of moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); and
2. Member must be 18 years of age or older; and
3. A minimum of a 4 week trial of a Tier-2 tumor necrosis factor (TNF) blocker 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
4. Prior stabilization on the medication documented within the last 100 days; and
5. For Entyvio® subcutaneous (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
6. 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
7. 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.

Erelzi® (Etanercept-szza) and Eticovo® (Etanercept-ykro) 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 Enbrel® (etanercept) 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.

Gamifant® (Emapalumab-lzsg) Approval Criteria [Primary Hemophagocytic Lymphohistiocytosis (HLH) Diagnosis]:

1. An FDA approved indication for the treatment of adult and pediatric members with primary HLH with refractory, recurrent, or progressive disease or who are intolerant to conventional HLH therapy; and
2. Diagnosis of primary HLH must be confirmed by 1 of the following:
    a. Genetic testing confirming mutation of a gene known to cause primary HLH (e.g., *PRF*, *UNC13D*, *STX11*); or
    b. Family history consistent with primary HLH; or
    c. Member meets 5 of the following 8 diagnostic criteria:
        i. Fever; or
        ii. Splenomegaly; or
        iii. Cytopenias affecting at least 2 of 3 lineages in the peripheral blood (hemoglobin <9g/dL, platelets <100 x 10^9/L, neutrophils <1 x 10^9/L); or
        iv. Hypertriglyceridemia (fasting triglycerides >3mmol/L or ≥265mg/dL) and/or hypofibrinogenemia (≤1.5g/L); or
        v. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy; or
        vi. Low or absent natural killer (NK)-cell activity; or
        vii. Hyperferritinemia (ferritin ≥500mcg/L); or
        viii. High levels of soluble interleukin-2 receptor (soluble CD25 ≥2,400U/mL); and
3. Gamifant® must be prescribed by, or in consultation with, a physician who specializes in the treatment of immune deficiency disorders; and
4. Member must have at least 1 of the following:
    a. Failure of at least 1 conventional HLH treatment (e.g., etoposide, dexamethasone, cyclosporine); or
    b. Documentation of progressive disease despite conventional HLH treatment; or
    c. A patient-specific, clinically significant reason why conventional HLH treatment is not appropriate for the member must be provided; and
5. Prescriber must verify dexamethasone dosed at least 5mg/m^2/day will be used concomitantly with Gamifant®; and
6. Prescriber must verify member has received or will receive prophylaxis for herpes zoster, *Pneumocystis jirovecii,* and fungal infection(s); and

7. Prescriber must verify member will be monitored for tuberculosis (TB), adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) every 2 weeks and 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 has not received hematopoietic stem cell transplantation (HSCT).

Hadlima™ (Adalimumab-bwwd), Humira® (Adalimumab), or 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; 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.

Hadlima™ (Adalimumab-bwwd), Humira® (Adalimumab), or 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.

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

1. An FDA approved indication of SJIA or AOSD; and
2. The member should not be using a tumor necrosis factor (TNF) blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and

3. Ilaris® should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. Dosing should not be more often than once every 4 weeks; and
    a. Weight-based dosing in members 2 years of age and older (the member's recent weight must be provided):
        i. Body weight ≥7.5kg: 4mg/kg subcutaneous injection every 4 weeks (maximum 300mg/dose); and
5. Recent trials of 1 Tier-1 medication and all appropriate Tier-2 medications that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
6. Prior stabilization on the Tier-3 medication documented within the last 100 days; and
7. Approvals will be for the duration of 1 year.

Ilaris® (Canakinumab) Approval Criteria [Cryopyrin-Associated Periodic Syndromes (CAPS) Diagnosis]:

1. An FDA approved indication of CAPS verified by genetic testing [which includes Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)] in adult and pediatric members 4 years of age and older; and
2. Member must not be using a tumor necrosis factor (TNF) blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Ilaris® should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. The following dosing requirements must be met:
    a. Dosing should not be more often than once every 8 weeks; and
    b. Weight-based dosing (the member's recent weight must be provided):
        i. Body weight >40kg: 150mg; or
        ii. Body weight 15kg to 40kg: 2mg/kg (if inadequate response, dose may be increased to 3mg/kg); and
5. Approvals will be for the duration of 1 year.

Ilaris® (Canakinumab) Approval Criteria [Gout Flare Diagnosis]:

1. An FDA approved indication for the treatment of gout flare; and
2. Member must have had ≥3 gout flares in the previous year; and
3. Member must meet 1 of the following:
    a. Inadequate response or intolerance to recent trials of oral colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroids (oral, intraarticular, and/or intramuscular) used for the treatment of previous gout flare(s); or

   b. Colchicine, NSAIDs, and corticosteroids are contraindicated for the member (specific information regarding contraindication must be submitted); and
4. A patient-specific, clinically significant reason why the member cannot use Kineret® (anakinra) must be provided; and
5. Approvals will be for (1) 150mg dose at a time. Subsequent approvals will require documentation that the member responded well to previous treatment with Ilaris®; and
6. Approvals will not be granted more often than once every 12 weeks.

Ilaris® (Canakinumab) Approval Criteria [Tumor Necrosis Factor Receptor-Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF) Diagnosis]:

1. Diagnosis of TRAPS with chronic or recurrent disease activity defined as 6 flares per year; or
2. Diagnosis of HIDS/MKD; or
3. Diagnosis of FMF with documented active disease despite colchicine therapy or documented intolerance to effective doses of colchicine; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Kevzara® (Sarilumab) Approval Criteria [Polymyalgia Rheumatica (PMR) Diagnosis]:

1. An FDA approved diagnosis of PMR; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify member has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper; and
4. Prescriber must verify Kevzara® will be used in combination with a tapering course of corticosteroids, unless contraindicated.

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

1. An FDA approved diagnosis of severe alopecia areata; and
2. For Litfulo®, member must be 12 to 20 years of age; or
3. For Leqselvi™ or Olumiant®, member must be 18 to 20 years of age; and
4. Prescriber must confirm the member or caregiver has been counseled regarding the covered age range for the requested product and that the medication will no longer be covered once the member turns 21 years of age; and
5. Member's baseline Severity of Alopecia Tool (SALT) score must be provided and must be ≥50; and
6. Must be prescribed by a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and

7. Prescriber must agree to screen for tuberculosis and viral hepatitis prior to initiating treatment; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
9. Prescriber must provide documentation of patient-specific, clinically significant information (e.g., impacting member's mental health or ability to function in day-to-day living, reason why no treatment or cosmetic solutions are not appropriate) to demonstrate the medical necessity of this medication for this member; and
10. Member must have documented trials within the last 6 months that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance to all alternatives):
    a. Medium potency to very-high potency Tier-1 topical corticosteroid used for at least 12 weeks; or
    b. Oral corticosteroid used for at least 6 weeks; or
    c. Cyclosporine; or
    d. Methotrexate; or
    e. Contact immunotherapy (e.g., diphenylcyclopropenone, squaric acid dibutyl ester); and
11. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
12. Prescriber must verify female members are not breastfeeding; and
13. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the pregnancy registry; and
14. Initial approvals will be for a duration of 24 weeks of treatment; and
15. Reauthorization may be considered if the prescriber documents the member is responding well to treatment as indicated by a reduction in the member's SALT score (current SALT score must be provided).

Lupkynis® (Voclosporin) Approval Criteria:

1. An FDA approved indication for the treatment of adults with active lupus nephritis (LN) in combination with a background immunosuppressive therapy regimen; and
    a. Lupkynis® must be used in combination with mycophenolate mofetil and low dose oral corticosteroids; and
2. Member must be 18 years of age or older; and
3. Lupkynis® must be prescribed by a nephrologist, rheumatologist, or other specialist with expertise in the treatment of LN; and
4. Member's current urine protein-to-creatinine ratio (UPCR) must be provided and must be ≥1.5mg/mg; and

5. Member's current estimated glomerular filtration rate (eGFR) must be provided and must be >45mL/min/1.73m^2 prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor renal function regularly during treatment with Lupkynis® and modify the dose as needed in accordance with the package labeling; and
6. Member's current blood pressure (BP) must be ≤165/105mmHg prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor BP regularly during treatment with Lupkynis® and agree to discontinue treatment if BP is >165/105mmHg or member experiences a hypertensive emergency; and
7. Member must not be taking strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) concomitantly with Lupkynis®; and
8. Prescriber must verify member has been counseled on proper administration of Lupkynis® including taking it on an empty stomach every 12 hours; and
9. Lupkynis® will not be approved in combination with biologic therapies or cyclophosphamide; and
10. A quantity limit of 180 capsules per 30 days will apply; and
11. 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 the member's UPCR. If the member does not experience therapeutic benefit by 6 months, discontinuation of Lupkynis® should be considered.

Orencia® (Abatacept) Approval Criteria [Acute Graft Versus Host Disease (aGVHD) Prophylaxis in Hematopoietic Stem Cell Transplant (HSCT) Diagnosis]:

1. An FDA approved indication for the prophylaxis of aGVHD in members undergoing HSCT; and
2. Member must be 2 years of age or older; and
3. Member is undergoing HSCT with a matched or 1 allele-mismatched unrelated donor; and
4. Must be used in combination with a calcineurin inhibitor and methotrexate.

Otezla® (Apremilast) 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. Quantity limits according to package labeling will apply.

Otulfi® (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Selarsdi™ (Ustekinumab-aekn), 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) 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.

Rinvoq® LQ (Upadacitinib Oral Solution) Approval Criteria:

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

Rituxan® (Rituximab) 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).

Rituxan® (Rituximab) 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.

Saphnelo® (Anifrolumab-fnia) Approval Criteria:

1. An FDA approved indication for the treatment of adult patients with moderate-to-severe systemic lupus erythematosus (SLE), who are receiving standard therapy; and
2. Member must be 18 years of age or older; and
3. Documented inadequate response to at least 1 of the following medications appropriate to member's specific disease state:
    a. High-dose oral corticosteroids; or
    b. Methotrexate; or
    c. Azathioprine; or
    d. Mycophenolate; or
    e. Cyclophosphamide; or
    f. Hydroxychloroquine/chloroquine; and
4. Member must not have severe active lupus nephritis (LN) or severe active central nervous system lupus; and
5. Saphnelo® will not be approved for combination use with biologic therapies or cyclophosphamide; and
6. 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.

Siliq® (Brodalumab) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. Members must also be enrolled in the Siliq® Risk Evaluation and Mitigation Strategy (REMS) program for approval; and
3. Members with a concomitant diagnosis of Crohn's disease will not be approved; and
4. Initial authorizations of Siliq® (brodalumab) will be for the duration of 12 weeks at which time the prescriber must verify the member is responding to treatment. If an adequate response has not been achieved after 12 to 16 weeks of treatment with brodalumab, consideration should be given to discontinuing therapy.

Spevigo® (Spesolimab-sbzo) Approval Criteria [Intravenous (IV) Flare Dosing]:

1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP) flares; and
2. Prescriber must verify the member has presence of macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques; and
3. Member must be currently experiencing a moderate-to-severe GPP flare meeting all the following criteria:

   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score must be provided and must be ≥3; and
   b. Presence of fresh pustules (new appearance or worsening of pustules); and
   c. GPPPGA pustulation sub-score must be provided and must be ≥2; and
   d. ≥5% of body surface area (BSA) covered with erythema and the presence of pustules; and
4. Member must be 12 years of age or older; and
5. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and
6. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo®; and
7. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections prior to each dose of Spevigo®; and
8. Approvals will be for 1 dose of Spevigo®. A second dose of Spevigo® may be approved 1 week after the first dose if the prescriber submits documentation that the member has been evaluated and continues to experience GPP flare symptoms; and
9. A quantity limit of 2 doses per year will apply (the safety and efficacy of additional doses of Spevigo® have not been assessed); and
   a. Requests for additional doses of Spevigo® to treat new GPP flares occurring within 1 year (after successful resolution of the previous flare) will be reviewed on a case-by-case basis and will require the prescriber to submit patient-specific, clinically significant information documenting the clinical necessity of additional treatment despite the lack of adequate safety and efficacy data; and
10. Subsequent requests for new GPP flares (after 1 year) will require the member to meet all initial approval criteria, and information regarding the member's response to previous treatment with Spevigo® must be submitted. Members who did not experience resolution of pustules after previous treatment will not be approved for additional use of Spevigo®.

Spevigo® (Spesolimab-sbzo) Approval Criteria [Subcutaneous (Sub-Q) Non-Flare Dosing]:

1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP); and

2. Prescriber must verify the member has presence of macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques; and
3. Member must be 12 years of age or older; and
4. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and
5. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo®; and
6. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections during treatment with Spevigo®; and
7. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) may be approved if the prescriber documents the member is responding well to the medication.

Tavneos® (Avacopan) Approval Criteria:

1. An FDA approved diagnosis as adjunctive treatment of adult members with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis [granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)] in combination with standard therapy including corticosteroids; and
2. Member must be 18 years of age or older; and
3. Tavneos® must be used in combination with standard immunosuppressive therapy including corticosteroids; and
4. Prescriber must agree to monitor liver function tests prior to initiating Tavneos®, every 4 weeks after the start of therapy for the first 6 months of treatment, and as clinically indicated thereafter; and
5. Prescriber must agree to screen the member for hepatitis B virus (HBV) infection prior to initiating treatment with Tavneos®; and
6. Prescriber must verify the member has no active, serious infections, including localized infections and will closely monitor member for the development of signs and symptoms of infection during and after treatment with Tavneos®; and
7. A quantity limit of 180 tablets per 30 days will apply.

Xeljanz® (Tofacitinib Oral Solution) Approval Criteria:

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

Utilization of Targeted Immunomodulator Agents: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	3,310	17,955	$148,317,164.90	$8,260.49	$271.77	148,597	545,740
Aetna	521	1,095	$8,830,119.64	$8,064.04	$275.42	8,940	32,060
Humana	577	1,302	$11,179,992.35	$8,586.78	$286.34	12,076	39,045
OCH	500	984	$8,052,159.82	$8,183.09	$274.71	8,241	29,311
2024 Total	**3,612**	**21,336**	**$176,379,436.71**	**$8,266.75**	**$272.97**	**177,854**	**646,156**
Fiscal Year 2025							
FFS	1,650	8,271	$68,824,060.56	$8,321.13	$272.09	79,542	252,944
Aetna	956	5,211	$42,998,810.98	$8,251.55	$280.15	45,566	153,483
Humana	893	5,410	$47,292,740.51	$8,741.73	$287.67	51,239	164,399
OCH	936	5,033	$41,611,364.27	$8,267.71	$279.20	40,869	149,039
2025 Total	**3,889**	**23,925**	**$200,726,976.32**	**$8,389.84**	**$278.84**	**217,216**	**719,865**
% Change	**7.70%**	**12.10%**	**13.80%**	**1.50%**	**2.20%**	**22.10%**	**11.40%**
Change	**277**	**2,589**	**$24,347,539.61**	**$123.09**	**$5.87**	**39,362**	**73,709**

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.

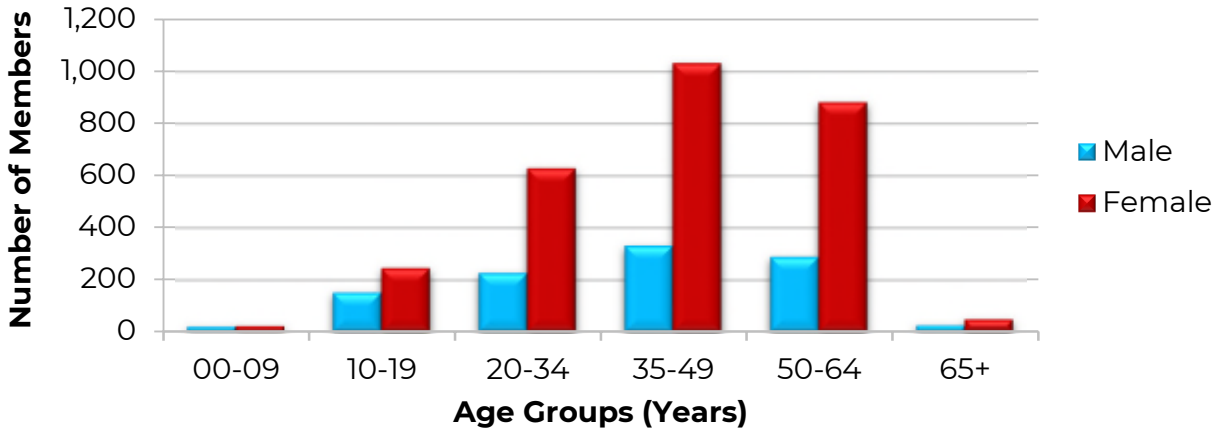
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	878	4,207	$14,533,260.69	$3,454.54	4.79
Aetna	38	69	$186,110.60	$2,697.26	1.82
Humana	8	10	$40,250.42	$4,025.04	1.25
OCH	73	139	$395,673.02	$2,846.57	1.9
2024 Total	**906**	**4,425**	**$15,155,294.73**	**$3,424.93**	**4.88**
Fiscal Year 2025					
FFS	417	1,731	$6,224,553.49	$3,595.93	4.15
Aetna	217	935	$2,740,962.28	$2,931.51	4.31
Humana	130	527	$1,455,128.71	$2,761.16	4.05
OCH	217	1,129	$2,736,502.73	$2,423.83	5.2
2025 Total	**893**	**4,322**	**$13,157,147.21**	**$3,044.23**	**4.84**
% Change	**-1.43%**	**-2.33%**	**-13.18%**	**-11.12%**	**-0.82%**
Change	**-13**	**-103**	**-$1,998,147.52**	**-$380.70**	**-0.04**

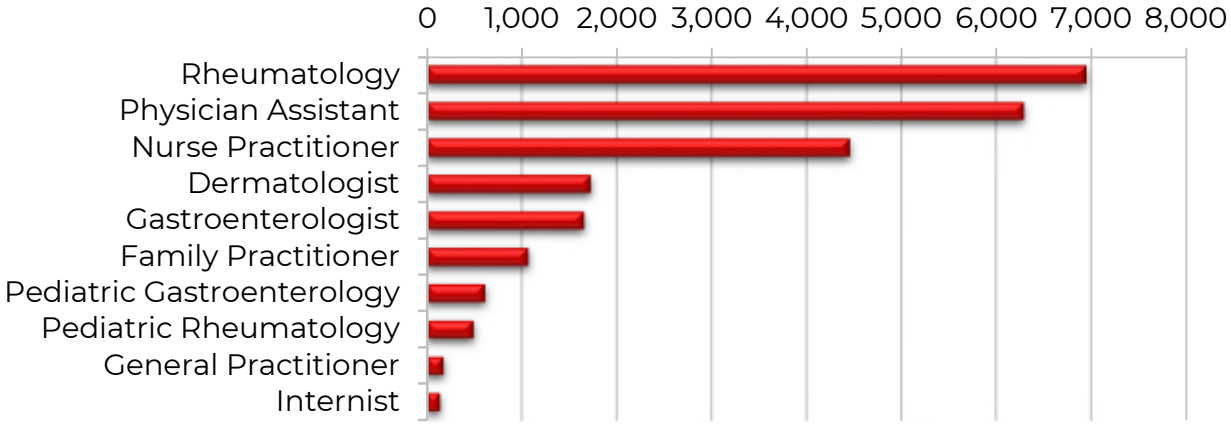
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective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

- Aggregate drug rebates collected during fiscal year 2024 for targeted immunomodulator agents totaled $136,822,458.51.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2024 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2025 (7/1/2024 to 6/30/2025) are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Targeted Immunomodulator Agents: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Targeted Immunomodulator Agents by Number of Claims: Pharmacy Claims (All Plans)



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

Prior Authorization of Targeted Immunomodulator Agents

There were 6,776 prior authorization requests submitted for targeted immunomodulator agents during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	1,808	43%	1,762	42%	606	15%	**4,176**
Aetna	682	68%	181	18%	138	14%	**1,001**
Humana	401	70%	0	0%	175	30%	**576**
OCH	541	53%	176	17%	306	30%	**1,023**
Total	**3,432**	**51%**	**2,119**	**31%**	**1,225**	**18%**	**6,776**

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

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28]

Anticipated Patent Expiration(s):

- Xeljanz® (tofacitinib oral solution and tablet): June 2026
- Olumiant® (baricitinib tablet): November 2032
- Sotyktu® (deucravacitinib tablet): November 2033
- Xeljanz® XR [tofacitinib extended-release (ER) tablet]: September 2034
- Otezla® (apremilast tablet): November 2034
- Velsipity® (etrasimod tablet): June 2036
- Rinvoq® LQ (upadacitinib oral solution): October 2036
- Lupkynis® (voclosporin capsule): December 2037
- Rinvoq® (upadacitinib tablet): March 2038
- Tavneos® (avacopan capsule): May 2041
- Litfulo® (ritlecitinib capsule): October 2041
- Leqselvi™ (deuruxolitinib tablet): October 2044

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

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), 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), Otezla XR™ (apremilast ER), and Starjemza™ (ustekinumab-hmny) 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 hidradenitis suppurativa (HS) and uveitis; and
    a. Note: These changes are to be implemented on 01/01/2026; and
8. Moving unbranded Remicade® (infliximab) from Tier-3 to Tier-2 and updating the infliximab approval criteria based on net cost; and
9. Updating the rituximab and tocilizumab approval criteria based on the current FDA approved indications for the biosimilar products; and
10. Updating the Entyvio® (vedolizumab) approval criteria based on net cost and currently available Tier-2 options for CD and UC.

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
6-mercaptopurine	adalimumab (Humira®)+± **- Branded Only**	abatacept (Orencia®, Orencia® ClickJect™)¤	**adalimumab (Humira®)+± - Unbranded Only**
azathioprine	**adalimumab-adaz (Hyrimoz®)+± - Unbranded Only**	certolizumab pegol (Cimzia®)	adalimumab-aacf (Idacio®)+±
hydroxychloroquine	adalimumab-aqvh (Yusimry®)+±	deucravacitinib (Sotyktu®)	adalimumab-aaty (Yuflyma®)+±
leflunomide	adalimumab-bwwd (Hadlima™)+± **- Branded Only**	golimumab (Simponi®, Simponi Aria®)	adalimumab-adaz (Hyrimoz®)+± **- Branded Only**
mesalamine	**adalimumab-fkjp (Hulio®)+± - Unbranded Only**	infliximab (Remicade®)± **- Branded Only**	adalimumab-adbm (Cyltezo®)+±
methotrexate	**adalimumab-ryvk (Simlandi®)+± - Branded Only**	infliximab-abda (Renflexis®)±	adalimumab-afzb (Abrilada™)+±
minocycline	anakinra (Kineret®)	infliximab-axxq (Avsola®)±	adalimumab-atto (Amjevita®)+±
NSAIDs	apremilast (Otezla®)ß	sarilumab (Kevzara®)§	**adalimumab-bwwd (Hadlima™)+± - Unbranded Only**

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
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-kfce (Yesintek™)±		brodalumab (Siliq®)**
	ustekinumab-srlf (Imuldosa®)±		canakinumab (Ilaris®)¥
	ustekinumab-stba (Steqeyma®)± - Branded Only		deuruxolitinib (Leqselvi™)€
	ustekinumab-ttwe (Pyzchiva®)± - Branded Only		**emapalumab-lzsg (Gamifant®)****
			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

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
			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-hmny (Starjemza™)±
			ustekinumab-stba (Steqeyma®)± - Unbranded Only
			ustekinumab-ttwe (Pyzchiva®)± **- Unbranded Only**
			vedolizumab subcutaneous (sub-Q) (Entyvio®)**
			voclosporin (Lupkynis®)**

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

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to participate in supplemental rebates.

±Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.

πUnique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.

βUnique 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).
[π]Unique 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).
[Δ]Unique 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; 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. A diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 5 abscesses or inflammatory nodules; 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. A diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 5 abscesses or inflammatory nodules; 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® (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), Starjemza™ (Ustekinumab-hmny), 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), 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.

Utilization Details of Targeted Immunomodulator Agents: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 PRODUCTS						
ADALIMUMAB PRODUCTS						
HUMIRA PEN INJ 40MG/0.4ML	7,514	1,344	$58,799,035.09	$7,825.26	5.59	29.29%
HUMIRA PEN INJ 80MG/0.8ML	791	131	$11,365,523.82	$14,368.55	6.04	5.66%
HUMIRA INJ 40MG/0.4ML	505	129	$3,963,112.95	$7,847.75	3.91	1.97%
HUMIRA PEN INJ 40MG/0.8ML	417	94	$3,591,197.65	$8,611.98	4.44	1.79%
HUMIRA INJ 20MG/0.2ML	178	24	$1,236,893.31	$6,948.84	7.42	0.62%
HUMIRA KIT 40MG/0.8ML	171	45	$1,392,291.36	$8,142.05	3.8	0.69%
HUMIRA PEN KIT CD/UC/HS 80MG/0.8ML	145	141	$2,908,615.59	$20,059.42	1.03	1.45%
HUMIRA PEN KIT PS/UV 80MG/0.8ML & 40MG/0.4ML	104	101	$1,390,353.88	$13,368.79	1.03	0.69%
HUMIRA INJ 10MG/0.1ML	23	4	$173,327.93	$7,536.00	5.75	0.09%
HADLIMA PUSH INJ 40MG/0.4ML	18	10	$16,601.44	$922.30	1.8	0.01%
HADLIMA INJ 40MG/0.4ML	16	2	$17,472.17	$1,092.01	8	0.01%
YUSIMRY INJ 40MG/0.8ML	7	1	$6,988.15	$998.31	7	0.00%
HADLIMA INJ 40MG/0.8ML	1	1	$1,049.41	$1,049.41	1	0.00%
SUBTOTAL	**9,890**	**2,027**	**$84,862,462.75**	**$8,580.63**	**4.88**	**42.28%**
ETANERCEPT PRODUCTS						
ENBREL SRCLK INJ 50MG/ML	3,923	774	$30,083,537.65	$7,668.50	5.07	14.99%
ENBREL INJ 50MG/ML	375	76	$2,846,641.29	$7,591.04	4.93	1.42%
ENBREL MINI INJ 50MG/ML	100	17	$798,800.51	$7,988.01	5.88	0.40%
ENBREL INJ 25MG/0.5ML	57	10	$247,228.30	$4,337.34	5.7	0.12%
ENBREL INJ 25MG	21	6	$105,698.31	$5,033.25	3.5	0.05%
SUBTOTAL	**4,476**	**883**	**$34,081,906.06**	**$7,614.37**	**5.07**	**16.98%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APREMILAST PRODUCTS						
OTEZLA TAB 30MG	1,105	233	$5,467,838.15	$4,948.27	4.74	2.72%
OTEZLA TAB 10/20/30MG	101	92	$506,722.68	$5,017.06	1.1	0.25%
OTEZLA TAB 20MG	22	6	$113,902.91	$5,177.41	3.67	0.06%
OTEZLA TAB 10/20MG	8	8	$40,939.48	$5,117.44	1	0.02%
SUBTOTAL	**1,236**	**339**	**$6,129,403.22**	**$4,959.06**	**3.65**	**3.05%**
INFLIXIMAB PRODUCTS						
INFLECTRA INJ 100MG	146	40	$112,989.18	$773.90	3.65	0.06%
SUBTOTAL	**146**	**40**	**$112,989.18**	**$773.90**	**3.65**	**0.06%**
ANAKINRA PRODUCTS						
KINERET INJ 100MG/0.67ML	63	10	$511,693.69	$8,122.12	6.3	0.25%
SUBTOTAL	**63**	**10**	**$511,693.69**	**$8,122.12**	**6.3**	**0.25%**
USTEKINUMAB PRODUCTS						
YESINTEK INJ 90MG/ML	2	1	$6,014.78	$3,007.39	2	0.00%
SUBTOTAL	**2**	**1**	**$6,014.78**	**$3,007.39**	**2**	**0.00%**
TIER-2 SUBTOTAL	**15,813**	**2,622***	**$125,704,469.68**	**$7,949.44**	**6.03**	**62.62%**
TIER-3 PRODUCTS						
ABATACEPT PRODUCTS						
ORENCIA CLICKJECT INJ 125MG/ML	447	97	$2,468,518.95	$5,522.41	4.61	1.23%
ORENCIA INJ 125MG/ML	104	18	$576,468.60	$5,542.97	5.78	0.29%
ORENCIA INJ 250MG	15	2	$19,821.17	$1,321.41	7.5	0.01%
ORENCIA INJ 87.5MG/0.7ML	5	2	$7,689.70	$1,537.94	2.5	0.00%
SUBTOTAL	**571**	**119**	**$3,072,498.42**	**$5,380.91**	**4.8**	**1.53%**
TOFACITINIB PRODUCTS						
XELJANZ TAB 5MG	231	43	$1,325,406.32	$5,737.69	5.37	0.66%
XELJANZ XR TAB 11MG	224	66	$1,297,556.59	$5,792.66	3.39	0.65%
XELJANZ TAB 10MG	21	3	$120,955.40	$5,759.78	7	0.06%
XELJANZ SOL 1MG/ML	5	4	$28,051.31	$5,610.26	1.25	0.01%
SUBTOTAL	**481**	**116**	**$2,771,969.62**	**$5,762.93**	**4.15**	**1.38%**
CERTOLIZUMAB PRODUCTS						
CIMZIA PREFL KIT 200MG/ML	322	72	$2,654,737.46	$8,244.53	4.47	1.32%
CIMZIA START KIT 200MG/ML	19	18	$316,271.40	$16,645.86	1.06	0.16%
CIMZIA KIT 200MG	7	2	$11,399.07	$1,628.44	3.5	0.01%
SUBTOTAL	**348**	**92**	**$2,982,407.93**	**$8,570.14**	**3.78**	**1.49%**
GOLIMUMAB PRODUCTS						
SIMPONI INJ 50MG/0.5ML AUTO	99	19	$587,954.85	$5,938.94	5.21	0.29%
SIMPONI INJ 50MG/0.5ML SYR	18	2	$109,192.91	$6,066.27	9	0.05%
SIMPONI ARIA SOL 50MG/4ML	5	1	$11,152.25	$2,230.45	5	0.01%
SUBTOTAL	**122**	**22**	**$708,300.01**	**$5,805.74**	**5.55**	**0.35%**
SARILUMAB PRODUCTS						
KEVZARA INJ 200MG/1.14ML AUTO	82	15	$354,886.79	$4,327.89	5.47	0.18%
KEVZARA INJ 150MG/1.14ML AUTO	1	1	$4,615.12	$4,615.12	1	0.00%
KEVZARA INJ 200MG/1.14ML SYR	1	1	$4,615.12	$4,615.12	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**84**	**17**	**$364,117.03**	**$4,334.73**	**4.94**	**0.18%**
INFLIXIMAB PRODUCTS						
REMICADE INJ 100MG	69	10	$149,575.33	$2,167.76	6.9	0.07%
INFLIXIMAB INJ 100MG	3	1	$5,060.07	$1,686.69	3	0.00%
AVSOLA INJ 100MG	1	1	$4,511.41	$4,511.41	1	0.00%
SUBTOTAL	**73**	**12**	**$159,146.81**	**$2,180.09**	**6.08**	**0.08%**
DEUCRAVACITINIB PRODUCTS						
SOTYKTU TAB 6MG	63	16	$422,591.35	$6,707.80	3.94	0.21%
SUBTOTAL	**63**	**16**	**$422,591.35**	**$6,707.80**	**3.94**	**0.21%**
TOCILIZUMAB PRODUCTS						
TYENNE INJ 162MG/0.9ML AUTO	46	15	$106,076.88	$2,306.02	3.07	0.05%
TYENNE INJ 162MG/0.9ML SYR	10	6	$23,120.54	$2,312.05	1.67	0.01%
SUBTOTAL	**56**	**21**	**$129,197.42**	**$2,307.10**	**2.67**	**0.06%**
VEDOLIZUMAB PRODUCTS						
ENTYVIO INJ 300MG	20	6	$138,583.33	$6,929.17	3.33	0.07%
SUBTOTAL	**20**	**6**	**$138,583.33**	**$6,929.17**	**3.33**	**0.07%**
TIER-3 SUBTOTAL	**1,818**	**389***	**$10,748,811.92**	**$5,912.44**	**4.67**	**5.35%**
SPECIAL PA PRODUCTS						
UPADACITINIB PRODUCTS						
RINVOQ TAB 15MG ER	856	158	$5,474,765.97	$6,395.75	5.42	2.73%
RINVOQ TAB 30MG ER	366	60	$2,319,093.06	$6,336.32	6.1	1.16%
RINVOQ TAB 45MG ER	83	35	$993,568.74	$11,970.71	2.37	0.49%
RINVOQ LQ SOL 1MG/ML	17	2	$69,188.42	$4,069.91	8.5	0.03%
SUBTOTAL	**1,322**	**255**	**$8,856,616.19**	**$6,699.41**	**5.18**	**4.41%**
SECUKINUMAB PRODUCTS						
COSENTYX UNO INJ 300MG/2ML	406	85	$4,473,409.33	$11,018.25	4.78	2.23%
COSENTYX PEN INJ 300MG DOSE	377	61	$3,172,814.24	$8,415.95	6.18	1.58%
COSENTYX PEN INJ 150MG/ML	227	39	$2,066,129.95	$9,101.89	5.82	1.03%
COSENTYX INJ 150MG/ML SYR	47	9	$412,327.45	$8,772.92	5.22	0.21%
COSENTYX INJ 75MG/0.5ML	21	2	$78,922.73	$3,758.23	10.5	0.04%
COSENTYX INJ 300 DOSE SYR	18	9	$181,189.47	$10,066.08	2	0.09%
SUBTOTAL	**1,096**	**205**	**$10,384,793.17**	**$9,475.18**	**5.35**	**5.17%**
BELIMUMAB PRODUCTS						
BENLYSTA INJ 200MG/ML AUTO	1,009	173	$4,958,562.33	$4,914.33	5.83	2.47%
BENLYSTA INJ 200MG/ML SYR	31	5	$152,650.41	$4,924.21	6.2	0.08%
SUBTOTAL	**1,040**	**178**	**$5,111,212.74**	**$4,914.63**	**5.84**	**2.55%**
IXEKIZUMAB PRODUCTS						
TALTZ INJ 80MG/ML AUTO	594	97	$4,752,302.83	$8,000.51	6.12	2.37%
TALTZ INJ 80MG/ML SYR	60	12	$387,330.81	$6,455.51	5	0.19%
TALTZ INJ 40MG/0.5ML SYR	35	7	$229,929.30	$6,569.41	5	0.11%
TALTZ INJ 20MG/0.25ML SYR	8	1	$57,145.99	$7,143.25	8	0.03%
SUBTOTAL	**697**	**117**	**$5,426,708.93**	**$7,785.81**	**5.96**	**2.70%**
RISANKIZUMAB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SKYRIZI PEN INJ 150MG/ML	315	119	$6,574,405.76	$20,871.13	2.65	3.28%
SKYRIZI INJ 360MG/2.4ML	271	69	$5,737,556.56	$21,171.80	3.93	2.86%
SKYRIZI INJ 150MG/ML	27	12	$569,127.80	$21,078.81	2.25	0.28%
SKYRIZI SOL 60MG/ML	3	3	$26,932.83	$8,977.61	1	0.01%
SKYRIZI INJ 180MG/1.2ML	3	2	$67,184.70	$22,394.90	1.5	0.03%
SUBTOTAL	**619**	**205**	**$12,975,207.65**	**$20,961.56**	**3.02**	**6.46%**
USTEKINUMAB PRODUCTS						
STELARA INJ 90MG/ML	338	71	$9,299,004.10	$27,511.85	4.76	4.63%
STELARA INJ 45MG/0.5ML	66	23	$905,236.46	$13,715.70	2.87	0.45%
STELARA INJ 45MG/0.5ML	16	5	$227,505.61	$14,219.10	3.2	0.11%
STELARA INJ 5MG/ML	1	1	$6,671.57	$6,671.57	1	0.00%
USTEKINUMAB INJ 45MG/0.5ML	1	1	$3,655.41	$3,655.41	1	0.00%
SUBTOTAL	**422**	**101**	**$10,442,073.15**	**$24,744.25**	**4.18**	**5.20%**
TOCILIZUMAB PRODUCTS						
ACTEMRA INJ ACTPEN 162MG/0.9ML	219	36	$896,354.72	$4,092.94	6.08	0.45%
ACTEMRA INJ 162MG/0.9ML	85	12	$332,231.27	$3,908.60	7.08	0.17%
ACTEMRA INJ 80MG/4ML	1	1	$2,132.55	$2,132.55	1	0.00%
SUBTOTAL	**305**	**49**	**$1,230,718.54**	**$4,035.14**	**6.22**	**0.61%**
GUSELKUMAB PRODUCTS						
TREMFYA INJ 100MG/ML	215	57	$2,930,761.11	$13,631.45	3.77	1.46%
TREMFYA INJ 100MG/ML	17	5	$244,053.04	$14,356.06	3.4	0.12%
TREMFYA INJ 200MG/2ML	10	5	$262,310.02	$26,231.00	2	0.13%
TREMFYA CROHN'S INJ 200MG/2ML	2	1	$58,288.58	$29,144.29	2	0.03%
TREMFYA INJ 200MG/20ML	1	1	$14,577.85	$14,577.85	1	0.01%
SUBTOTAL	**245**	**69**	**$3,509,990.60**	**$14,326.49**	**3.55**	**1.75%**
CANAKINUMAB PRODUCTS						
ILARIS INJ 150MG/ML	111	15	$2,498,617.27	$22,510.07	7.4	1.24%
SUBTOTAL	**111**	**15**	**$2,498,617.27**	**$22,510.07**	**7.4**	**1.24%**
BIMEKIZUMAB PRODUCTS						
BIMZELX INJ 160MG/ML AUTO	51	14	$731,612.01	$14,345.33	3.64	0.36%
BIMZELX INJ 160MG/ML SYR	24	4	$372,410.48	$15,517.10	6	0.19%
BIMZELX INJ 320MG/2ML AUTO	23	8	$554,842.38	$24,123.58	2.88	0.28%
SUBTOTAL	**98**	**26**	**$1,658,864.87**	**$16,927.19**	**3.77**	**0.83%**
ADALIMUMAB PRODUCTS						
ADALIMUMAB-ADAZ INJ 40MG/0.4ML	62	16	$93,386.01	$1,506.23	3.88	0.05%
AMJEVITA INJ 40MG/0.8ML	12	1	$39,595.80	$3,299.65	12	0.02%
ADALIMUMAB-AATY KIT 40MG/0.4ML	5	1	$10,437.05	$2,087.41	5	0.01%
ADALIMUMAB-RYVK INJ 40MG/0.4ML	2	1	$7,050.60	$3,525.30	2	0.00%
ADALIMUMAB-FKJP KIT 40MG/0.8ML	2	1	$2,012.82	$1,006.41	2	0.00%
AMJEVITA INJ 40MG/0.4ML	1	1	$1,396.63	$1,396.63	1	0.00%
ADALIMUMAB-ADAZ INJ 20MG/0.2ML	1	1	$1,326.71	$1,326.71	1	0.00%
SIMLANDI KIT 40MG/0.4ML	1	1	$1,049.41	$1,049.41	1	0.00%
ADALIMUMAB-ADAZ INJ 80MG/0.8ML	1	1	$2,642.01	$2,642.01	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYRIMOZ-PED INJ CROHN'S 80MG/0.8ML & 40MG/0.4ML	1	1	$7,112.62	$7,112.62	1	0.00%
SUBTOTAL	**88**	**25**	**$166,009.66**	**$1,886.47**	**3.52**	**0.08%**
RITLECITINIB PRODUCTS						
LITFULO CAP 50MG	85	13	$348,256.90	$4,097.14	6.54	0.17%
SUBTOTAL	**85**	**13**	**$348,256.90**	**$4,097.14**	**6.54**	**0.17%**
AVACOPAN PRODUCTS						
TAVNEOS CAP 10MG	40	7	$682,244.55	$17,056.11	5.71	0.34%
SUBTOTAL	**40**	**7**	**$682,244.55**	**$17,056.11**	**5.71**	**0.34%**
BRODALUMAB PRODUCTS						
SILIQ INJ 210MG/1.5ML	40	6	$226,848.35	$5,671.21	6.67	0.11%
SUBTOTAL	**40**	**6**	**$226,848.35**	**$5,671.21**	**6.67**	**0.11%**
BARICITINIB PRODUCTS						
OLUMIANT TAB 2MG	23	4	$75,107.20	$3,265.53	5.75	0.04%
OLUMIANT TAB 1MG	6	1	$28,127.14	$4,687.86	6	0.01%
SUBTOTAL	**29**	**5**	**$103,234.34**	**$3,559.80**	**5.8**	**0.05%**
VOCLOSPORIN PRODUCTS						
LUPKYNIS CAP 7.9MG	22	3	$337,184.96	$15,326.59	7.33	0.17%
SUBTOTAL	**22**	**3**	**$337,184.96**	**$15,326.59**	**7.33**	**0.17%**
INFLIXIMAB PRODUCTS						
ZYMFENTRA INJ 120MG/ML AUTO	13	1	$46,985.11	$3,614.24	13	0.02%
ZYMFENTRA INJ 120MG/ML SYR	3	1	$17,831.49	$5,943.83	3	0.01%
SUBTOTAL	**16**	**2**	**$64,816.60**	**$4,051.04**	**8**	**0.03%**
SPESOLIMAB PRODUCTS						
SPEVIGO INJ 150MG/ML	7	1	$129,078.30	$18,439.76	7	0.06%
SUBTOTAL	**7**	**1**	**$129,078.30**	**$18,439.76**	**7**	**0.06%**
VEDOLIZUMAB PRODUCTS						
ENTYVIO PEN INJ 108MG/0.68ML	5	2	$31,739.95	$6,347.99	2.5	0.02%
SUBTOTAL	**5**	**2**	**$31,739.95**	**$6,347.99**	**2.5**	**0.02%**
ANIFROLUMAB PRODUCTS						
SAPHNELO SOL 300MG/2ML	3	1	$16,036.11	$5,345.37	3	0.01%
SUBTOTAL	**3**	**1**	**$16,036.11**	**$5,345.37**	**3**	**0.01%**
RILONACEPT PRODUCTS						
ARCALYST INJ 220MG	2	2	$46,471.67	$23,235.84	1	0.02%
SUBTOTAL	**2**	**2**	**$46,471.67**	**$23,235.84**	**1**	**0.02%**
TILDRAKIZUMAB PRODUCTS						
ILUMYA INJ 100MG/ML	2	1	$26,970.22	$13,485.11	2	0.01%
SUBTOTAL	**2**	**1**	**$26,970.22**	**$13,485.11**	**2**	**0.01%**
SPECIAL PA SUBTOTAL	**6,294**	**1,157***	**$64,273,694.72**	**$10,211.90**	**5.44**	**32.02%**
TOTAL	**23,925**	**3,889***	**$200,726,976.32**	**$8,389.84**	**6.15**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; CAP = capsule; CD = Crohn's disease; ER = extended-release; HS = hidradenitis suppurativa; INJ = injection; PED = pediatric; PREFL = prefilled; PS = psoriasis; SOL = solution; SRCLK = SureClick; SYR = syringe; TAB = tablet; UC = ulcerative colitis; UV = uveitis
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
BENLYSTA IV INJ (J0490)	889	135	$3,022,563.85	$3,399.96	6.59
SIMPONI ARIA INJ (J1602)	595	129	$813,919.04	$1,367.93	4.61
SAPHNELO INJ (J0491)	462	96	$2,392,186.86	$5,177.89	4.81
INFLECTRA INJ (Q5103)	355	91	$180,571.08	$508.65	3.9
REMICADE INJ (J1745)	320	62	$423,763.50	$1,324.26	5.16
RITUXAN INJ (J9312)	268	103	$1,540,316.28	$5,747.45	2.6
ENTYVIO INJ (J3380)	256	63	$1,597,875.82	$6,241.70	4.06
RENFLEXIS INJ (Q5104)	238	43	$331,904.47	$1,394.56	5.53
ACTEMRA INJ (J3262)	229	33	$512,789.64	$2,239.26	6.94
ORENCIA INJ (J0129)	211	44	$754,715.49	$3,576.85	4.8
TRUXIMA INJ (Q5115)	129	41	$213,031.62	$1,651.41	3.15
CIMZIA INJ (J0717)	90	15	$128,482.22	$1,427.58	6
AVSOLA INJ (Q5121)	69	12	$49,250.97	$713.78	5.75
RUXIENCE INJ (Q5119)	64	22	$95,052.46	$1,485.19	2.91
RIABNI INJ (Q5123)	63	15	$112,520.50	$1,786.04	4.2
SKYRIZI IV INJ (J2327)	61	27	$625,332.12	$10,251.35	2.26
ILARIS INJ (J0638)	7	3	$225,018.00	$32,145.43	2.33
TREMFYA INJ (J1628)	6	2	$77,898.00	$12,983.00	3
STELARA IV INJ (J3358)	6	6	$23,069.28	$3,844.88	1
ILUMYA INJ (J3245)	2	1	$26,464.00	$13,232.00	2
OMVOH INJ (J2267)	1	1	$10,422.00	$10,422.00	1
STELARA SQ INJ (J3357)	1	1	$0.01	$0.01	1
TOTAL	**4,322⁺**	**893***	**$13,157,147.21**	**$3,044.23**	**4.84**

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

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Appendix R

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

Oklahoma Health Care Authority
October 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.

Utilization of HAE 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	21	$643,617.53	$30,648.45	$1,079.90	410	596
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**	**21**	**$643,617.53**	**$30,648.45**	**$1,079.90**	**410**	**596**
Fiscal Year 2025							
FFS	3	24	$656,526.76	$27,355.28	$974.08	226	674
Aetna	4	6	$190,527.77	$31,754.63	$1,351.26	139	141
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	1	2	$88,978.29	$44,489.15	$1,588.90	56	56
2025 Total	**8**	**32**	**$936,032.82**	**$29,251.03**	**$1,074.66**	**421**	**871**
% Change	**166.70%**	**52.40%**	**45.40%**	**-4.60%**	**-0.50%**	**2.70%**	**46.10%**
Change	**5**	**11**	**$292,415.29**	**-$1,397.42**	**-$5.24**	**11**	**275**

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	1	1	$15,921.60	$15,921.60	1
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**1**	**1**	**$15,921.60**	**$15,921.60**	**1**
Fiscal Year 2025					
FFS	0	0	$0.00	$0.00	0
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2025 Total	**0**	**0**	**$0.00**	**$0.00**	**0**
% Change	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**
Change	**-1**	**-1**	**-$15,921.60**	**-$15,921.60**	**-1**

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 HAE Medications: Pharmacy Claims (All Plans)

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

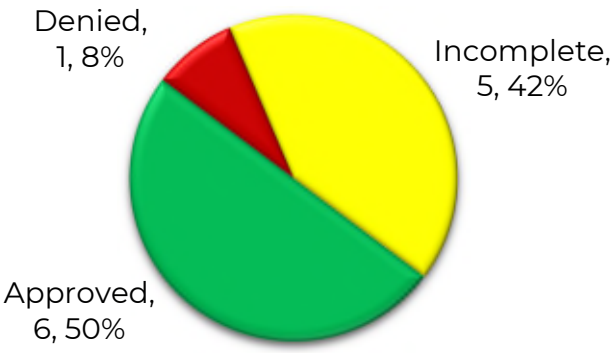
Top Prescriber Specialties of HAE Medications by Number of Claims: Pharmacy Claims (All Plans)

- There were 32 pharmacy claims for HAE medications during fiscal year 2025, all of which were prescribed by allergists.

Prior Authorization of HAE Medications

There were 12 prior authorization requests submitted for HAE 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	3	43%	4	57%	0	0%	**7**
Aetna	2	100%	0	0%	0	0%	**2**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	1	34%	1	33%	1	33%	**3**
Total	**6**	**50%**	**5**	**42%**	**1**	**8%**	**12**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health

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

Anticipated Patent Expiration(s):

- Dawnzera® (donidalorsen): May 2035
- Ekterly® (sebetralstat): January 2039
- Orladeyo® (berotralstat): November 2039

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.

Pipeline:

- **Orladeyo® (Berotralstat) Oral Granules:** Biocryst Pharmaceuticals announced the FDA accepted a New Drug Application (NDA) for Orladeyo® (berotralstat) oral granules for patients with HAE 2 to 11 years of age. If approved, this formulation would be the first oral prophylactic therapy for pediatric patients younger than 12 years of age with HAE. The Prescription Drug User Fee Act (PDUFA) date has been extended from September 2025 to December 12, 2025.

Andembry® (Garadacimab-gxii) Product Summary[7,8]

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[9]

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	$678.132.00
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[10,11]

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:

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	$15,429.12
Berinert® (C1 esterase inhibitor) 500 IU vial	$11,379.45
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.

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 and recommends the prior authorization of Ekterly® (sebetralstat) with placement into the Special PA Tier of the HAE Treatment Products PBPA category (changes shown in red):

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

PA = prior authorization

Initial Approval Criteria for All HAE Treatment Products:

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

HAE Treatment Products Tier-2 Approval Criteria:

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

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

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

Utilization Details of HAE Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TAKHZYRO INJ 150MG/ML	14	1	$360,076.62	$25,719.76	14	38.47%
ORLADEYO CAP 150MG	11	3	$472,880.64	$42,989.15	3.67	50.52%
ICATIBANT INJ 30MG/3ML	4	4	$38,691.27	$9,672.82	1	4.13%
BERINERT INJ 500 UNIT	2	1	$21,145.52	$10,572.76	2	2.26%
ORLADEYO CAP 110MG	1	1	$43,238.77	$43,238.77	1	4.62%
TOTAL	**32**	**8***	**$936,032.82**	**$29,251.03**	**4**	**100%**

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

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Appendix S

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

Oklahoma Health Care Authority
October 2025

Current Prior Authorization Criteria

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 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. 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.

Rivaroxaban (generic Xarelto®) Approval Criteria:

1. Authorization of generic rivaroxaban (in place of brand Xarelto®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred).

Savaysa® (Edoxaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF); or
   b. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant; and
2. Requests for therapy for the treatment of DVT and PE must verify that the member has undergone 5 to 10 days of initial therapy with a parenteral anticoagulant; and
3. Members with NVAF must not have a creatinine clearance (CrCl) >95mL/min due to increased risk of ischemic stroke compared to warfarin at the highest dose studied (60mg); and

4. A patient-specific, clinically significant reason why the member cannot use Eliquis® (apixaban), Pradaxa® (dabigatran), and Xarelto® (rivaroxaban) must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Xarelto® (Rivaroxaban) Oral Suspension Approval Criteria:

1. Xarelto® 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 rivaroxaban tablets must be provided; and
2. Clinical exceptions for the age restriction may be considered for members with documented dysphagia.

Utilization of Anticoagulants and Platelet Aggregation Inhibitors: Fiscal Year 2025

Comparison of Fiscal Years: Anticoagulants (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	7,624	35,383	$16,130,418.75	$455.88	$14.68	1,884,080	1,098,753
Aetna	769	1,519	$755,369.87	$497.28	$16.87	79,659	44,787
Humana	930	1,919	$980,761.99	$511.08	$17.26	100,230	56,818
OCH	753	1,444	$700,528.64	$485.13	$16.37	75,387	42,789
2024 Total	**8,095**	**40,265**	**$18,567,079.25**	**$461.12**	**$14.94**	**2,139,356**	**1,243,147**
Fiscal Year 2025							
FFS	5,232	22,337	$10,840,434.75	$485.31	$16.13	1,192,219	671,960
Aetna	1,446	6,323	$3,274,104.07	$517.81	$16.36	351,565	200,120
Humana	1,713	8,165	$4,240,912.29	$519.40	$16.95	444,199	250,174
OCH	1,486	6,987	$3,453,642.56	$494.30	$16.70	367,948	206,762
2025 Total	**8,539**	**43,812**	**$21,809,093.67**	**$497.79**	**$16.41**	**2,355,931**	**1,329,016**
% Change	**5.50%**	**8.80%**	**17.50%**	**8.00%**	**9.80%**	**10.10%**	**6.90%**
Change	**444**	**3,547**	**$3,242,014.42**	**$36.67**	**$1.47**	**216,575**	**85,869**

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 2024 for the anticoagulants totaled $19,283,039.99.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2024 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates

[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.

for fiscal year 2025 (7/1/2024 to 6/30/2025) are still being collected at this time. The costs included in this report do not reflect net costs.

Comparison of Fiscal Years: Platelet Aggregation Inhibitors (All Plans)

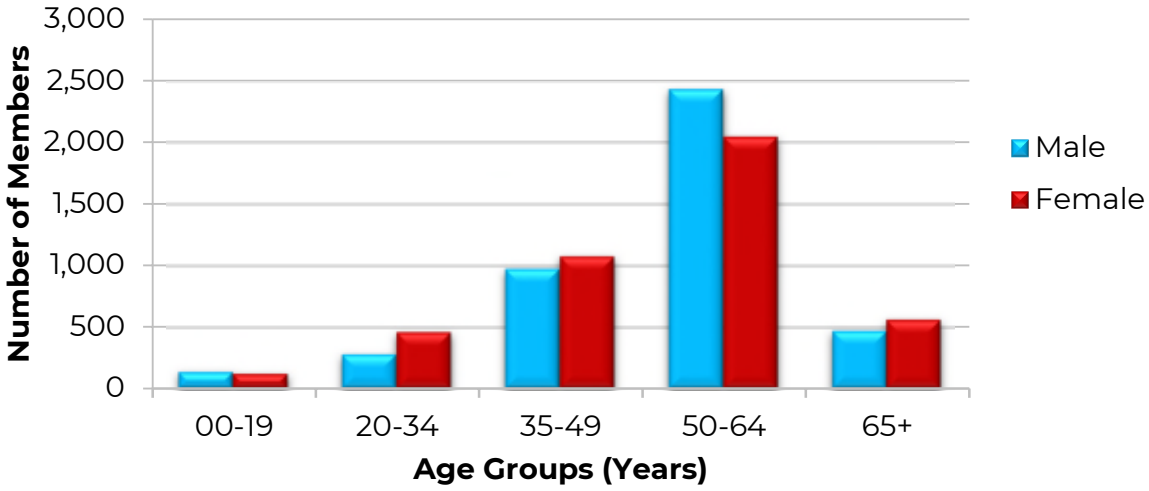
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	5,989	18,928	$1,558,887.20	$82.36	$1.55	1,096,213	1,004,107
Aetna	518	732	$75,011.93	$102.48	$1.83	45,208	40,911
Humana	714	1,074	$114,267.72	$106.39	$2.01	63,521	56,789
OCH	533	731	$79,962.71	$109.39	$1.99	45,034	40,204
2024 Total	**6,334**	**21,465**	**$1,828,129.56**	**$85.17**	**$1.60**	**1,249,976**	**1,142,011**
Fiscal Year 2025							
FFS	3,434	10,743	$695,885.19	$64.78	$1.27	588,510	548,716
Aetna	966	3,041	$313,585.15	$103.12	$1.91	183,231	164,600
Humana	1,323	4,371	$422,930.18	$96.76	$1.84	254,669	229,253
OCH	1,003	2,830	$266,875.06	$94.30	$1.59	183,748	168,277
2025 Total	**5,975**	**20,985**	**$1,699,275.58**	**$80.98**	**$1.53**	**1,210,158**	**1,110,846**
% Change	**-5.70%**	**-2.20%**	**-7.00%**	**-4.90%**	**-4.40%**	**-3.20%**	**-2.70%**
Change	**-359**	**-480**	**-$128,853.98**	**-$4.19**	**-$0.07**	**-39,818**	**-31,165**

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.

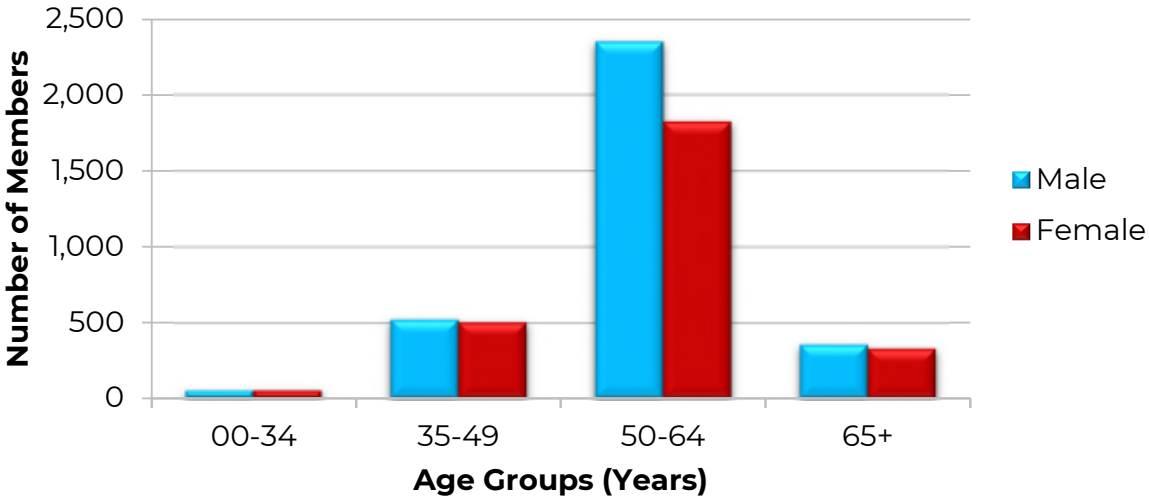
- Aggregate drug rebates collected during fiscal year 2024 for platelet aggregation inhibitors totaled $1,339,988.80.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2024 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2025 (7/1/2024 to 6/30/2025) are still being collected at this time. 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.

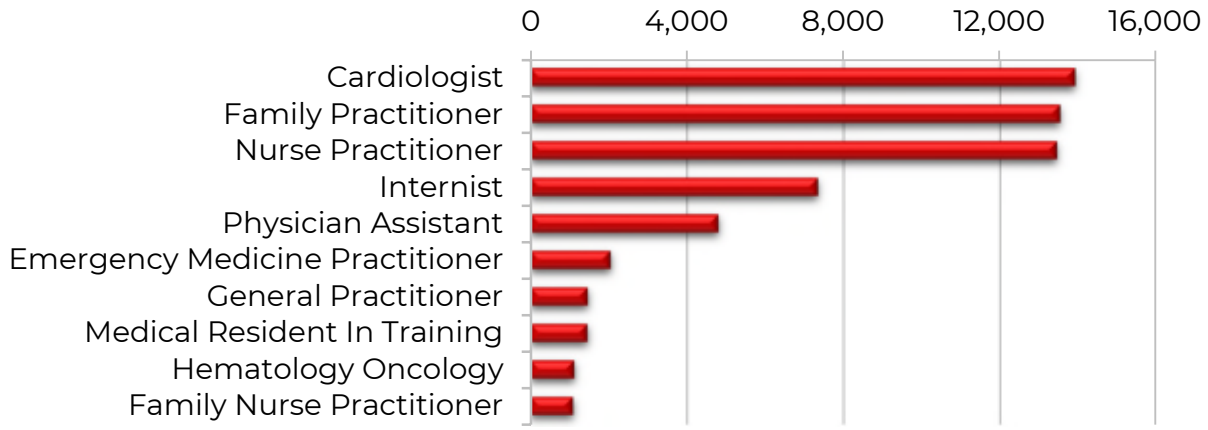
Demographics of Members Utilizing Anticoagulants: Pharmacy Claims (All Plans)



Demographics of Members Utilizing Platelet Aggregation Inhibitors: Pharmacy Claims (All Plans)



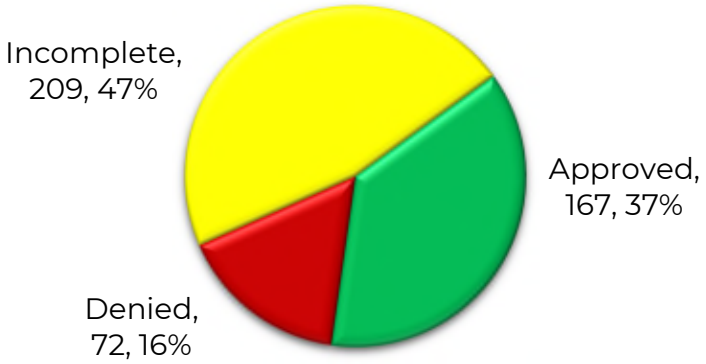
Top Prescriber Specialties of Anticoagulants and Platelet Aggregation Inhibitors by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors

There were 448 prior authorization requests submitted for the anticoagulants and platelet aggregation inhibitors during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	124	37%	187	56%	22	7%	**333**
Aetna	9	23%	12	30%	19	48%	**40**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	34	45%	10	13%	31	41%	**75**
Total	**167**	**37%**	**209**	**47%**	**72**	**16%**	**448**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health

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

Anticipated Patent Expiration(s):

- Pradaxa® (dabigatran pellets): March 2026
- Savaysa® (edoxaban tablets): March 2028
- Pradaxa® (dabigatran capsules): July 2031
- Eliquis® (apixaban tablets and tablets for oral suspension): August 2031
- Brilinta® (ticagrelor tablets): July 2036
- Xarelto® (rivaroxaban tablets): July 2039
- Eliquis® Sprinkle (apixaban capsule for oral suspension): May 2041

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.

Guideline Update(s):

- **American Society of Hematology (ASH)/International Society on Thrombosis and Haemostasis (ISTH) Guideline Update(s):** The ASH/ISTH released a 2024 updated guideline for the treatment of VTE in pediatric patients. This is an update to the 2018 ASH guideline to provide recommendations and guidance on the optimal use of anticoagulants in the pediatric population, predominantly on whether to treat or not to treat and which type of treatment is optimal dependent on the clinical situation. The recommendations also include that the decision to treat or not requires individual consideration of the risk-to-benefit ratio. In addition, specific information is given about the use of various anticoagulants in pediatric patients for the treatment of VTE.

Pipeline:

- **Milvexian:** Milvexian is an investigational, oral factor XIa (FXIa) inhibitor being studied for the prevention and treatment of major thrombotic conditions in the Librexia program. The Librexia program includes 3 clinical trials that are studying milvexian in approximately 50,000 patients for ischemic stroke, acute coronary syndrome (ACS), and atrial fibrillation. All 3 indications are currently in Phase 3 and have been granted Fast Track designation by the FDA.
- **REGN7508 and REGN9933:** REGN7508 and REGN9933 are investigational monoclonal antibodies that target distinct domains of Factor XI. REGN7508 targets the catalytic domain and is designed to maximize anticoagulant activity while minimizing bleeding risks, and REGN9933 targets the A2 domain to provide an additional option for patients with the highest bleeding risk who would not be candidates for current available anticoagulants. Two open-label, active-controlled Phase 2 trials (ROXI-VTE-I and ROXI-VTE-II) were conducted to evaluate REGN7508 and REGN9933 for the prevention of asymptomatic or symptomatic VTE after unilateral total knee arthroplasty. On the measure of VTE rates at venogram following surgery, a pooled analysis across both trials showed REGN7508 was superior to enoxaparin and non-inferior to apixaban, and REGN9933 was non-inferior to enoxaparin. All VTE events were asymptomatic, except for one symptomatic case of pulmonary embolism in the apixaban arm. Phase 3 trials are expected to begin in 2025.

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.

Utilization Details of Anticoagulants: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APIXABAN PRODUCTS						
ELIQUIS TAB 5MG	26,282	5,437	$14,797,270.00	$563.02	4.83	67.85%
ELIQUIS TAB 2.5MG	3,093	796	$1,623,092.32	$524.76	3.89	7.44%
ELIQUIS ST P TAB 5MG	300	286	$213,095.00	$710.32	1.05	0.98%
SUBTOTAL	**29,675**	**6,519**	**$16,633,457.32**	**$560.52**	**4.55**	**76.27%**
RIVAROXABAN PRODUCTS						
XARELTO TAB 20MG	5,582	1,026	$3,086,190.82	$552.88	5.44	14.15%
XARELTO TAB 2.5MG	1,269	231	$693,783.29	$546.72	5.49	3.18%
XARELTO TAB 10MG	1,069	277	$570,099.18	$533.30	3.86	2.61%
XARELTO TAB 15MG	607	200	$349,182.91	$575.26	3.04	1.60%
XARELTO SUS 1MG/ML	410	79	$345,293.45	$842.18	5.19	1.58%
XARELTO ST P TAB 15/20MG	33	33	$31,348.35	$949.95	1	0.14%
RIVAROXABAN TAB 2.5MG	4	3	$1,439.70	$359.93	1.33	0.01%
SUBTOTAL	**8,974**	**1,849**	**$5,077,337.70**	**$565.78**	**4.85**	**23.28%**
WARFARIN PRODUCTS						
WARFARIN TAB 5MG	1,622	398	$20,167.02	$12.43	4.08	0.09%
WARFARIN TAB 1MG	636	161	$8,687.22	$13.66	3.95	0.04%
WARFARIN TAB 4MG	579	142	$6,636.98	$11.46	4.08	0.03%
WARFARIN TAB 3MG	449	115	$5,530.53	$12.32	3.9	0.03%
WARFARIN TAB 10MG	380	101	$4,294.69	$11.30	3.76	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
WARFARIN TAB 7.5MG	351	111	$4,086.42	$11.64	3.16	0.02%
WARFARIN TAB 2MG	345	100	$4,139.67	$12.00	3.45	0.02%
WARFARIN TAB 2.5MG	315	104	$4,154.93	$13.19	3.03	0.02%
WARFARIN TAB 6MG	293	70	$3,457.85	$11.80	4.19	0.02%
JANTOVEN TAB 5MG	38	14	$541.48	$14.25	2.71	0.00%
JANTOVEN TAB 2MG	16	4	$192.26	$12.02	4	0.00%
JANTOVEN TAB 6MG	9	5	$159.33	$17.70	1.8	0.00%
JANTOVEN TAB 2.5MG	3	1	$54.00	$18.00	3	0.00%
JANTOVEN TAB 3MG	3	2	$43.77	$14.59	1.5	0.00%
JANTOVEN TAB 4MG	1	1	$16.54	$16.54	1	0.00%
JANTOVEN TAB 7.5MG	1	1	$10.52	$10.52	1	0.00%
JANTOVEN TAB 1MG	1	1	$10.10	$10.10	1	0.00%
SUBTOTAL	**5,042**	**1331**	**$62,183.31**	**$12.33**	**3.79**	**0.29%**
DABIGATRAN PRODUCTS						
PRADAXA CAP 150MG	102	16	$20,401.81	$200.02	6.38	0.09%
DABIGATRAN CAP 75MG	2	1	$250.56	$125.28	2	0.00%
PRADAXA CAP 75MG	1	1	$201.62	$201.62	1	0.00%
DABIGATRAN CAP 150MG	1	1	$120.85	$120.85	1	0.00%
PRADAXA PAK 40MG	1	1	$4,823.22	$4,823.22	1	0.02%
PRADAXA PAK 50MG	1	1	$4,823.22	$4,823.22	1	0.02%
SUBTOTAL	**108**	**21**	**$30,621.28**	**$283.53**	**5.14**	**0.14%**
EDOXABAN PRODUCTS						
SAVAYSA TAB 60MG	12	1	$5,066.57	$422.21	12	0.02%
SAVAYSA TAB 30MG	1	1	$427.49	$427.49	1	0.00%
SUBTOTAL	**13**	**2**	**$5,494.06**	**$422.62**	**6.5**	**0.03%**
TOTAL	**43,812**	**8,539***	**$21,809,093.67**	**$497.79**	**5.13**	**100%**

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

Utilization Details of Platelet Aggregation Inhibitors: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLOPIDOGREL PRODUCTS						
CLOPIDOGREL TAB 75MG	15,934	5,159	$225,641.72	$14.16	3.09	13.28%
CLOPIDOGREL TAB 300MG	1	1	$29.46	$29.46	1	0.00%
SUBTOTAL	**15,935**	**5,160**	**$225,671.18**	**$14.16**	**3.09**	**13.28%**
TICAGRELOR PRODUCTS						
BRILINTA TAB 90MG	2,897	628	$1,265,521.24	$436.84	4.61	74.47%
BRILINTA TAB 60MG	369	69	$156,279.04	$423.52	5.35	9.20%
TICAGRELOR TAB 90MG	191	144	$12,063.85	$63.16	1.33	0.71%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TICAGRELOR TAB 60MG	23	19	$9,185.46	$399.37	1.21	0.54%
SUBTOTAL	**3,480**	**860**	**$1,443,049.59**	**$414.67**	**4.05**	**84.92%**
PRASUGREL PRODUCTS						
PRASUGREL TAB 10MG	1,466	276	$28,048.21	$19.13	5.31	1.65%
PRASUGREL TAB 5MG	93	15	$1,990.24	$21.40	6.2	0.12%
SUBTOTAL	**1,559**	**291**	**$30,038.45**	**$19.27**	**5.36**	**1.77%**
ASPIRIN/DIPYRIDAMOLE PRODUCTS						
ASA/DIPYRIDA CAP 25-200MG	11	1	$516.36	$46.94	11	0.03%
SUBTOTAL	**11**	**1**	**$516.36**	**$46.94**	**11**	**0.03%**
TOTAL	**20,985**	**5,975***	**$1,699,275.58**	**$80.98**	**3.51**	**100%**

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

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Appendix T

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: September 22, 2025

FDA Responds to Evidence of Possible Association Between Autism and Acetaminophen Use During Pregnancy

The FDA initiated the process for a label change for acetaminophen (Tylenol® and similar products) to reflect evidence suggesting that the use of acetaminophen by pregnant women may be associated with an increased risk of neurological conditions such as autism and attention-deficit/hyperactivity disorder (ADHD) in children. The agency also issued a related letter alerting physicians nationwide.

Evidence in recent years has suggested a correlation between acetaminophen use during pregnancy and subsequent diagnosis of conditions like autism and ADHD. Multiple large-scale cohort studies, including the Nurses' Health Study II and the Boston Birth Cohort, find this association. Some studies have described that the risk may be most pronounced when acetaminophen is taken chronically throughout pregnancy.

It is important to note that while an association between acetaminophen and neurological conditions has been described in many studies, a causal relationship has not been established and there are contrary studies in the scientific literature. It is also noted that acetaminophen is the only over-the-counter drug approved for use to treat fevers during pregnancy, and high fevers in pregnant women can pose a risk to their children. Additionally, aspirin and ibuprofen have well-documented adverse impacts on the fetus.

FDA NEWS RELEASE

For Immediate Release: September 22, 2025

FDA Takes Action to Make a Treatment Available for Autism Symptoms

The FDA initiated the approval of leucovorin calcium tablets for patients with cerebral folate deficiency (CFD), a neurological condition that affects folate into the brain. Individuals with CFD have been observed to have developmental delays with autistic features (e.g., challenges with social communication, sensory processing, and repetitive behaviors), seizures, and problems with movement and coordination.

The FDA has conducted a systematic analysis of literature published between 2009-2024, including published case reports with patient-level information, as well as mechanistic data, and has determined that the

information supports a finding that leucovorin calcium can help individuals suffering from CFD.

The FDA is working with GSK, the innovator of Wellcovorin® (leucovorin calcium), on a process to include the essential scientific information needed for the safe and effective use of these drug products for adults and pediatric patients with CFD. As the New Drug Application (NDA) holder for this medicine, GSK has preliminarily agreed to work with the FDA on this relabeling effort.

CFD has also been reported in a broader patient population with neuropsychiatric symptoms, including autistic features, and detectable serum autoantibodies to the folate receptor alpha; however, there are limitations on the available data for the use of leucovorin in this population and additional studies are needed to assess safety and efficacy.

FDA NEWS RELEASE

For Immediate Release: September 23, 2025

FDA Grants Accelerated Approval to First Treatment for Barth Syndrome

The FDA granted accelerated approval to Forzinity™ (elamipretide) injection as the first treatment for Barth syndrome, in patients weighing at least 30 kg. Barth syndrome is a rare, serious and life-threatening disease of the mitochondria.

Barth syndrome primarily affects males, typically starts with severe heart failure in infancy, and causes premature death. Patients who survive into adolescence and adulthood often have fatigue, poor stamina, and exercise intolerance. The quality of life and daily functioning of patients with Barth syndrome are significantly affected throughout their lives.

Forzinity™ works by binding to the inner part of the mitochondria, improving mitochondrial structure and function. The FDA granted Forzinity™ accelerated approval. This pathway can allow earlier approval of medications that treat serious conditions and fill an unmet medical need on the basis of a measure that is considered reasonably likely to predict patient benefit but does not directly assess the benefit to the patient. Forzinity™'s accelerated approval is based on improved strength of the muscle used to straighten the leg at the knee. The FDA considers this improvement reasonably likely to predict patient benefit, such as an ability to stand more easily or walk farther. As a condition of accelerated approval, the FDA is requiring the manufacturer of Forzinity™ to conduct a post-approval randomized, double-blind, placebo-controlled trial to confirm that the changes seen on knee muscle strength translate into patient benefit.

Forzinity™ is administered subcutaneously once daily. The most common side effects identified in clinical trials were mild-to-moderate injection site reactions. Serious reactions to Forzinity™ have also been reported. The application was granted priority review, and Forzinity™ was granted a rare pediatric disease designation. The FDA granted the

accelerated approval of Forzinity™, as well as a rare pediatric disease priority review voucher, to Stealth Biotherapeutics Inc.

FDA NEWS RELEASE

For Immediate Release: September 10, 2025

FDA Issues New Guidance to Expand Non-Opioid Options for Chronic Pain, Curb Misuse

Despite recent declines, opioids remain commonly prescribed to about 1 in 5 U.S. adults who live with chronic pain, as effective alternatives are limited. As part of its broader strategy to address the opioid crisis, the U.S. FDA issued draft guidance titled "Development of Non-Opioid Analgesics for Chronic Pain" to accelerate safe and effective non-opioid treatments and to reduce prescription-related opioid misuse.

The new draft guidance emphasizes efficient drug development approaches, with specific attention to trial design, appropriate patient populations, and meaningful outcomes- such as reducing the need for opioid use. The draft guidance outlines regulatory considerations related to:

- Establishing indications for different scopes (e.g., broader categories covering multiple chronic pain conditions versus individual chronic pain indications); and
- Designing clinical trials that ensure robust evaluation of safety and efficacy, including innovative trial designs and the role of mechanistic understanding of both the drug and the chronic pain conditions being treated; and
- Evaluating the ability of non-opioid drugs to avoid, reduce, or eliminate opioid use; and
- Incorporating statistical principles, patient-reported outcomes, and the use of expedited programs to support drug development in this area.

The guidance fulfills a mandate under Section 3001(b) of the SUPPORT Act, which requires the FDA to issue guidance to help address challenges related to developing non-opioid treatments for pain management. The FDA's broader strategy to address the opioid crisis includes requiring safety labeling changes for opioid pain drugs (e.g., OxyContin®) to better reflect current evidence; enhancing enforcement around the importation and sale of illegal opioid products; and facilitating the development of non-opioid alternatives.

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

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

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous 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***
Indocyanine Green Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lactated Ringers Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***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***
Somatropin 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***