OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
April 8, 2026
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – April 8, 2026

DATE: April 1, 2026

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

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

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Enclosed are the following items related to the April 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

SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – Appendix C

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Action Item – Vote to Prior Authorize Nypozi™ (Filgrastim-txid) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers – Appendix D

Action Item – Vote to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt) – Appendix E

Action Item – Vote to Prior Authorize Daybue® Stix (Trofinetide Packet), Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide) and Update the Approval Criteria for the Growth-Related Disorder Medications – Appendix F

Action Item – Vote to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel) – Appendix G

Action Item – Vote to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) and Update the Approval Criteria for the Dry Eye Disease (DED) Medications – Appendix H

Action Item – Vote to Prior Authorize Zolymbus™ (Bimatoprost 0.1% Gel) and Update the Approval Criteria for the Glaucoma Medications – Appendix I

Action Item – Vote to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) and Update the Approval Criteria for the Topical Antibiotic Products – Appendix J

Action Item – Vote to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib) and Update the Approval Criteria for the Leukemia and Lymphoma Medications – Appendix K

Action Item – Annual Review of Multiple Sclerosis (MS) Medications – Appendix L

Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj)– Appendix M

Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution) – Appendix N

Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Voyxact® (Sibeprenlimab-szsi) – Appendix O

Annual Review of Spinal Muscular Atrophy (SMA) Medications and 30-Day Notice to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve) – Appendix P

Annual Review of Interstitial Lung Disease Medications and 30-Day Notice to Prior Authorize Jascayd® (Nerandomilast) – Appendix Q

30-Day Notice to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue-agdc) – Appendix R

Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Eydenzelt® (Aflibercept-boav) – Appendix S

Annual Review of Sofdra™ (Sofpironium 12.45% Topical Gel) – Appendix T

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

Future Business

Adjournment

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Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – April 8, 2026 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**
   A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Cassidy Blaiss –	participating in person
Ms. Jennifer Boyett –	participating in person
Dr. Christen Ground –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Bethany Holderread –	participating in person
Dr. Matt John –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. Edna Patatanian –	participating in person
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.
- In lieu of speaking at the DUR Board meeting, written correspondence by members or providers may be submitted to DURPublicComment@okhca.org. Other written correspondence is not permitted.

Items to be presented by Dr. Haymore, Chairman:

2. Public Comment Forum

A. Acknowledgement of Speakers for Public Comment

Items to be presented by Dr. Haymore, Chairman:

3. Action Item – Approval of DUR Board Meeting Minutes – See Appendix A

A. March 11, 2026 DUR Board Meeting Minutes
B. March 11, 2026 DUR Board Recommendations Memorandum
C. Correspondence

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

4. Update on the Medication Coverage Authorization Unit – See Appendix B

A. Pharmacy Help Desk Activity for March 2026
B. Medication Coverage Activity for March 2026

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

5. SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – See Appendix C

A. SoonerPsych Prescriber Mailing Summary
B. SoonerPsych Example Gauge
C. SoonerPsych Trends
D. Pediatric SoonerPsych Prescriber Mailing Summary
E. Pediatric SoonerPsych Trends

F. Conclusions
G. Summary

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

6. Action Item – Vote to Prior Authorize Nypozi™ (Filgrastim-txid) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers – See Appendix D

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

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

7. Action Item – Vote to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt) – See Appendix E

A. Market News and Updates
B. Fesilty™ (Fibrinogen, Human-chmt) Product Summary
C. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Daybue® Stix (Trofinetide Packet), Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide) and Update the Approval Criteria for the Growth-Related Disorder Medications – See Appendix F

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

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

9. Action Item – Vote to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel) – See Appendix G

A. Market News and Updates
B. Waskyra™ (Etuvetidigene Autotemcel) Product Summary
C. College of Pharmacy Recommendations

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

10. Action Item – Vote to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) and Update the Approval Criteria for the Dry Eye Disease (DED) Medications – See Appendix H

A. Market News and Updates
B. Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Product Summary
C. College of Pharmacy Recommendations

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

11. Action Item – Vote to Prior Authorize Zolymbus™ (Bimatoprost 0.1% Gel) and Update the Approval Criteria for the Glaucoma Medications – See Appendix I

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

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

12. Action Item – Vote to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) and Update the Approval Criteria for the Topical Antibiotic Products – See Appendix J

A. College of Pharmacy Recommendations

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

13. Action Item – Vote to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib) and Update the Approval Criteria for the Leukemia and Lymphoma Medications – See Appendix K

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

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

14. Action Item – Annual Review of Multiple Sclerosis (MS) Medications – See Appendix L

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

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

15. Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj)– See Appendix M

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

H. Utilization Details of Lung Cancer Medications

<u>Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:</u>

16. Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution) – See Appendix N

A. Current Prior Authorization Criteria
B. Utilization of ADHD and Narcolepsy Medications
C. Prior Authorization of ADHD and Narcolepsy Medications
D. Oklahoma Resources
E. Market News and Updates
F. Product Summaries
G. College of Pharmacy Recommendations
H. Utilization Details of ADHD and Narcolepsy Medications

<u>Items to be presented by Dr. Moss, Dr. Haymore, Chairman:</u>

17. Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Voyxact® (Sibeprenlimab-szsi) – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of IgAN Medications
C. Prior Authorization of IgAN Medications
D. Market News and Updates
E. Voyxact® (Sibeprenlimab-szsi) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of IgAN Medications

<u>Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:</u>

18. Annual Review of Spinal Muscular Atrophy (SMA) Medications and 30-Day Notice to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve) – See Appendix P

A. Current Prior Authorization Criteria
B. Utilization of SMA Medications
C. Prior Authorization of SMA Medications
D. Market News and Updates
E. Itvisma® (Onasemnogene Abeparvovec-brve) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of SMA Medications

<u>Items to be presented by Dr. Grimes, Dr. Haymore, Chairman:</u>

19. Annual Review of Interstitial Lung Disease (ILD) Medications and 30-Day Notice to Prior Authorize Jascayd® (Nerandomilast) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of ILD Medications

C. Prior Authorization of ILD Medications
D. Market News and Updates
E. Jascayd® (Nerandomilast) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of ILD Medications

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

20. 30-Day Notice to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue-agdc) – See Appendix R

A. Introduction
B. Rethymic® (Allogeneic Processed Thymus Tissue-agdc) Product Summary
C. College of Pharmacy Recommendations

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

21. Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Eydenzelt® (Aflibercept-boav) – See Appendix S

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

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

22. Annual Review of Sofdra™ (Sofpironium 12.45% Topical Gel) – See Appendix T

A. Current Prior Authorization Criteria
B. Utilization of Sofdra™ (Sofpironium 12.45% Topical Gel)
C. Prior Authorization of Sofdra™ (Sofpironium 12.45% Topical Gel)
D. Market News and Updates
E. College of Pharmacy Recommendations

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

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

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

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

There is no DUR Board meeting scheduled for May 2026.

A. Anti-Emetic Medications
B. Antiviral Medications
C. Atypical Antipsychotic Medications
D. Genitourinary and Gynecologic Cancer Medications
E. Urea Cycle Disorder (UCD) Medications

F. Various Special Formulations
*Future product and class reviews subject to change.

25. Adjournment

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

NOTE: Oklahoma Medicaid transitioned from a fee-for-service (FFS) pharmacy benefit to a managed care pharmacy benefit for most members on April 1, 2024. At that time, the majority of SoonerCare members were transitioned to one of the three managed care SoonerSelect plans: Aetna, Humana, or Oklahoma Complete Health. SoonerSelect data has been provided to the College of Pharmacy and has been used in analyses throughout this DUR Board meeting packet. The data included in this DUR Board meeting packet combines FFS and managed care utilization data. The managed care utilization and prior authorization (PA) data reported in this packet is based solely on the data provided by the SoonerSelect plans.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING MARCH 11, 2026

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

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

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

Melissa Miller, State Medicaid Director		X
Christine Picart; Director QA/QI	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	
***Legal representative:**		
Gwendolyn Bell, J.D.; Deputy General Counsel	X	
Travis Dennis, J.D.; Deputy General Counsel		X
Gentry Kincade, J.D.; Deputy General Counsel		X
Conner Mulvaney, J.D.; Deputy General Counsel		X

OTHERS PRESENT:	
Kim Greenburg, Acadia	Peter Barrio, United Therapeutics
Chrissie Cleghorn, Liquidia	Nina Golde, Soleno Therapeutics
Ben Skoog, Acadia	Paul Miner, Ascendis
Ginger Papesh, Novo Nordisk	Sejal Upadhyaya, Novo Nordisk
Todd Paulsen, Novo Nordisk	Todd Thomas, United Therapeutics
Kristen Winters, Centene	Bryan Steffan, Boehringer
Deidra Williams, Humana	John Kingrey, Integris
Andrew Delgado, Bristol Myers Squibb	Brent Parker, Merck
Lee Stout, Chiesi	Irene Chung, Aetna
Marc Parker, VS Health Group	Saurabh Patel, AbbVie
Mike Thiem, Incyte	Jennifer Lauper, Bristol Myers Squibb
Michael Sullivan, Amgen	Lisa Dunn, Amgen
Pam Storey, PTC Therapeutics	Dave Miley, Teva
Kellie Vazzana, Alkermes	Taylor Charles, Artia Solutions
Brad Burris, Liquidia	Kathrin Kucharski, Sarepta Therapeutics
Mae Kwong, Soleno Therapeutics	Phillip Held, United Therapeutics
J.R. Brawner, Novo Nordisk	Shawn Akey, Concis Labs
Jennifer Golwyn, Ascendis	Michelle Bice, Soleno Therapeutics
Lindsey Baker, Genentech	Rodney Brown, Genentech
Jennifer Woulfe, United Therapeutics	Todd Dickerson, Jazz Pharmaceutical
Emily Frans, United Therapeutics	Eardie Curry, Genentech
Phillip Lohec, Viatris Inc	

PRESENT FOR PUBLIC COMMENT:	
John Kingrey, Integris	Ben Skoog, Acadia
Nina Golde, Soleno Therapeutics	Paul Miner, Ascendis
Sejal Upadhyaya, Novo Nordisk	

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 2:</u> **PUBLIC COMMENT FORUM**

2A: AGENDA ITEM NO. 6 JOHN KINGREY
2B: AGENDA ITEM NO. 9 SEJAL UPADHYAYA
2C: AGENDA ITEM NO. 14 BEN SKOOG
2D: AGENDA ITEM NO. 14 NINA GOLDE
2E: AGENDA ITEM NO. 14 PAUL MINER
2F: AGENDA ITEM NO. 14 SEJAL UPAHYAYA
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 3:</u> **APPROVAL OF DUR BOARD MEETING MINUTES**

3A: FEBRUARY 11, 2026 DUR MINUTES
Materials included in agenda packet; presented by Dr. Patatanian
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 4:</u> **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT**

4A: PHARMACY HELPDESK ACTIVITY FOR FEBRUARY 2026
4B: MEDICATION COVERAGE ACTIVITY FOR FEBRUARY 2026
Non-presentation item; materials included in agenda packet by Dr. O'Halloran
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> **SPRING PIPELINE UPDATE**

5A: INTRODUCTION
5B: PRODUCT SUMMARIES
5C: PIPELINE TABLE
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> **VOTE TO PRIOR AUTHORIZE YUTREPIA™ (TREPROSTINIL POWDER FOR INHALATION) AND UPDATE THE APPROVAL CRITERIA FOR THE PULMONARY HYPERTENSION MEDICATIONS**

6A: MARKET NEWS AND UPDATES
6B: YUTREPIA™ (TREPROSTINIL POWDER FOR INHALATION) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Holderread moved to approve; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> **VOTE TO PRIOR AUTHORIZE BREKIYA® [DIHYDROERGOTAMINE (DHE) AUTOINJECTOR] AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-MIGRAINE MEDICATIONS**

7A: MARKET NEWS AND UPDATES
7B: COST COMPARISON: DHE PRODUCTS
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Blaiss moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> **VOTE TO PRIOR AUTHORIZE CARDAMYST™ (ETRIPAMIL NASAL SPRAY)**

8A: MARKET NEWS AND UPDATES
8B: CARDAMYST™ (ETRIPAMIL NASAL SPRAY) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

<u>AGENDA ITEM NO. 9:</u> ANNUAL REVIEW OF HEMOPHILIA MEDICATIONS
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF HEMOPHILIA MEDICATIONS
9C: PRIOR AUTHORIZATION OF HEMOPHILIA MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: OKLAHOMA HEALTH CARE AUTHORITY RECOMMENDATIONS
9F: UTILIZATION DETAILS OF HEMOPHILIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Ratterman
Dr. Holderread moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> ANNUAL REVIEW OF MUSCULAR DYSTROPHY MEDICATIONS
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
10C: PRIOR AUTHORIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF MUSCULAR DYSTROPHY MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Muñoz moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF LEUKEMIA AND LYMPHOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KOMZIFTI™ (ZIFTOMENIB), LYMPHIR™ (DENILEUKIN DIFTITOX-XCDL), LUNSUMIO VELO™ (MOSUNETUZUMAB-AXGB), NILOTINIB D-TARTRATE, AND PHYRAGO™ (DASATINIB)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF LEUKEMIA AND LYMPHOMA MEDICATIONS
11C: PRIOR AUTHORIZATION OF LEUKEMIA AND LYMPHOMA MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF LEUKEMIA AND LYMPHOMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 12:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE FESILTY™ (FIBRINOGEN, HUMAN-CHMT)
12A: INTRODUCTION
12B: FESILTY™ (FIBRINOGEN, HUMAN-CHMT) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 13:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE WASKYRA™ ETUVETIDIGENE AUTOTEMCEL)
13A: INTRODUCTION
13B: WASKYRA™ (ETUVETIDIGENE AUTOTEMCEL) PRODUCT SUMMARY

13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF GROWTH-RELATED DISORDER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DAYBUE® STIX (TROFINETIDE PACKET), PALSONIFY™ (PALTUSOTINE), VYKAT™ XR [DIAZOXIDE CHOLINE EXTENDED-RELEASE (ER)] AND YUVIWEL® (NAVEPEGRITIDE)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF GROWTH-RELATED DISORDER MEDICATIONS
14C: PRIOR AUTHORIZATION OF GROWTH-RELATED DISORDER MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: PRODUCT SUMMARIES
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF GROWTH-RELATED DISORDER MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF GLAUCOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZOLYMBUS™ (BIMATOPROST OPHTHALMIC GEL)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF GLAUCOMA MEDICATIONS
15C: PRIOR AUTHORIZATION OF GLAUCOMA MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY MEDICATIONS
15F: UTILIZATION DETAILS OF GLAUCOMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND STEM CELL MOBILIZERS AND 30-DAY NOTICE TO PRIOR AUTHORIZE NYPOZI™ (FILGRASTIM-TXID)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF G-CSFS AND STEM CELL MOBILIZERS
16C: PRIOR AUTHORIZATION OF G-CSFS AND STEM CELL MOBILIZERS
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS
16F: UTILIZATION DETAILS OF G-CSFS AND STEM CELL MOBILIZERS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 17:</u> ANNUAL REVIEW OF DRY EYE DISEASE (DED) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE TRYPTYR® (ACOLTREMON 0.003% OPHTHALMIC SOLUTION)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF DED MEDICATIONS
17C: PRIOR AUTHORIZATION OF DED MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: TRYPTYR® (ACOLTREMON 0.003% OPHTHALMIC SOLUTION) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF DED MEDICATIONS

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

<u>AGENDA ITEM NO. 18:</u> ANNUAL REVIEW OF TOPICAL ANTIBIOTIC PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CLINDESSE® (CLINDAMYCIN PHOSPHATE 2% VAGINAL CREAM)
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF TOPICAL ANTIBIOTIC PRODUCTS
18C: PRIOR AUTHORIZATION OF TOPICAL ANTIBIOTIC PRODUCTS
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF TOPICAL ANTIBIOTIC PRODUCTS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 19:</u> U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. O'Halloran
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 20:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
20A: AGE-RELATED MACULAR DEGENERATION (AMD) MEDICATIONS
20B: ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS
20C: INTERSTITIAL LUNG DISEASE (ILD) MEDICATIONS
20D: LUNG CANCER MEDICATIONS
20E: MULTIPLE SCLEROSIS (MS) MEDICATIONS
20F: PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) MEDICATIONS
20G: RETHYMIC® (ALLOGENIC PROCESSED THYMUS TISSUE-AGDC)
20H: SOFDRA™ (SOFPIRONIUM)
20I: SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS
*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 25:</u> ADJOURNMENT
Dr. Patatanian called for adjournment of the meeting.
Dr. Blaiss moved to approve; seconded by Dr. Muñoz
The meeting was adjourned at 5:37pm.
ACTION: MOTION CARRIED

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: March 13, 2026

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

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

Subject: DUR Board Recommendations from Meeting on March 11, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Spring 2026 Pipeline Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Yutrepia™ (Treprostinil Powder for Inhalation) and Update the Approval Criteria for the Pulmonary Hypertension Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Yutrepia™ (treprostinil powder for inhalation) with criteria similar to Tyvaso DPI® (treprostinil powder for inhalation) and recommends updating the Tyvaso DPI® criteria for clarity, based on clinical practice, and based on recommendations from the DUR Board to remove criteria #4 and #5 to reduce barriers to treatment with the dry powder inhaler (DPI) formulations (changes shown in red):

ORI-4403 • P.O. BOX 26901 • OKLAHOMA CITY, OKLAHOMA 73126-0901 • (405) 271-9039 • FAX: (405) 271-2615

Tyvaso DPI® (Treprostinil Powder for Inhalation) and Yutrepia™ (Treprostinil Powder for Inhalation) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Pulmonary arterial hypertension (PAH); or
    b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and
        i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. For a diagnosis of PAH:
    a. Member must have previous failed trials of at least 1 of each of the following categories or have a contraindication to use of all alternatives:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
4. ~~A patient-specific, clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and~~
5. ~~For a diagnosis of PH-ILD, a patient-specific, clinically significant reason (beyond convenience) why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.~~

The College of Pharmacy also recommends updating the Opsynvi® (macitentan) and Opsumit® (macitentan/tadalafil) approval criteria based on the discontinuation of the Risk Evaluation and Mitigation Strategy (REMS) program (changes shown in red):

Opsumit® (Macitentan) and Opsynvi® (Macitentan/Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
    a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Requests for Opsynvi® will also require a patient-specific, clinically significant reason why the member cannot use Opsumit® in combination with generic sildenafil or tadalafil; and
5. ~~Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program or the Macitentan-Containing Products REMS program; and~~

6. Female members of reproductive potential must have a negative pregnancy test prior to initiation of Opsumit® or Opsynvi® and, if pregnancy occurs during therapy, Opsumit® or Opsynvi® must be discontinued immediately; and
7. A quantity limit of 30 tablets per 30 days will apply.

Lastly, the College of Pharmacy recommends updating the Uptravi® (selexipag) and Winrevair™ (sotatercept-csrk) based on clinical practice (changes shown in red):

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. ~~Member must be 18 years of age or older; and~~
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination) or have a contraindication to use of all alternatives:
    a. Adcirca® (tadalafil), Adempas® (riociguat), or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
4. Medical supervision by a pulmonary specialist or cardiologist; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

Winrevair™ (Sotatercept-csrk) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. ~~Member must be 18 years of age or older; and~~
3. Member is currently taking PAH medications from at least 2 of the following categories for ≥90 days or has a contraindication to use of all alternatives:
    a. Phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil, tadalafil) or soluble guanylate cyclase stimulator (e.g., riociguat); or
    b. Endothelin-receptor antagonist (e.g., ambrisentan, bosentan); or
    c. Prostacyclin analogue or receptor agonist (e.g., epoprostenol, treprostinil); and
4. Prescriber must verify that Winrevair™ will be used concurrently with member's current PAH therapies; and
5. Medical supervision by a pulmonary specialist and/or cardiologist; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the preparation, subcutaneous (sub-Q) administration, and proper storage of Winrevair™; and
7. Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and

8. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 4 months after the last dose; and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. A quantity limit of 1 kit every 3 weeks will apply.
    a. Members requiring (2) 45mg or (2) 60mg vials based on their body weight will not be approved for multiple 1-vial kits but should use the 2-vial kits to achieve the dose required.

Recommendation 4: Vote to Prior Authorize Brekiya® [Dihydroergotamine (DHE) Autoinjector] and Update the Approval Criteria for the Anti-Migraine Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the current Anti-Migraine Medications Product Based Prior Authorization (PBPA) category based on the new FDA approval, product discontinuation, and net costs (changes shown in red):

1. Prior authorization of Brekiya® (DHE autoinjector) and placement into the Special PA Tier with the following additional criteria; and
2. Updating the approval criteria for Ubrelvy® (ubrogepant) and Zavzpret™ (zavegepant nasal spray).

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	**DHE autoinjector (Brekiya®)**
naratriptan tablet (Amerge®)	sumatriptan/ naproxen tablet (Treximet®)	DHE nasal spray (Migranal®)	DHE injection (D.H.E. 45®)
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)		sumatriptan autoinjector pen and vial (Imitrex®)	ergotamine sublingual tablet (Ergomar®)
sumatriptan tablet (Imitrex®)		sumatriptan nasal spray (Imitrex®)	lasmiditan tablet (Reyvow®)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			meloxicam/rizatriptan (Symbravo®)
			rimegepant ODT (Nurtec® ODT)
			sumatriptan injection (Imitrex® STATdose System)

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DHE = dihydroergotamine; ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
    b. A quantity limit of 20 tablets per 28 days will apply.
2. Use of Brekiya® [dihydroergotamine (DHE) autoinjector] or D.H.E. 45® ~~[dihydroergotamine~~ (DHE~~)~~ injection)~~]~~ will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray) and lower-tiered triptan medications.
3. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)][+]:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
    c. A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same

criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.
[+]Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.

4. Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
5. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).
6. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications~~,~~ and Nurtec® ODT (rimegepant)~~, and Reyvow® (lasmiditan)~~; and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
7. Use of Imitrex® STATdose System (sumatriptan injection), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

Additionally, the College of Pharmacy recommends updating the approval criteria for Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), and Emgality® (galcanezumab-gnlm) based on the FDA age expansion for Ajovy® (changes shown in red):

Aimovig® (Erenumab-aooe), Ajovy® (Fremanezumab-vfrm), and Emgality® (Galcanezumab-gnlm) Approval Criteria [Migraine Diagnosis]:

1. An FDA approved indication for the preventive treatment of migraine ~~in adults~~; and
2. Member must be 18 years of age or older;~~ and~~ or
    a. For Ajovy®, pediatric members must be 6 to 17 years of age, weigh at least 45kg, and have a diagnosis of episodic migraine, as defined below; and
3. Member has documented chronic migraine or episodic migraine headaches:

   a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or
   b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and
4. Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
   a. Red flags; and
   b. Possible indicators of secondary headache; and
   c. Medication overuse; and
5. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
6. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
7. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
8. Quantity limits will apply based on FDA-approved dosing:
   a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
   b. For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for adults only for a quantity limit override upon meeting Ajovy® approval criteria; and
   c. For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as 2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.

Recommendation 5: Vote Prior Authorize Cardamyst™ (Etripamil Nasal Spray)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Cardamyst™ (etripamil nasal spray) with the following criteria (shown in red):

Cardamyst™ (Etripamil Nasal Spray) Approval Criteria:

1. An FDA approved indication of the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm; and
2. Member must 18 years of age or older; and

3. Member must not have any of the contraindications for use of Cardamyst™, including:
   a. Hypersensitivity to Cardamyst™ or any of its components; and
   b. New York Heart Association (NYHA) Class II to IV heart failure; and
   c. Wolff-Parkinson-White (WPW), Lown-Ganong-Levine (LGL) syndromes, or manifest pre-excitation (delta wave) on a 12-lead electrocardiogram (ECG); and
   d. Sick sinus syndrome without a permanent pacemaker; and
   e. Second degree atrioventricular (AV) Mobitz 2 block or higher degree of AV block; and
4. Prescriber must verify the member or caregiver will be counseled on all of the following:
   a. PSVT symptoms; and
   b. Timing of Cardamyst™ administration in relation to the onset of the PSVT episode; and
   c. The proper storage and administration of Cardamyst™; and
   d. When to contact a health care provider or seek emergency medical attention; and
5. Prescriber must verify members with a history of hypotensive episodes or those at increased risk for hemodynamic instability will be monitored appropriately when initiating Cardamyst™; and
6. Must be prescribed by, or in consultation with, a cardiologist or a specialist with expertise in the treatment of PSVT; and
7. Approvals will be for up to 6 cartons (i.e., 12 nasal spray devices) per year; and
   a. A quantity limit of 1 carton (i.e., 2 nasal spray devices) per 30 days will apply; or
   b. For requests exceeding the quantity limit, clinical documentation (i.e., recent office notes) supporting the need for additional supply must be provided for consideration of a quantity limit override; and
8. Subsequent approvals may be granted if the prescriber documents the member has responded well to treatment and continues to require treatment with Cardamyst™.

Recommendation 6: Fiscal Year 2025 Annual Review of Hemophilia Medications

MOTION CARRIED by unanimous approval.

The Oklahoma Health Care Authority recommends updating the approval criteria for Alhemo® (concizumab-mtci) based on the new FDA approved label expansion (changes shown in red):

Alhemo® (Concizumab-mtci) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following:
    a. Hemophilia A or B with inhibitors; ~~and~~ or
    b. Severe hemophilia A (factor VIII ≤1%) without inhibitors; or
    c. Moderately severe or severe hemophilia B (factor XI ≤2%) without inhibitors; and
2. Member must be 12 years of age or older; and
3. Member's recent weight (taken within the past 3 months) must be provided and must be ≥25kg; and
4. Member must not be undergoing immune tolerance induction (ITI); and
5. For members without an inhibitor, a patient-specific, clinically significant reason why continuing the member's current prophylaxis therapy is not appropriate must be provided; and
6. Member must not have a history of or be at high risk for thromboembolic events; and
7. Female members of reproductive potential must meet the following:
    a. Must not be pregnant; or
        i. If member is pregnant or becomes pregnant during treatment, the risk to the fetus must be weighed against the benefit to the mother; and
    b. Must agree to use effective birth control during treatment and for at least 7 weeks after the last dose; and
8. Prescriber must agree the member will not be continuing on other prophylactic therapies; and
9. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
10. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Alhemo®; and
11. Prescriber must verify that the member has been counseled on the potential risk of thrombosis; and
12. Prescriber must verify the member has been counseled on the use of bypassing agents or factor concentrate at the lowest possible dose for breakthrough bleeding episodes based on severity and location of bleed; and
13. Requests must be for an FDA approved dosing regimen as outlined in the package labeling; and
14. Initial approvals will be for 3 months for the loading dose of 1mg/kg on day 1 and 0.2mg/kg daily until individualization of the maintenance dose has been achieved. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.

<u>Recommendation 7: Fiscal Year 2025 Annual Review of Muscular Dystrophy Medications</u>

<u>MOTION CARRIED</u> by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Elevidys (delandistrogene moxeparvovec-rokl) based on the FDA label updates (changes shown in red):

Elevidys (Delandistrogene Moxeparvovec-rokl) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be at least 4 years of age; and
3. Prescriber must attest the member is ambulatory and the results of 1 of the following tests must be submitted:
    a. North Star Ambulatory Assessment (NSAA); or
    b. 6-minute walk test (6MWT); or
    c. 10-meter walk test (10mWT); or
    d. Ascend 4 Steps; or
    e. Time to Rise (TTR); or
    f. 100-meter timed test; and
4. Elevidys must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Member's baseline anti-AAVrh74 total binding antibody titers must be <1:400; and
6. Member must not have any deletion in exon 8 and/or exon 9 in the *DMD* gene; and
7. If the member has a deletion in the *DMD* gene in exon 1 to 17 and/or exons 59 to 71, the prescriber must verify the member will be monitored for a severe immune-mediated myositis reaction; and
8. Member must not have preexisting liver impairment [defined as gamma-glutamyl transferase (GGT) >2x upper limit of normal (ULN) or total bilirubin >ULN not due to Gilbert's syndrome] or active hepatic viral infection due to the high risk of acute serious liver injury and acute liver failure; and
9. Member must not receive any vaccinations within 4 weeks of Elevidys infusion; and
10. Member must not have any active or recent infections (within 4 weeks of Elevidys infusion) and if the member does have an active or recent infection (within 4 weeks of Elevidys infusion), the prescriber must verify Elevidys infusion will be postponed ~~until infection has resolved~~; and
11. Prescriber must confirm the member has been instructed to maintain proximity to an appropriate health care facility, as determined by the

health care provider, for at least 2 months following the Elevidys infusion; and

12. Prescriber must verify the member will initiate a corticosteroid regimen 1 day prior to the infusion of Elevidys and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling; and
13. Prescriber must verify liver function tests (LFTs) (e.g., GGT, total bilirubin) will be performed prior to Elevidys administration and will be monitored weekly for the first 3 months following Elevidys infusion then as clinically indicated; and
14. Prescriber must confirm the oral corticosteroid regimen will be modified according to the package labeling for members with liver function abnormalities following Elevidys infusion and prompt consultation with a specialist (i.e., gastroenterologist or hepatologist) will occur if acute serious liver injury or impending acute liver failure is suspected; and
15. Prescriber must verify troponin-I will be monitored before the Elevidys infusion and weekly for the first month following infusion then as clinically indicated; and
16. Prescriber must verify that platelet counts will be monitored before the Elevidys infusion and weekly for the first 2 weeks following infusion then as clinically indicated; and
17. Prescriber must verify the member and/or caregiver will be given a copy of the Elevidys medication guide and it will be reviewed with the member and/or caregiver including when to contact their health care provider; and
18. Member will not be approved for concomitant treatment with exon skipping therapy (e.g., Amondys 45, Exondys 51, Viltepso®, Vyondys 53) following Elevidys infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys approval); and
19. Member's current weight (kg) taken within the past 6 months must be provided on the request to ensure accurate weight-based dosing according to package labeling; and
20. Approvals will be for 1 dose per member per lifetime.

The College of Pharmacy also recommends updating the approval criteria for Emflaza® (deflazacort) based on the FDA approval of the branded generics Jaythari® (deflazacort), Kymbee™ (deflazacort), and Pyquvi™ (deflazacort) and net cost (changes shown in red):

Emflaza® (Deflazacort), Jaythari® (Deflazacort), Kymbee™ (Deflazacort), and Pyquvi™ (Deflazacort) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 2 years of age or older; and

3. ~~Emflaza®~~ Deflazacort must be prescribed by, or in consultation with, a prescriber who specializes in the treatment of DMD; and
4. Member must have a minimum 6-month trial of prednisone that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with ~~Emflaza®~~ deflazacort or a patient specific, clinically significant reason why the member cannot use prednisone must be provided; and
5. For ~~Emflaza®~~ deflazacort suspension, a patient-specific, clinically significant reason why the member cannot use the tablet formulation in the place of oral suspension even when the tablets are crushed must be provided; and
6. Emflaza® is brand preferred. Requests for generic deflazacort including branded generics, Jaythari®, Kymbee™, and Pyquvi™, will require a patient-specific, clinically significant reason why the member cannot use the brand Emflaza® formulation; and
7. Prescriber must verify the member has had a baseline eye examination; and
8. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
9. For continued authorization, an updated weight must be provided, and the member must have had a repeat eye exam with results that are acceptable to the prescriber; and
10. For the tablets, a quantity limit of 30 tablets per 30 days will apply, and for the suspension, a quantity limit of 39mL (3 bottles) per 30 days will apply. Quantity limit override requests will be approved as appropriate based on the member's recent weight taken within the last 30 days.

Finally, the College of Pharmacy also recommends updating the exon skipping therapies approval criteria based on clinical practice (changes shown in red):

Amondys 45 (Casimersen), Exondys 51 (Eteplirsen), Viltepso® (Viltolarsen), and Vyondys 53 (Golodirsen) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must have a confirmed mutation of the *DMD* gene that is amenable to exon skipping for the requested medication (results of genetic testing must be submitted); and
3. Member must not have previously received Elevidys (delandistrogene moxeparvovec-rokl); and
4. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and

5. Prescriber must verify the member's renal function will be appropriately assessed prior to initiation of therapy and monitored during treatment; and
6. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
7. ~~A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:~~
   a. ~~6-minute walk test (6MWT); or~~
   b. ~~Forced vital capacity percent predicted (FVCpp); and~~
8. The requested exon-skipping therapy will not be approved for concurrent use with any other exon-skipping therapies for DMD; and
9. ~~Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and~~
10. ~~Subsequent approvals will be for the duration of 1 year. For yearly approvals, the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and~~
11. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document the member is tolerating and benefiting from treatment, as indicated by improvement, stabilization, or a slower progression of disease compared to the typical DMD progression (i.e., improved functional tests, strength, or pulmonary function test); and
12. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Recommendation 8: Fiscal Year 2025 Annual Review of Leukemia and Lymphoma Medications and 30-Day Notice to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib)

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

Recommendation 9: 30-Day Notice to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt)

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

Recommendation 10: 30-Day Notice to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel)

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

Recommendation 11: Fiscal Year 2025 Annual Review of Growth-Related Disorder Medications and 30-Day Notice to Prior Authorize Daybue® Stix (Trofinetide Packet), Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide)

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

Recommendation 12: Fiscal Year 2025 Annual Review of Glaucoma Medications and the 30-Day Notice to Prior Authorize Zolymbus™ (Bimatoprost 0.01% Gel)

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

Recommendation 13: Fiscal Year 2025 Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Nypozi™ (Filgrastim-txid)

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

Recommendation 14: Fiscal Year 2025 Annual Review of Dry Eye Disease (DED) Medications and 30-Day Notice to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution)

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

Recommendation 15: Fiscal Year 2025 Annual Review of Topical Antibiotic Products and 30-Day Notice to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream)

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

Recommendation 16: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 17: Future Business

NO ACTION REQUIRED.

Advanced Heart Failure Clinic

Oklahoma Heart Institute

Steven Stroud, MD

1120 S. Utica Ave

Tulsa, OK 74104

March 6, 2026

Oklahoma Health Care Authority

Drug Utilization Review Board

4345 N. Lincoln Blvd.

Oklahoma City, OK 73105

Dear Members of the Drug Utilization Review Board,

I am writing to request formulary consideration for Yutrepia for my pulmonary arterial hypertension and pulmonary hypertension interstitial lung disease patients. Yutrepia is unique in that has been studied for use in treating both groups of patients. In the Inspire trial, Yutrepia was studied in the treatment of Pulmonary Arterial Hypertension, showing improved exercise ability and sustained tolerability with long term data of patients still on therapy two years later. In the ASCENT trial, Yutrepia was studied in the treatment of Pulmonary Hypertension-Interstitial Lung disease, showing improvement in 6-minute walk distance and exercise capacity. Previous inhaled prostacyclins have been challenging to increase to higher doses due to increasingly severe side effects which often lead to patients discontinuing therapy. Nebulized prostacyclins are delivered by cumbersome devices which must be set up and cleaned daily, while dry powder prostacyclins are more portable and need less maintenance, leading to a better quality of life for patients.

It is critical that we use the safest, most efficient medication to improve and maintain an acceptable quality of life for our pulmonary arterial hypertension and pulmonary hypertension interstitial lung disease patients. As a board-certified heart failure and transplant cardiologist, I have prescribed Yutrepia to provide my patients with a tolerable and effective treatment that also improves and protects their quality of life. I am requesting formulary consideration for Yutrepia to ensure the ability to prescribe the best treatment possible for our pulmonary hypertension patients. Ensuring providers have access to multiple therapeutic options is imperative as patients often require individualized treatment approaches due to clinical needs and tolerability.

Thank you for your consideration,

Steven Stroud, MD

Director of Pulmonary Hypertension

Oklahoma Heart Institute

Letter of Support for VYKAT XR (Diazoxide Choline) Coverage for Pediatric Patients with Prader-Willi Syndrome

Dear Members of the Drug Utilization Review Board:

I am a board-certified Pediatric Endocrinologist at INTEGRIS Health in Oklahoma City. I am writing to advocate on behalf of my patients for the inclusion of VYKAT XR (diazoxide choline extended-release) on the formulary of OHCA for the treatment of hyperphagia in pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

Prader-Willi syndrome (PWS) is a rare neurobehavioral-metabolic disease that leads to behavioral difficulties, endocrinopathies, severe hyperphagia, hypotonia, and neurocognitive problems. Hyperphagia, if not controlled, leads to severe obesity and its sequelae of metabolic disease.

VYKAT XR represents a significant therapeutic advancement for PWS which has had limited treatment options and substantial morbidity and mortality.

FDA Approval and Indication: VYKAT XR received FDA approval for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with PWS on March 26, 2025 (1). This approval was based on rigorous clinical trial data demonstrating both efficacy and safety in this vulnerable patient population. VYKAT XR is the first and only FDA-approved medication specifically indicated for hyperphagia in PWS, addressing a critical unmet medical need.

Clinical Efficacy: The efficacy of VYKAT XR was established in a 16-week randomized, double-blind, placebo-controlled withdrawal study involving 77 patients (mean age 14.9 years, range 7-29 years) who had previously received VYKAT XR for a mean duration of 3.3 years (1, 2). The primary endpoint, change in Hyperphagia Questionnaire for Clinical Trials (HQ-CT) total score, demonstrated statistically significant superiority of VYKAT XR over placebo (least square mean change 2.6 vs 7.6, $p < 0.01$) (2). Importantly, patients withdrawn from VYKAT XR experienced worsening hyperphagia, while those continuing treatment maintained control of this life-threatening symptom.

Long-term data from 125 participants treated for up to 52 weeks demonstrated sustained improvements in HQ-CT scores (mean change -9.9, $p<0.01$), with greater benefits observed in patients with more severe baseline hyperphagia (3). Importantly, the medication also demonstrated significant improvements in aggressive behaviors ($p < 0.01$), anxiety ($p < 0.01$), and compulsivity ($p < 0.01$)—all core features of PWS that substantially impact quality of life and caregiver burden (3).

Body Composition and Metabolic Benefits: Beyond hyperphagia control, VYKAT XR demonstrated favorable effects on body composition and metabolic parameters. Treatment resulted in significant increases in lean body mass ($p < 0.01$) and reductions in fat mass (3, 4). Patients receiving VYKAT XR gained less weight and had smaller increases in BMI z-scores compared to placebo (LS mean weight difference -1.6 kg, 95% CI -3.1 to -0.1; LS mean z-score difference -0.09, 95% CI -0.17 to -0.01) (2). Metabolic improvements included reductions in leptin, insulin, and insulin resistance, as well as increased adiponectin (all $p < 0.01$) (3).

Safety Profile: VYKAT XR was well tolerated in clinical trials involving pediatric patients. In the Phase 3 program, 125 patients received VYKAT XR for up to 4.86 years (median 3.0 years) (1). The most common treatment-emergent adverse events included hypertrichosis, peripheral edema, and hyperglycemia—effects that are manageable with appropriate monitoring (1, 3). Importantly, adverse events infrequently resulted in discontinuation (7.2%) (3). No serious adverse events occurred in the VYKAT XR arm during the randomized withdrawal study (2).

The FDA label provides clear guidance for monitoring fasting glucose and HbA1c, with specific protocols for dosage adjustment if hyperglycemia occurs (1). This structured monitoring approach allows for safe use in the pediatric PWS population, which already requires close medical supervision.

Unmet Medical Need: Prader-Willi syndrome is a rare genetic neurobehavioral-metabolic disorder characterized by life-threatening hyperphagia that, if uncontrolled, leads to severe obesity and associated complications including type 2 diabetes, cardiovascular disease, and premature death. Prior to VYKAT XR approval, no FDA-approved pharmacologic treatments existed for hyperphagia in PWS. Management relied solely on environmental controls, locked kitchens, and constant supervision—measures that are burdensome for families and often insufficient to prevent dangerous weight gain and food-seeking behaviors.

Impact on Disease Severity and Caregiver Burden: Clinical trial data demonstrated that VYKAT XR treatment reduced overall disease severity as assessed by both clinicians and caregivers (both $p < 0.01$) (3). The medication has the potential to reduce the burden of care for families managing this challenging condition, improving quality of life for both patients and their caregivers.

VYKAT XR represents an evidence-based, FDA-approved treatment option for a serious rare disease with limited therapeutic alternatives. The clinical trial data demonstrate statistically significant and clinically meaningful improvements in hyperphagia, behavioral symptoms, body composition, and metabolic parameters in pediatric patients with PWS. The safety profile is acceptable with appropriate monitoring protocols. Denying coverage for this medication would deprive children with PWS of the only FDA-approved treatment for their life-threatening hyperphagia.

I therefore respectfully request the Oklahoma Drug Utilization Review Board to approve formulary inclusion of VYKAT XR for pediatric patients 4 years of age and older with Prader-Willi syndrome and hyperphagia, consistent with its FDA-approved indication.

Thank you for your consideration.

Sincerely,

Ankur Rughani, MD
Pediatric Endocrinologist
3330 NW 56th Street
Oklahoma City, OK 73112

References

1. VYKAT XR. Food and Drug Administration. Updated date: 2025-03-26.
2. Diazoxide Choline Extended-Release Tablets in Prader-Willi Syndrome: A Randomized, Double-Blind, Withdrawal Period Study. Miller JL, Bridges N, Felner EI, et al. The Journal of Clinical Endocrinology and Metabolism. 2026;:dgaf661. doi:10.1210/clinem/dgaf661.
3. Diazoxide Choline Extended-Release Tablet in People With Prader-Willi Syndrome: Results From Long-Term Open-Label Study. Miller JL, Gevers E, Bridges N, et al. Obesity (Silver Spring, Md.). 2024;32(2):252-261. doi:10.1002/oby.23928.
4. Diazoxide Choline Extended-Release Tablet in People With Prader-Willi Syndrome: A Double-Blind, Placebo-Controlled Trial. Miller JL, Gevers E, Bridges N, et al. The Journal of Clinical Endocrinology and Metabolism. 2023;108(7):1676-1685. doi:10.1210/clinem/dgad014.

March 9, 2026

To the Members of the Oklahoma Drug Utilization Board,

On behalf of the Prader-Willi Syndrome Association | USA (PWSA | USA) and the families we represent nationwide, we urge you to ensure coverage of medications that treat hyperphagia in Prader-Willi syndrome (PWS), including VYKAT XR, the first therapy approved by the FDA for this indication.

It is critical to distinguish that hyperphagia is not the same as obesity. While obesity may be a secondary outcome, hyperphagia itself is a chronic neurological condition that drives an unrelenting and life-threatening hunger. This is not a matter of willpower or diet; it is a hallmark of PWS that leads to constant food-seeking, high levels of anxiety, dangerous behaviors, and extreme burdens on families and caregivers.

Reducing hyperphagia can have a profound impact on other debilitating symptoms of PWS. Families and clinicians report improvements in anxiety, obsessive and compulsive tendencies, aggression, and behavioral crises when hyperphagia is addressed. These improvements ripple beyond the individual, helping to stabilize family life, reduce caregiver stress, and prevent costly medical complications, including obesity-related comorbidities and hospitalizations.

The approval of VYKAT XR represents a long-awaited breakthrough for the PWS community, but it is only meaningful if access is ensured. Families who have endured decades without options to treat hyperphagia should not face additional barriers due to lack of coverage.

For the thousands of individuals living with PWS in the United States, coverage of treatments like VYKAT XR is a medical necessity. We respectfully ask your committee to approve access to these therapies so that individuals with PWS may live safer, healthier lives, and so that families may finally have relief from one of the most devastating symptoms of this disease.

Thank you for your thoughtful consideration and for your commitment to supporting individuals and families affected by rare and complex conditions.

Dorothea Lantz
Director of Community Engagement
Prader-Willi Syndrome Association | USA
Dlantz@pwsausa.org

INTEGRIS

Pulmonary Hypertension Center of Oklahoma

3400 NW Expressway, Suite 200
Oklahoma City, OK 73112
P: 405-553-0581
F: 405-713-4634

March 9, 2026

To whom it may concern,

Pulmonary arterial hypertension (PAH) and pulmonary hypertension related to interstitial lung disease (PH-ILD) are associated with significant morbidity and risk of mortality for patients. While no cures are available, expansions of treatment have significantly improved survival and quality of life for patients affected. However, treatments for these conditions are burdensome and associated with significant side effects. As such, having access to multiple options for medications significantly improves our ability to treat these patients effectively.

As PH specialists at INTEGRIS Baptist Medical Center in Oklahoma City, we work with these patients on a daily basis and are well acquainted with the challenges of treatment for these diseases. At this time, one of the issues we are facing is access to dry powder inhaler (DPI) options for inhaled treprostrinil. As you are aware, the current formulary only includes the nebulized forms of inhaled treprostinil (Tyvaso). While this medication is effective, it is extremely burdensome for patients to use effectively. The medication requires four times daily dosing, with each administration taking around 15 minutes, equating to a significant amount of time daily for this medication. Further, the nebulizer device is cumbersome to transport for patients that are out of the house for any significant portions of the day.

DPI formulations of inhaled treprostinil (Tyvaso and Yutrepia) have been shown to be at least as effective as the nebulized form of Tyvaso and are consistently preferred by patients for their portability as ease of use. The BREEZE study (Pulm Circ. 2022 Apr 7;12(2):e12063) demonstrated a small but clinically significant improvement in 6-minute walk distance and assessments of quality of life and symptom burden in patients transitioned from nebulized Tyvaso to the DPI formulation. Further, patients far preferred the DPI formulation to the nebulizer, and all patients completed the study and transitioned to the open label extension phase, consistent with their satisfaction with the treatment. Strikingly, the number of patients indicating they strongly agree the statement that the medication is “easy to use” increased from 12% with the nebulizer to 91% with the DPI formulation ($p<0.0001$). We have been using this medication consistently in patients for years and have seen significant improvements in PH related symptoms and quality of life.

INTEGRIS

Pulmonary Hypertension Center of Oklahoma

3400 NW Expressway, Suite 200
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Similarly, Yutrepia offers similar benefits to patients. The INSPIRE trial (Pulm Circ. 2022 Jul 1;12(3):e12119) demonstrated that patients transitioned from nebulized Tyvaso or started on prostacyclin-naïve patients had a trend towards improvement in 6MWD and improvements in quality-of-life assessments. Further, over 80% of patients strongly preferred the DPI inhaler to the nebulized form after 4 months.

We believe Medicaid patients with PAH and PH-ILD would greatly benefit from having reliable access to these medications. Ideally, we would have access to both forms of inhaled treprostinil as they each have some unique characteristics that offer potential better tolerability for individual patients. For example, Yutrepia and Tyvaso are formulated with different excipients which may impact tolerability and cough for patients. Yutrepia utilizes a low-resistance device, but requires two breaths per capsule to deliver the dose. Further, capsules must be placed in the inhaler and punctured with squeezing two buttons, which may be cumbersome for patients with significant arthritis or reduced dexterity. Tyvaso DPI utilizes a cartridge system and a higher-resistance device which delivers medication with low required flow rates and only requires one breath per cartridge. Essentially, each medication offers benefits to specific patients, and it would benefit PH patients in Oklahoma to have both of these medications available as part of the Medicaid formulary.

We ask you to strongly consider covering these crucial, life-changing medications for Medicaid patients in the state of Oklahoma as an important step to help these patients to lead fuller, healthier lives.

Sincerely,

Nicholas Shelburne, MD

John Kingrey, MD

Pulmonary Hypertension Center of Oklahoma

INTEGRIS Baptist Medical Center

Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MARCH 2026

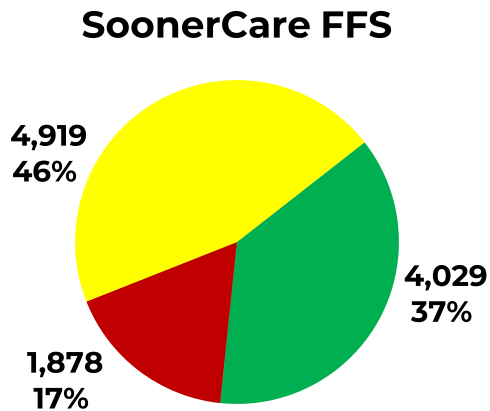
Approved
Denied
Incomplete

9,248
37%

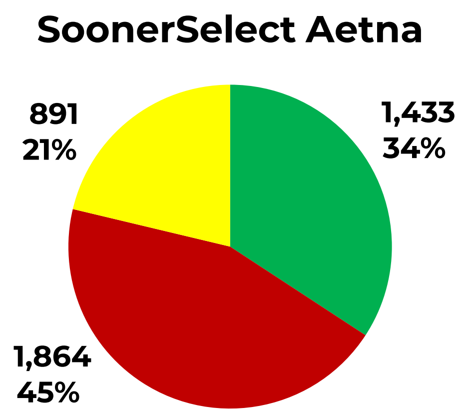
8,807
36%

6,797
27%

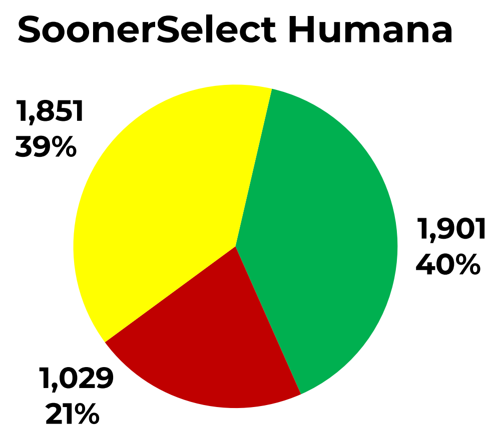
SoonerCare FFS



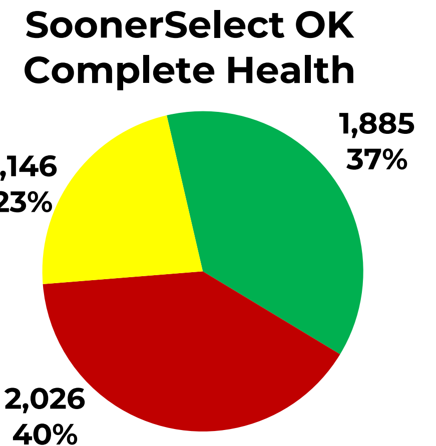
SoonerSelect Aetna



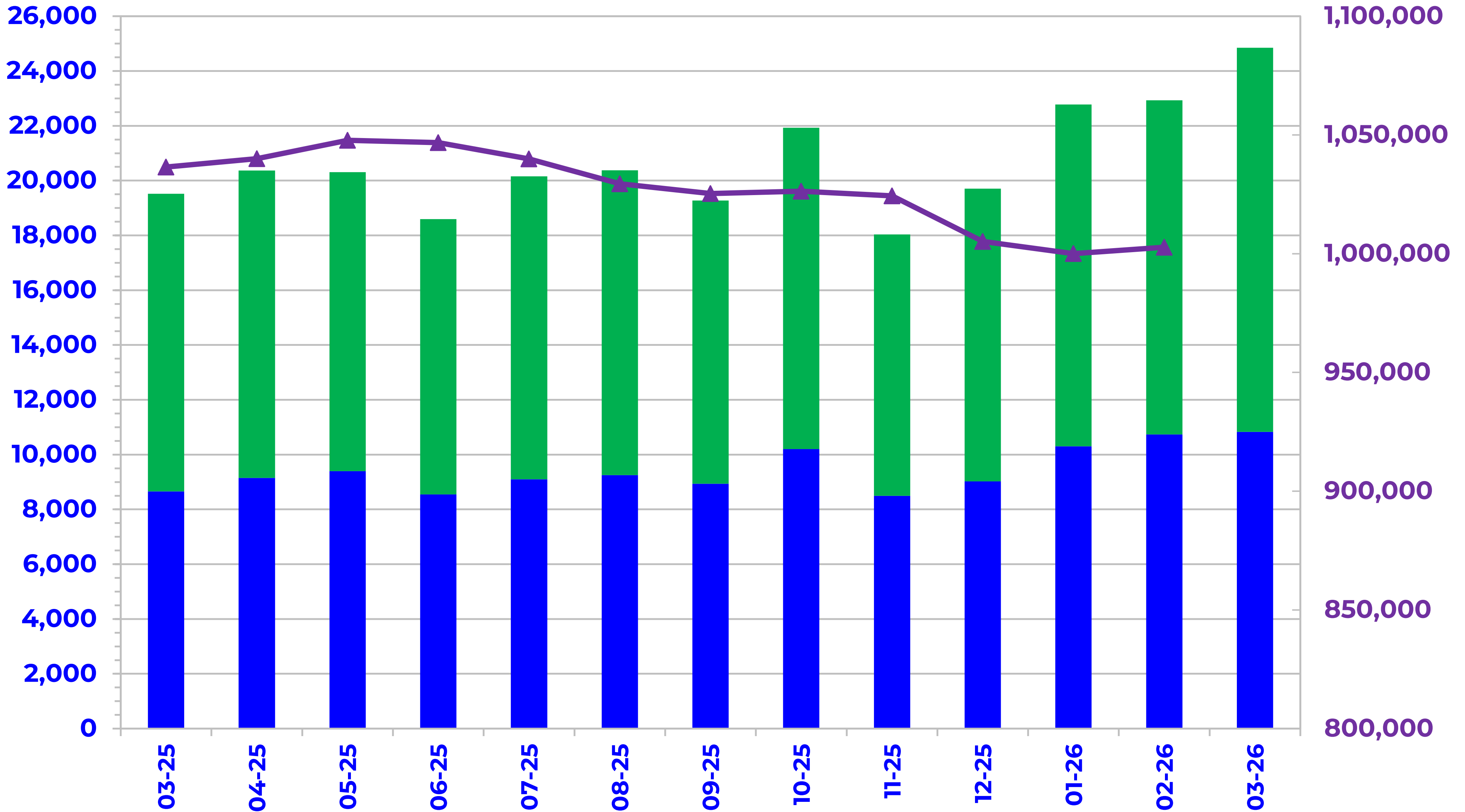
SoonerSelect Humana



SoonerSelect OK Complete Health

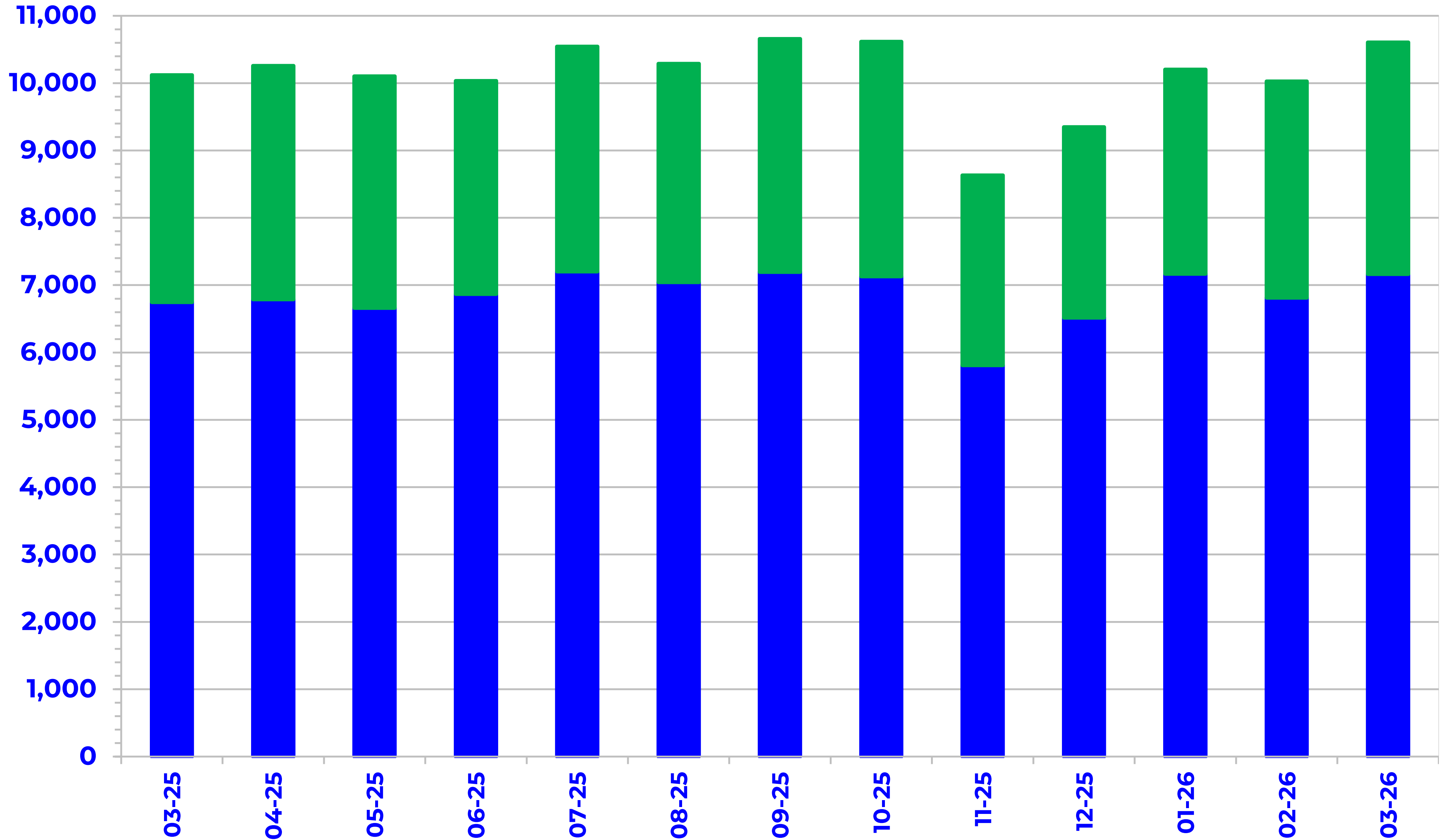


PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: MARCH 2025 – MARCH 2026



SoonerCare FFS Prior Authorization Activity

3/1/2026 Through 3/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	3	1	2	0	179
Amphetamines	942	500	96	346	357
Analgesics - Anti-Inflammatory	255	103	40	112	350
Analgesics - Nonnarcotic	5	0	0	5	0
Analgesics - Opioid	396	153	32	211	136
Androgens - Anabolic	82	13	22	47	338
Anorectal and Related Products	3	0	1	2	0
Anorexiants Non-Amphetamine	1	0	1	0	0
Anthelmintics	15	4	1	10	115
Anti-Infective Agents - Misc.	27	8	6	13	21
Anti-Obesity Agents	404	62	223	119	99
Antianxiety Agents	26	5	0	21	221
Antiasthmatic and Bronchodilator Agents	534	90	112	332	417
Antibiotics	41	12	2	27	145
Anticoagulants	13	3	2	8	360
Anticonvulsants	252	110	18	124	382
Antidepressants	281	82	37	162	483
Antidiabetics	1,584	500	318	766	375
Antidotes and Specific Antagonists	8	2	1	5	360
Antiemetics	24	2	3	19	94
Antifungals	6	3	0	3	107
Antihistamines	27	5	11	11	359
Antihyperlipidemics	63	12	14	37	365
Antihypertensives	57	39	2	16	509
Antimyasthenic/Cholinergic Agents	2	1	0	1	360
Antineoplastics and Adjunctive Therapies	251	152	6	93	178
Antiparkinson and Related Therapy Agents	11	3	1	7	1,091
Antipsychotics/Antimanic Agents	410	163	45	202	356
Antivirals	24	10	4	10	75
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	336	213	27	96	1,001
Beta Blockers	16	7	0	9	881
Calcium Channel Blockers	19	4	2	13	724
Cardiotonics	1	0	0	1	0
Cardiovascular Agents - Misc.	118	57	5	56	564
Contraceptives	36	13	1	22	528
Corticosteroids	11	3	2	6	267
Cough/Cold/Allergy	3	1	1	1	6
Dermatologicals	549	154	160	235	242
Diagnostic Products	36	17	3	16	152
Dietary Products/Dietary Management Products	1	0	1	0	0
Digestive Aids	8	4	0	4	358
Diuretics	17	5	1	11	652
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	9	1	5	3	360
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	191	82	22	87	269

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogens	13	1	0	12	360
Gastrointestinal Agents - Misc.	372	91	94	187	268
Genitourinary Agents - Misc.	8	4	0	4	1,091
Gout Agents	11	6	2	3	482
Hematological Agents - Misc.	14	8	0	6	326
Hematopoietic Agents	44	12	9	23	129
Histamine H3-receptor Antagonist/Inverse Agonists	4	1	1	2	360
Hypnotics/Sedatives/Sleep Disorder Agents	65	10	17	38	202
Laxatives	24	11	2	11	217
Medical Devices and Supplies	307	53	78	176	308
Migraine Products	503	147	147	209	246
Minerals and Electrolytes	11	4	2	5	109
Miscellaneous Therapeutic Classes	95	46	12	37	350
Multivitamins	3	1	0	2	358
Musculoskeletal Therapy Agents	60	2	13	45	191
Nasal Agents - Systemic and Topical	20	2	4	14	192
Neuromuscular Agents	94	44	22	28	352
Ophthalmic Agents	76	18	11	47	226
Other*	73	21	5	47	174
Otic Agents	48	11	10	27	17
Passive Immunizing and Treatment Agents	14	2	1	11	34
Progestins	3	0	1	2	0
Psychotherapeutic and Neurological Agents - Misc.	258	88	49	121	292
Respiratory Agents - Misc.	39	20	4	15	311
Stimulants - Misc.	186	102	18	66	349
Thyroid Agents	13	1	1	11	1,091
Ulcer Drugs/Antispasmodics/Anticholinergics	113	16	15	82	894
Urinary Antispasmodics	73	14	14	45	538
Vaccines	1	1	0	0	179
Vaginal and Related Products	4	0	2	2	0
Vitamins	55	5	40	10	77
Total	**9,702**	**3,341**	**1,804**	**4,557**	
Overrides					
Brand	29	14	4	11	412
Compound	14	13	1	0	16
Dosage Change	185	168	0	17	22
High Dose	1	1	0	0	26
Ingredient Duplication	1	0	0	1	0
Lost/Broken Rx	42	36	3	3	15
MAT Override	2	0	0	2	0
NDC vs Age	141	88	18	35	513
NDC vs Sex	13	10	1	2	359
Nursing Home Issue	64	61	2	1	24
Opioid MME Limit	146	21	10	115	154
Opioid Quantity	17	13	0	4	177
Other	26	16	5	5	10
Prescriber Temp Unlock	2	0	0	2	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Quantity vs Days Supply	391	219	25	147	360
STBS/STBSM	16	8	3	5	87
Step Therapy Exception	6	1	2	3	7
Third Brand Request	28	19	0	9	15
Overrides Total	**1,124**	**688**	**74**	**362**	
Total Regular PAs + Overrides	**10,826**	**4,029**	**1,878**	**4,919**	

Denial Reasons	
Unable to verify required trials.	4,326
Does not meet established criteria.	1,918
Lack required information to process request.	550
Other PA Activity	
Duplicate Requests	1,327
Letters	58,355
No Process	4
Helpdesk Initiated Prior Authorizations	366
PAs Missing Information	356
Pharmacotherapy	76
Changes to Existing PAs	674

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

SoonerSelect Aetna Prior Authorization Activity

3/1/2026 Through 3/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	325	214	94	17	78
Analgesics - Anti-Inflammatory	130	82	26	22	133
Analgesics - Nonnarcotic	11	1	6	4	0
Analgesics - Opioid	125	65	43	17	48
Androgens - Anabolic	58	5	50	3	73
Anorectal and Related Products	6	0	6	0	0
Anthelmintics	7	2	5	0	5
Antianxiety Agents	39	5	6	28	73
Antiasthmatic and Bronchodilator Agents	200	31	128	41	35
Antibiotics	29	2	8	19	19
Anticoagulants	15	2	1	12	0
Anticonvulsants	67	17	18	32	93
Antidepressants	267	67	112	88	114
Antidiabetics	559	149	308	102	77
Antiemetics	24	1	4	19	365
Antifungals	1	0	1	0	0
Antihistamines	33	12	18	3	219
Antihyperlipidemics	49	6	18	25	0
Antihypertensives	20	1	2	17	0
Anti-Infective Agents - Misc.	21	15	2	4	114
Antineoplastics and Adjunctive Therapies	31	11	3	17	78
Anti-Obesity Agents	265	32	213	20	38
Antiparkinson and Related Therapy Agents	3	0	0	3	0
Antipsychotics/Antimanic Agents	166	45	72	49	100
Antivirals	5	0	4	1	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	90	72	18	0	177
Beta Blockers	24	4	1	19	0
Calcium Channel Blockers	13	1	1	11	365
Cardiovascular Agents - Misc.	42	18	13	11	84
Contraceptives	12	5	7	0	0
Corticosteroids	10	9	1	0	359
Cough/Cold/Allergy	1	1	0	0	30
Dermatologicals	332	117	156	59	41
Diagnostic Products	46	26	10	10	90
Dietary Products/Dietary Management Products	1	0	1	0	0
Digestive Aids	1	0	0	1	0
Diuretics	23	0	0	23	0
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	54	30	22	2	119
Estrogens	13	4	3	6	0
Gastrointestinal Agents - Misc.	103	41	46	16	168
Genitourinary Agents - Misc.	3	0	3	0	0
Gout Agents	9	1	3	5	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hematological Agents - Misc.	8	1	1	6	365
Hematopoietic Agents	16	7	8	1	172
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	1	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	37	3	21	13	0
Laxatives	13	3	5	5	0
Medical Devices and Supplies	104	39	47	18	162
Migraine Products	244	92	140	12	93
Minerals and Electrolytes	19	6	2	11	274
Miscellaneous Therapeutic Classes	69	60	9	0	363
Musculoskeletal Therapy Agents	55	4	12	39	74
Nasal Agents - Systemic and Topical	19	0	6	13	0
Neuromuscular Agents	16	15	1	0	355
Ophthalmic Agents	34	9	17	8	122
Other	12	3	5	4	92
Otic Agents	13	2	11	0	0
Passive Immunizing and Treatment Agents	1	1	0	0	0
Pharmaceutical Adjuvants	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	29	7	17	5	106
Respiratory Agents - Misc.	5	4	1	0	243
Stimulants - Misc.	89	60	27	2	103
Thyroid Agents	3	0	1	2	0
Ulcer Drugs/Antispasmodics/Anticholinergics	71	10	22	39	46
Urinary Antispasmodics	23	8	11	4	137
Vaccines	1	1	0	0	184
Vaginal and Related Products	1	0	0	1	0
Vitamins	69	4	64	1	229
****Total**	**4,188**	**1,433**	**1,864**	**891**	

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

Overrides					
Brand	2	2	0	0	365
Other	891	0	0	891	0
Quantity Level Limit	25	25	0	0	413
Refill Too Soon	1	1	0	0	31
Step Therapy Met	4	4	0	0	30
Overrides Total	**923**	**32**	**0**	**891**	

Denial Reason	
Benefit	146
Experimental/Investigational	174
Lack Required Infomation to Process Request	137
Medical Necessity	1,390
Other	17
Other PA Activity	
Duplicate Requests	22
Letters	5,002
No Process	426
Changes to existing PAs	0
PAs missing info	11

*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

3/1/2026 Through 3/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	3	3	0	0	320
Amphetamines	19	4	3	12	274
Analgesics - Anti-Inflammatory	73	54	1	18	319
Analgesics - Nonnarcotic	7	0	1	6	0
Analgesics - Opioid	81	46	13	22	245
Androgens - Anabolic	83	24	44	15	230
Anorectal and Related Products	3	1	0	2	365
Anthelmintics	1	1	0	0	365
Antianxiety Agents	3	2	0	1	275
Antiasthmatic and Bronchodilator Agents	144	66	33	45	233
Antibiotics	8	0	0	8	0
Anticoagulants	4	3	0	1	304
Anticonvulsants	19	8	3	8	348
Antidepressants	77	24	16	37	465
Antidiabetics	349	116	126	107	282
Antiemetics	12	1	2	9	365
Antifungals	4	0	0	4	0
Antihistamines	4	1	0	3	364
Antihyperlipidemics	9	8	0	1	264
Antihypertensives	3	3	0	0	365
Anti-Infective Agents - Misc.	4	4	0	0	365
Antimyasthenic/Cholinergic Agents	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	62	42	1	19	194
Anti-Obesity Agents	296	56	134	106	53
Antiparkinson and Related Therapy Agents	1	0	0	1	0
Antipsychotics/Antimanic Agents	15	0	1	14	0
Antivirals	6	2	3	1	34
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	13	6	1	6	311
Beta Blockers	5	1	0	4	365
Calcium Channel Blockers	2	0	0	2	0
Cardiotonics	2	0	0	2	0
Cardiovascular Agents - Misc.	50	20	6	24	406
Contraceptives	63	21	17	25	179
Corticosteroids	11	5	0	6	237
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	216	117	27	72	252
Diagnostic Products	22	16	1	5	336
Digestive Aids	1	0	0	1	0
Diuretics	5	3	0	2	548
Endocrine and Metabolic Agents - Misc.	49	24	8	17	251
Estrogens	6	0	1	5	0
Gastrointestinal Agents - Misc.	104	57	20	27	213

*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
Genitourinary Agents - Misc.	1	0	0	1	0
Gout Agents	8	5	0	3	365
Hematological Agents - Misc.	3	2	1	0	548
Hematopoietic Agents	26	9	1	16	209
Hypnotics/Sedatives/Sleep Disorder Agents	10	2	1	7	244
Laxatives	3	2	0	1	365
Medical Devices and Supplies	31	15	1	15	938
Migraine Products	175	100	55	20	174
Minerals and Electrolytes	1	0	0	1	0
Miscellaneous Therapeutic Classes	10	6	0	4	304
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	46	13	20	13	341
Nasal Agents - Systemic and Topical	2	0	0	2	0
Neuromuscular Agents	43	14	7	22	115
Nutrients	1	0	0	1	0
Ophthalmic Agents	37	13	6	18	457
Other	16	3	1	12	366
Otic Agents	2	0	0	2	0
Passive Immunizing and Treatment Agents	4	0	0	4	0
Pharmaceutical Adjuvants	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	39	19	3	17	180
Respiratory Agents - Misc.	2	1	0	1	365
Stimulants - Misc.	15	7	3	5	365
Thyroid Agents	1	0	0	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	23	5	5	13	294
Urinary Antispasmodics	23	1	16	6	1,095
Vitamins	56	2	0	54	26
Total	**2,422**	**961**	**582**	**879**	
Overrides					
Dosage Change	149	59	48	42	147
High Dose	1	0	0	1	0
Ingredient Duplication	181	97	50	34	163
NDC vs Age	518	360	17	141	255
NDC vs Sex	1	0	0	1	0
Opioid MME Limit	7	7	0	0	368
Opioid Quantity	10	10	0	0	364
Other	251	75	105	71	100
Quantity vs Days Supply	256	161	40	55	250
STBS/STBSM	680	33	100	547	560
Step Therapy Exception	305	138	87	80	1,382
Overrides Total	**2,359**	**940**	**447**	**972**	
Total Regular PAs + Overrides	**4,781**	**1,901**	**1,029**	**1,851**	

Denial Reasons	
Alternatives Not Met	339
Medical Necessity	690

*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

3/1/2026 Through 3/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	341	168	132	41	1,087
Analgesics - Anti-Inflammatory	173	81	52	40	982
Analgesics - Nonnarcotic	19	0	17	2	0
Analgesics - Opioid	390	152	143	95	371
Androgens - Anabolic	84	5	64	15	1,095
Anorectal and Related Products	6	2	3	1	365
Anorexiants Non-Amphetamine	4	0	1	3	0
Anthelmintics	5	2	2	1	365
Antianxiety Agents	21	5	13	3	530
Antiasthmatic and Bronchodilator Agents	328	116	135	77	661
Antibiotics	23	8	7	8	501
Anticonvulsants	84	30	36	18	933
Antidepressants	176	53	100	23	854
Antidiabetics	803	357	310	136	973
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antidotes and Specific Antagonists	4	1	3	0	1,095
Antiemetics	27	7	9	11	252
Antifungals	6	2	3	1	292
Antihistamines	14	1	12	1	1,095
Antihyperlipidemics	35	5	18	12	1,095
Antihypertensives	10	4	6	0	1,095
Anti-Infective Agents - Misc.	9	3	1	5	222
Antineoplastics and Adjunctive Therapies	87	47	11	29	513
Anti-Obesity Agents	300	31	149	120	447
Antiparkinson and Related Therapy Agents	1	1	0	0	1,095
Antipsychotics/Antimanic Agents	172	67	60	45	966
Antivirals	4	1	0	3	279
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	121	72	35	14	1,077
Beta Blockers	2	1	1	0	365
Calcium Channel Blockers	12	5	5	2	609
Cardiovascular Agents - Misc.	39	14	9	16	995
Contraceptives	33	12	14	7	602
Corticosteroids	8	1	2	5	365
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	399	152	125	122	564
Diagnostic Products	30	16	10	4	729
Dietary Products/Dietary Management Products	1	0	1	0	0
Digestive Aids	3	2	0	1	1,095
Diuretics	2	1	0	1	302
Endocrine and Metabolic Agents - Misc.	56	22	28	6	996
Estrogens	31	16	9	6	1,016
Gastrointestinal Agents - Misc.	94	26	52	16	804
Genitourinary Agents - Misc.	1	0	0	1	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gout Agents	8	1	5	2	1,095
Hematological Agents - Misc.	9	4	4	1	890
Hematopoietic Agents	33	8	15	10	477
Histamine H3-Receptor Antagonist/Inverse Agonists	3	2	1	0	1,095
Hypnotics/Sedatives/Sleep Disorder Agents	33	6	21	6	258
Laxatives	25	7	9	9	298
Medical Devices and Supplies	134	75	27	32	1,042
Migraine Products	194	69	99	26	660
Minerals and Electrolytes	10	2	2	6	299
Miscellaneous Therapeutic Classes	21	12	6	3	684
Multivitamins	2	1	0	1	1,095
Musculoskeletal Therapy Agents	33	8	16	9	537
Nasal Agents - Systemic and Topical	12	3	7	2	316
Neuromuscular Agents	13	8	2	3	346
Nutrients	1	0	0	1	0
Ophthalmic Agents	48	12	28	8	352
Other	58	11	10	37	483
Otic Agents	24	3	17	4	365
Psychotherapeutic and Neurological Agents - Misc.	48	13	27	8	973
Respiratory Agents - Misc.	5	2	2	1	1,095
Stimulants - Misc.	151	76	48	27	883
Thyroid Agents	30	15	4	11	516
Ulcer Drugs/Antispasmodics/Anticholinergics	45	20	19	6	748
Urinary Antispasmodics	35	16	14	5	448
Vaccines	1	1	0	0	365
Vaginal and Related Products	1	0	0	1	0
Vasopressors	1	1	0	0	300
Vitamins	119	20	65	34	1,095
****Total**	**5,057**	**1,885**	**2,026**	**1,146**	

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

Denial Reasons	
Medical Necessity	2,026

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

Appendix C

SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

Oklahoma Health Care Authority
April 2026

SoonerPsych Prescriber Mailing Summary

The SoonerPsych program is an educational quarterly mailing to prescribers of antipsychotic (AP) medications. Each mailing includes a gauge showing how their prescribing compares to other SoonerCare prescribers of these medications and how their prescribing potentially differs from evidence-based recommendations. Each mailing also includes an informational page with evidence-based material related to the mailing topics. Mailing topics defined below are comprised of 5 modules: adherence, diagnosis, metabolic monitoring, poly-pharmacy, and opioid co-prescribing.

The SoonerPsych program has been using a "report card" format since April 2014 to evaluate use of atypical antipsychotic (AAP) medications. Beginning in April 2016, educational letters were sent to a consistent cohort of prescribers with all modules included in each mailing. Effective January 2017, data collection was expanded from a previous research-based approach to include additional diagnosis fields and monitoring fields (lipids and glucose) in order to provide a more clinically meaningful description for prescribers.

The mailing cohort list has historically been updated approximately every 2 years, and cohort prescribers receive 4 letters per year to more completely summarize their SoonerCare members taking these medications and to facilitate more conveniently following changes and improvements in their patients and prescribing patterns over time. However, the transition to a managed care model and changes to monitoring recommendations have prompted annual updates to the prescriber cohorts. To be included in a cohort, each prescriber must have a minimum number of SoonerCare members taking AP medications:

- January 2024-October 2024: at least 7 members
- January 2025-October 2025: at least 10 members
- January 2026-present: at least 11 members

Since July 2024, the SoonerPsych mailings have included data only for those members in the SoonerCare fee-for-service (FFS) population. Members covered by other health plans are excluded from all module calculations and from the patient lists included in each mailing.

Effective January 2025, data collection was expanded further to include co-prescribing of opioids in response to national guidance to state Medicaid

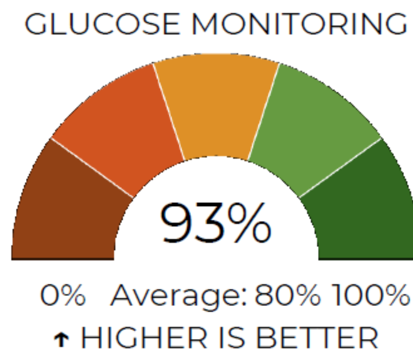
agencies from the Centers for Medicare & Medicaid Services (CMS). Effective January 2026, the list of AAP medications was expanded to include all AP medications (i.e., both typical and AAP) since the available evidence does not differentiate between the 2 classes for any of the topics covered in the SoonerPsych mailings. The January 2026 expansion also included medications whose mechanisms of action, and therefore, potential care concerns, define them as AP medications, even though they are often used for non-mental health treatment strategies (e.g., chlorpromazine, prochlorperazine). The following list defines the terms used for prescriber comparison within each module of the current SoonerPsych mailing:

- **Medication Adherence:** Members are considered adherent when their proportion of days covered (PDC), as calculated from pharmacy claims history for AP medications, is ≥80%. The prescriber adherence gauge shows the percentage of members receiving AP medications who are adherent during the most recent 12-month period.
- **Target Diagnosis:** Diagnoses with a strong indication for prescribing an AP medication include: schizophrenia, bipolar disorder, delusional disorders, other nonorganic psychoses, autism spectrum disorder, mood disorder, obsessive-compulsive disorder, and severe depression with or without psychotic features. The prescriber diagnosis gauge shows the percentage of members receiving AP medications who had ≥1 medical claim for ≥1 of the above diagnoses within the most recent 12-month period.
- **Metabolic Monitoring:** Metabolic monitoring includes both lipid and glucose monitoring. Lipid monitoring has historically been recommended for members receiving AP medications and who also have a diagnosis of hyperlipidemia. Effective January 2026, the requirement of a diagnosis of hyperlipidemia was removed based on evolving best practice recommendations of lipid monitoring for all members receiving AP medications, regardless of lipid-related diagnoses. Glucose monitoring remains a recommended best practice for all members receiving AP medications. The prescriber metabolic monitoring gauges show the percentage of members receiving AP medications whose most recent 12-month medical claims history includes the recommended lipid and glucose testing.
- **Poly-Pharmacy:** Poly-pharmacy is defined as having a pharmacy claims history which includes concurrent use of 2 or more AP medications for >90 days. The prescriber poly-pharmacy gauge shows the percentage of members receiving AP medications whose most recent 6-month history includes poly-pharmacy.
- **Opioid Co-Prescribing:** Opioid co-prescribing is defined as having a pharmacy claims history which includes concurrent use of both an opioid and an AP medication for >90 days. The opioid gauge shows the

percentage of members receiving AP medications whose most recent 12-month medical claims history includes opioid co-prescribing.

SoonerPsych Example Gauge

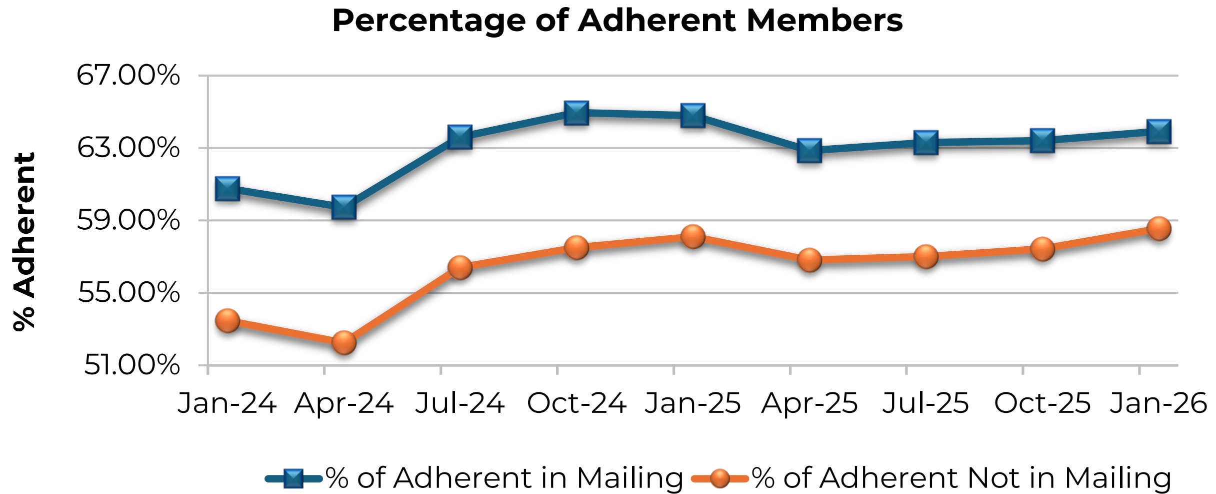
Each gauge includes the individual prescriber's performance in relation to the specific module, the average performance of other SoonerCare prescribers for comparison, and a statement summarizing the improvement metric for the specific module. The following is an example of one of the gauges included in the mailings.



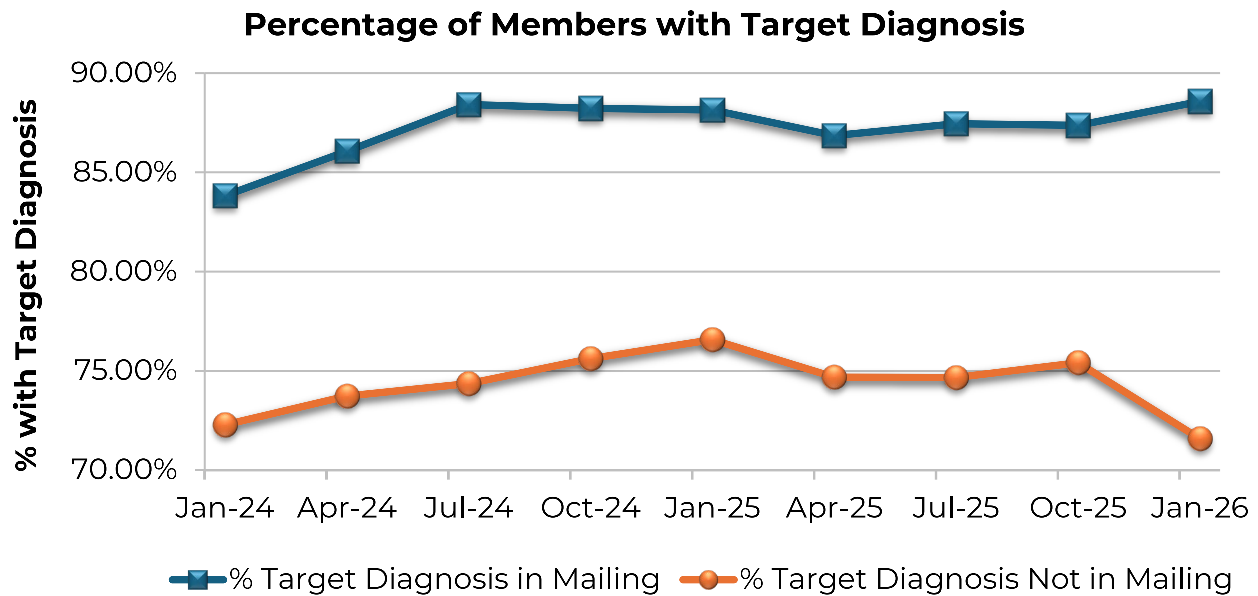
SoonerPsych Trends

The following graphs show the SoonerPsych trends for medication adherence, diagnosis, metabolic monitoring, poly-pharmacy, and opioid co-prescribing from January 2024 to January 2026. Members whose prescribers were included in the SoonerPsych mailings are designated separately from those members whose prescribers were not included in the mailings. It is important to note that the SoonerPsych data has been adjusted for outliers, based on input from the Drug Utilization Review (DUR) Board, to show a more meaningful comparison of prescribers included in the mailing and prescribers not included in the mailing.

The following graph shows the SoonerPsych trends for the percentage of adherent members. Members are considered adherent if their PDC was ≥80%. Please note, the vertical axis starts at 51% of members in order to reflect small changes.

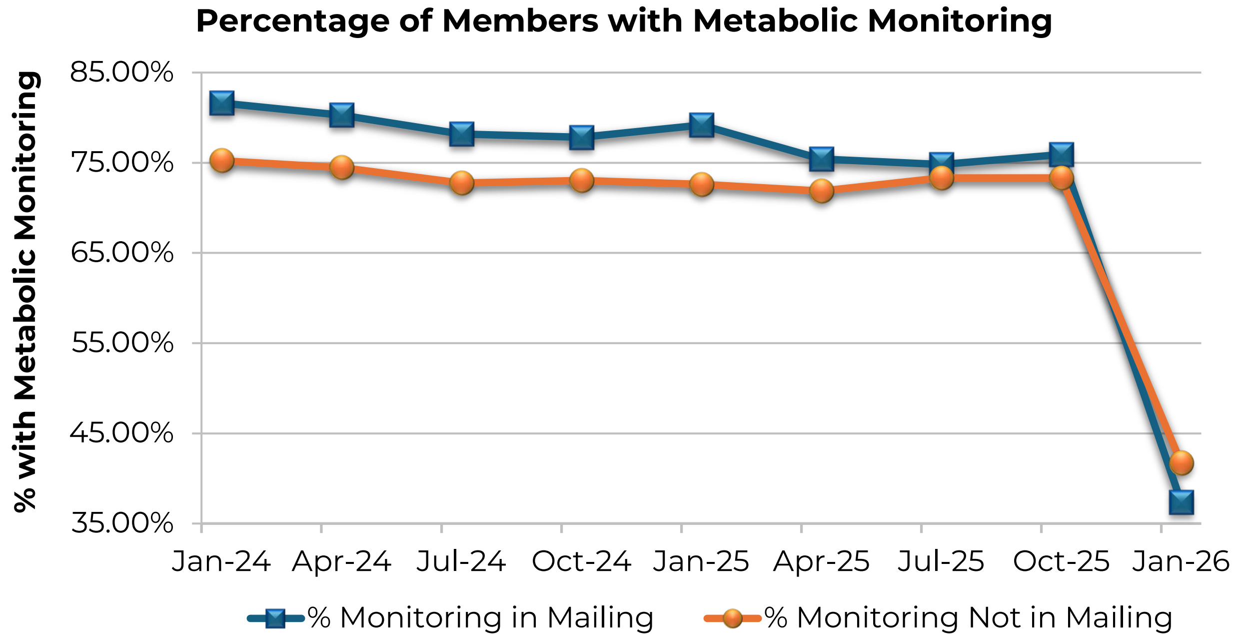


The following graph shows the SoonerPsych trends for the percentage of members having a diagnosis with a strong indication for prescribing an AP medication. Please note, the vertical axis starts at 70% of members in order to reflect small changes.

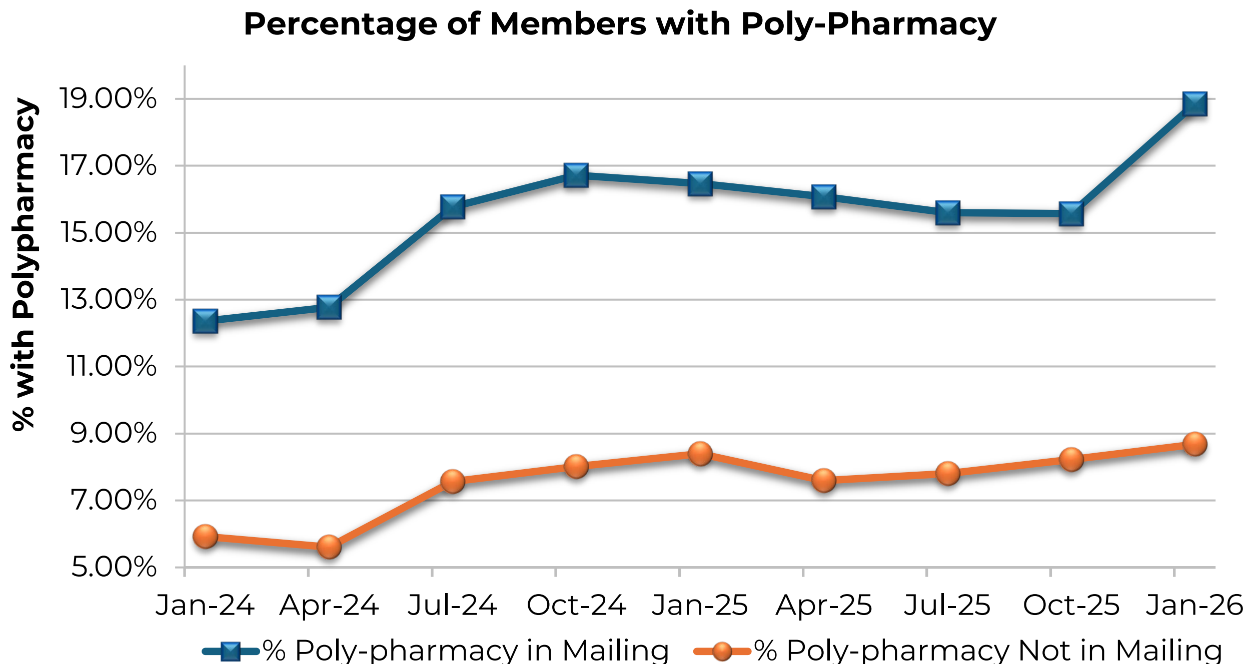


The following graph shows the SoonerPsych trends for the percentage of members who received the recommended metabolic monitoring (i.e., lipid and glucose monitoring) while on an AP medication. As noted above, prior to January 2026, a diagnosis of hyperlipidemia was required to assess lipid monitoring percentages. This requirement was removed based on current best practice recommendations, as lipid monitoring is now recommended for all members receiving AP medications, regardless of lipid-related diagnoses. The expanded pool of patients now eligible for lipid monitoring assessment is

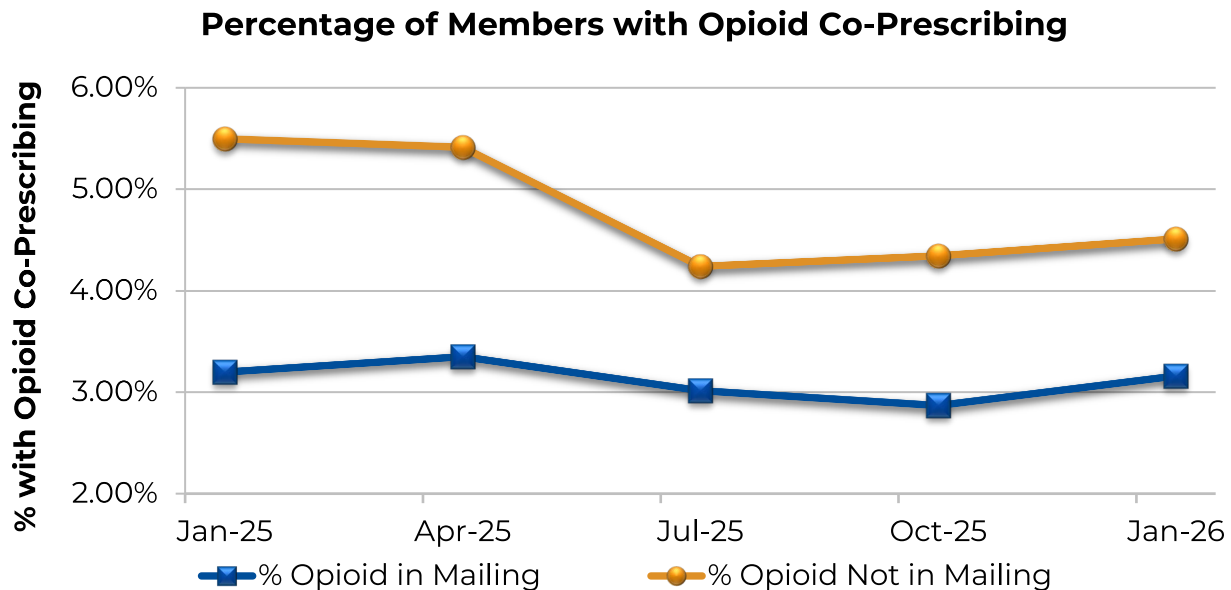
responsible for the sharp decline in metabolic monitoring rates. Please note, the vertical axis starts at 35% of members in order to reflect small changes.



The following graph shows the SoonerPsych trends for the percentage of members with poly-pharmacy. Please note, the vertical axis starts at 5.0% of members in order to reflect small changes, and a lower percentage is a better outcome, indicating less prescribing of concomitant AP medications.



The following graph shows the SoonerPsych trends for the percentage of members with opioid co-prescribing. Please note, the vertical axis starts at 2.0% of members in order to reflect small changes, and a lower percentage is a better outcome, indicating less prescribing of concomitant opioid and AP medications.



Pediatric SoonerPsych Prescriber Mailing Summary

The Oklahoma Health Care Authority (OHCA) is also responsible for establishing and maintaining an additional program to monitor and manage appropriate utilization of AP medications specifically for children, including children in the foster care system, as part of a requirement by CMS. To accomplish these purposes, the College of Pharmacy developed the Pediatric SoonerPsych program in October 2019. Pediatric SoonerPsych mailings are sent twice per year to prescribers caring for pediatric members receiving AP medications. Historically, specific prescriber focus has alternated on a semi-annual basis between all children and those children in the foster care system. With the transition to a managed care model, the number of pediatric foster care members in the fee-for-service population has decreased dramatically. Since June 2024, prescriber focus has been all pediatric members but with special attention given to highlight members in the foster care system. Pediatric SoonerPsych evaluates prescribing patterns and medical claims across 5 topics as described above: medication adherence, target diagnosis, metabolic monitoring, poly-pharmacy, and opioid co-prescribing. Pediatric SoonerPsych inclusion criteria are limited to prescribers whose prescribing of AP medications for pediatric SoonerCare members varies significantly when compared to other SoonerCare prescribers in 1 or more of the 5 topics listed above.

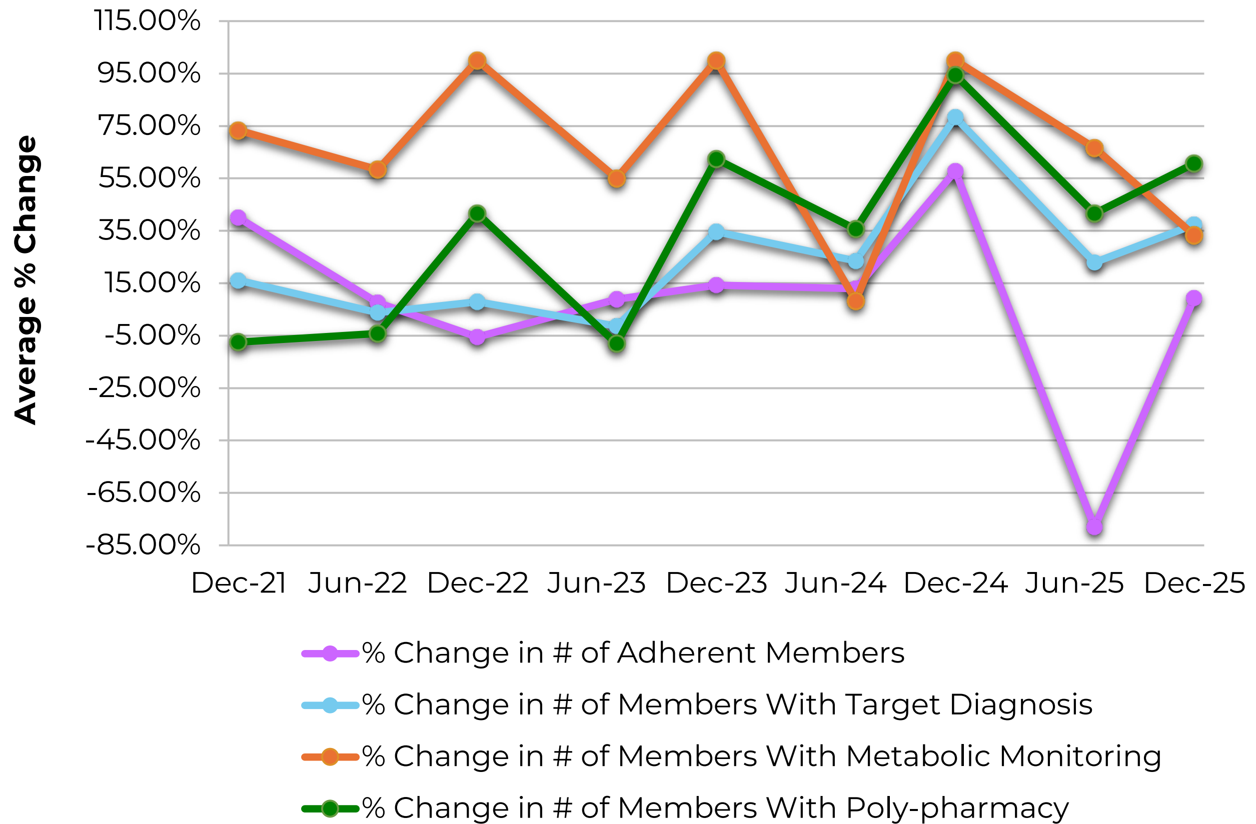
Unlike the SoonerPsych quarterly mailings, Pediatric SoonerPsych prescribers receive an educational mailing and member list if they are the last prescriber of record for an AP medication, and they are in the most concerning cohort of prescribers for the most recent time period. The most concerning cohort is determined separately for each module of the Pediatric SoonerPsych mailing, and at least 5 prescribers for each module are designated for the cohort.

Following receipt of the Pediatric SoonerPsych mailings, prescribers are offered a virtual or in-person visit by an academic detailing (AD) pharmacist, and they are encouraged to utilize several other resources. Historically, those resources have included consultation with an OHCA child psychiatrist and participation in the pediatric psychiatry Project ECHO (Extension for Community Health Care Outcomes) for medical education and care management and in the Oklahoma Statewide Psychiatry Access, Resources, and Knowledge (OKSPARK). Additional services through OHCA Care Management and Behavioral Health Care Management have also been encouraged. Historically, prescribers meeting criteria for pediatric members received mailings and educational offerings each December, and prescribers meeting criteria for pediatric members in the foster care system received mailings and educational offerings each June. Since June 2024, cohort prescribers receive these offerings in both June and December.

Pediatric SoonerPsych Trends

Across all topics, an overall trend towards more evidence-based prescribing has been observed. However, improvement in the area of adherence has historically proved difficult to measure with certainty. The Pediatric SoonerPsych educational materials emphasize the appropriate use of AP medications, within the clinical setting of appropriate diagnoses. Lowering the dose and/or frequency (i.e., tapering) of these medications with eventual discontinuation is suggested for members who do not meet diagnostic criteria. With this in mind, some intentional medication tapering may be represented as poor adherence.

The following graph shows the Pediatric SoonerPsych trends for the average percentage change during the 6-month post-AD period in number of adherent members, members with target diagnoses, members with recommended metabolic monitoring, and members with poly-pharmacy. Please note, the vertical axis starts at -85%, and a higher percentage change is a better outcome.



To date, only 1 provider had 1 pediatric member with concomitant opioid and AP medications for >90 days. Since 2019, nearly 125 prescribers have received the Pediatric SoonerPsych mailings, AD, and additional program resources. Each of the prescribers met inclusion criteria for 1 to 13 cohorts, with an average of 2.18 cohort inclusions per prescriber in the 13 mailings from 2019 to 2025.

Conclusions

SoonerPsych:
Recent SoonerPsych trends comparing January 2023 through January 2025 indicate overall increases in the percentage of adherent members and the percentage of members with a target diagnosis. Adherence improvements were similar to the improvements demonstrated by prescribers not in the mailings. Diagnosis improvements exceeded the improvements of prescribers not in the mailing. Notably, the inclusion of additional AP medications does not seem to have resulted in any decrease in the percentage of patients with a target diagnosis. While the percentage of members with metabolic monitoring appears to have recently worsened dramatically, the trend is due to expanding the defined population. The expanded population base is expected to lead to increased opportunities for

improved patient care. Changes in the trend will be more meaningful with future data reflecting the recent criteria changes. Similarly, the poly-pharmacy trend appears to have recently worsened, although to a lesser degree than the metabolic monitoring trend. The polypharmacy trend was improving prior to the inclusion of additional AP medications. Recent changes to a more comprehensive definition of AP medications are expected to lead to improved patient care. As noted above, prescriber data has been adjusted for outliers since 2019. Continuing to adjust the data for outliers and following the results of the new prescriber list over time may provide more opportunities for additional prescriber-specific interventions.

Overall, results indicate consistently receiving evidence-based educational mailings reminds prescribers of evidence-based practices and reduces some potentially inappropriate prescribing. Recent changes to the mailing format (including all modules in each mailing, mailing to consistent prescribers, and updating the prescriber mailing list), as well as expanding the data collection process and adjusting the data for outliers, are intended to sustain improvements and reduce waning interventions.

Pediatric SoonerPsych:
Since the initiation of the Pediatric SoonerPsych program, trends indicate overall improvements in the areas of diagnosis, metabolic monitoring, and poly-pharmacy. Improvements in the area of adherence are consistently difficult to determine, owing to the likely co-occurrences of true poor adherence and intentional tapering. The greatest improvements continue to be seen in the area of poly-pharmacy. Overall results indicate the Pediatric SoonerPsych focused mailing and educational offerings are likely leading to improvements in AP medication management resulting in a lower risk of overprescribing and increased rates of recommended metabolic monitoring.

Summary

The College of Pharmacy will continue to work with OHCA to improve educational mailings with the goal of improving the quality of care for SoonerCare members utilizing AP medications. The College of Pharmacy will also continue working to identify prescribers who may benefit from Pediatric SoonerPsych activities with the goal of promoting evidence-based use of AP medications for pediatric members. Future results of the SoonerPsych and Pediatric SoonerPsych activities will be reviewed with the DUR Board as they become available.

Appendix D

Vote to Prior Authorize Nypozi™ (Filgrastim-txid) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers

Oklahoma Health Care Authority
April 2026

Market News and Updates[1,2]

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

- **June 2024:** The FDA approved Nypozi™ (filgrastim-txid) as a biosimilar to Neupogen® (filgrastim) for the same FDA-approved indications. According to the FDA's National Drug Code (NDC) Directory, Nypozi™, a biosimilar of Neupogen® (filgrastim), began being marketed in September 2025.

Recommendations

The College of Pharmacy recommends the prior authorization of Nypozi™ (filgrastim-txid) with the following criteria (changes shown in red):

Nivestym® (Filgrastim-aafi), Nypozi™ (Filgrastim-txid), and Releuko® (Filgrastim-ayow) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), Neupogen® (filgrastim), or Zarxio® (filgrastim-sndz) 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.

The College of Pharmacy also recommends removing the prior authorization for Udenyca® (pegfilgrastim-cbqv) as a medical benefit and recommends updating the approval criteria for the pegfilgrastim products based on net costs (changes shown in red):

~~Neulasta® (Pegfilgrastim),~~ Nyvepria® (Pegfilgrastim-apgf), Stimufend® (Pegfilgrastim-fpgk), and Udenyca® (Pegfilgrastim-cbqv) Approval Criteria:

1. An FDA approved diagnosis; and

2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® (pegfilgrastim), Neulasta® Onpro® (pegfilgrastim) as a medical only benefit, ~~Nyvepria® (pegfilgrastim-apgf),~~ Udenyca® (pegfilgrastim-cbqv) as a medical only benefit, or Ziextenzo® (pegfilgrastim-bmez) 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. Neulasta® Onpro® (pegfilgrastim) and Udenyca® (pegfilgrastim-cbqv) ~~and Nyvepria® (pegfilgrastim-apgf)~~ will be covered as a medical only benefit without prior authorization.

Lastly, the College of Pharmacy recommends updating the approval criteria for Rolvedon® (eflapegrastim-xnst) and Ryzneuta® (efbemalenograstim alfa-vuxw) based on net costs (changes shown in red):

Rolvedon® (Eflapegrastim-xnst) and Ryzneuta® (Efbemalenograstim Alfa-vuxw) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® (pegfilgrastim), Neulasta® Onpro® (pegfilgrastim) as a medical only benefit, ~~Nyvepria® (pegfilgrastim-apgf),~~ Udenyca® (pegfilgrastim-cbqv) as a medical only benefit, or Ziextenzo® (pegfilgrastim-bmez) must be provided; and
3. Neulasta® Onpro® (pegfilgrastim) and Udenyca® (pegfilgrastim-cbqv) ~~and Nyvepria® (pegfilgrastim-apgf)~~ will be covered as a medical only benefit without prior authorization.

[1] Nypozi™ (Filgrastim-txid) – New Biosimilar Approval. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval_nypozi_2024-0703.pdf. Issued 06/28/2024. Last accessed 03/17/2026.
[2] U.S. Food and Drug Administration. National Drug Code Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/. Last accessed 03/17/2026.

Appendix E

Vote to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt)

Oklahoma Health Care Authority
April 2026

Market News and Updates[1]

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

- **December 2025:** The FDA approved Fesilty™ (fibrinogen, human-chmt) for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (CFD), including hypo- or afibrinogenemia.

Fesilty™ (Fibrinogen, Human-chmt) Product Summary[2,3]

Therapeutic Class: Human blood coagulation factor

Indication(s): Treatment of acute bleeding episodes in pediatric and adult patients with CFD, including hypo- or afibrinogenemia

- **Limitation(s) of Use:** Fesilty™ is not indicated for dysfibrinogenemia.

How Supplied: Sterile, lyophilized, white powder for solution for intravenous (IV) injection

- Fesilty™ is supplied in a kit containing 1 single-dose vial containing nominally 1 gram of human fibrinogen, (1) 50mL vial of sterile water for injection, and 1 sterile transfer system.
- The actual amount of fibrinogen in milligrams per vial is printed on the vial label and carton.

Dosing and Administration:

- Fesilty™ is for IV use after reconstitution only.
- The dose of Fesilty™ should be calculated in mg of fibrinogen per kg of body weight (BW) for each patient individually based on age, location and extent of the bleeding, plasma level of fibrinogen (mg/dL), and clinical condition of the patient.
- See the full *Prescribing Information* for calculations based on age when the baseline fibrinogen level is known and frequency and duration of dosing.
- When the baseline plasma fibrinogen level is not known, the recommended dose is 70mg/kg BW for patients of all ages.
- The target plasma fibrinogen level is 100mg/dL for minor bleeding and 150mg/dL for major bleeding.

Efficacy: The efficacy of Fesilty™ for on-demand treatment (ODT) and on-demand prophylaxis (ODP) was studied in an open-label, single arm, multicenter trial in 36 pediatric and adult patients with congenital hypo- or afibrinogenemia.

- Key Inclusion Criteria:
  - Known congenital afibrinogenemia or severe congenital hypofibrinogenemia
  - Plasma fibrinogen activity ≤0.5g/L and antigen ≤0.5g/L
- Key Exclusion Criteria:
  - Known dysfibrinogenemia phenotype or bleeding disorders other than CFD
  - History of esophageal variceal bleeding
  - Thrombotic event ≤6 months before enrollment
  - Inhibitory antibodies to fibrinogen
  - Treatment with fibrinogen-containing product or concomitant medication relevantly interacting with the coagulation system ≤2 weeks before study drug administration
- Intervention(s): All patients were given Fesilty™ as a single or repetitive IV infusion(s) for ODP/ODT of bleeding events.
  - The dose given was based on individual BW and fibrinogen levels.
  - The mean dose for 175 bleeding events was 70.1mg/kg for adults and 75.8mg/kg for pediatric patients.
- Endpoint(s):
  - Overall hemostatic response (OHR) based on a 4-point scale assessed by the investigator as excellent, good, moderate, or none
    - Good and excellent ratings were classified as successful
  - Mean change in maximum clot firmness (MCF) at 1 hour after infusion
- Results:
  - A total of 175 bleeding events (122 minor and 53 major) were treated with Fesilty™, with the majority being in adults (92 events) and a mean of 4.9 bleeding events per patient.
  - OHR was considered successful in 98.9% of adult patients and 100% of pediatric patients.
    - OHR was reported as excellent in 150 bleeding events (86%), good in 23 events (13%), and moderate in 2 events (1%).
  - The mean change in MCF was 10.76mm at 1 hour after Fesilty™ infusion.

Cost: Cost information for Fesilty™ is not yet available.

Recommendations

The College of Pharmacy recommends the prior authorization of Fesilty™ (fibrinogen, human-chmt) with the following criteria (shown in red):

Fesilty™ (Fibrinogen, Human-chmt) Approval Criteria:

1. An FDA approved diagnosis of congenital fibrinogen deficiency, including afibrinogenemia or hypofibrinogenemia; and
2. Member must not have dysfibrinogenemia; and
3. Documented plasma fibrinogen activity ≤0.5g/L and antigen ≤0.5g/L; and
4. Fesilty™ must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of congenital fibrinogen deficiency; and
5. A patient-specific, clinically significant reason why the member cannot use RiaSTAP® [fibrinogen concentrate (human)] or Fibryga® [fibrinogen (human)], which are available without prior authorization, must be provided; and
6. Fesilty™ will not be used concomitantly with RiaSTAP® or Fibryga®; and
7. Fesilty™ will be used for the treatment of acute bleeding or for the perioperative management of bleeding; and
8. Approval lengths will be based on duration of need.

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[1] Grifols. Grifols Receives US FDA Approval for New Fibrinogen Concentrate, Fesilty™ (Fibrinogen, Human-chmt). Available online at: https://www.grifols.com/en/view-news/-/news/grifols-receives-us-fda-approval-for-new-fibrinogen-concentrate-fesiltytm-fibrinogen-human-chmt. Issued 12/19/2025. Last accessed 03/17/2026.

[2] Fesilty™ (Fibrinogen, Human-chmt) Prescribing Information. Grifols Therapeutics. Available online at: https://www.fda.gov/media/190227/download?attachment. Last revised 12/2025. Last accessed 03/17/2026.

[3] Khayat C, El-Beshlawy A, Omar N, et al. Efficacy and Safety of Prophylaxis and Treatment of Bleeding Events with A Novel Fibrinogen Concentrate from Human Plasma in Patients with Congenital Fibrinogen Deficiency. *Thrombosis Research* 2026; 259:109616. doi: 10.1016/j.thromres.2026.109616.

Appendix F

Vote to Prior Authorize Daybue® Stix (Trofinetide Packet), Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide) and Update the Approval Criteria for the Growth-Related Disorder Medications

Oklahoma Health Care Authority
April 2026

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

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

- **March 2025:** The FDA approved Vykat™ XR (diazoxide choline ER) for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).
- **July 2025:** The FDA approved Skytrofa® (lonapegsomatropin-tcgd) for a new indication for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD). Previously, Skytrofa® was only FDA approved for use in pediatric patients.
- **September 2025:** The FDA approved Palsonify™ (paltusotine) for the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option.
- **December 2025:** The FDA approved Daybue® Stix (trofinetide) for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. This is a new formulation of trofinetide available as powder packets in 5,000mg, 6,000mg, and 8,000mg strengths. The powder contained in the packets must be dissolved in cold to room temperature water or a water-based beverage (e.g., juice, tea, lemonade, limeade, liquid hydration) to form an oral solution prior to administration. The recommended dosing for Daybue® Stix is the same as the recommended dosing for Daybue® (trofinetide) oral solution, which is available in 450mL bottle. The cost of Daybue Stix is $612.28 for each 5,000mg packet, $734.73 for each 6,000mg packet, or $979.64 for each 8,000mg packet.
- **February 2026:** The FDA approved Yuviwel® (navepegritide) to increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses.
- **February 2026:** The FDA approved Sogroya® (somapacitan-beco) for 3 new pediatric indications for treatment of patients 2.5 years of age and older with: short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age, growth failure associated with Noonan syndrome (NS), and idiopathic short stature (ISS).

Palsonify™ (Paltusotine) Product Summary[8]

Therapeutic Class: Somatostatin receptor agonist

Indication(s): Treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option

How Supplied: 20mg and 30mg oral tablets

Dosing and Administration:

- The recommended initial dosage is 40mg [(2) 20mg tablets] once daily.
- Palsonify™ should be taken orally once daily with water on an empty stomach, at least 6 hours after a meal (e.g., after overnight fasting) and at least 1 hour before the next meal.
- During the initiation period, the dose may temporarily be reduced to 20mg once daily if needed, based on tolerability. Once adverse reactions have resolved, the 40mg once daily dose should be resumed.
- After 2 to 4 weeks on the 40mg once daily dose, the dose may be titrated to 60mg once daily based on insulin-like growth factor 1 (IGF-1) levels.
- Additional dosage modifications may be required for drug interactions, including concomitant use with strong or moderate CYP3A4 inducers or proton pump inhibitors (PPIs).

Efficacy: The efficacy of Palsonify™ was evaluated in 2 randomized, double-blind, parallel group, placebo-controlled studies (Study 1 and Study 2). Study 1 enrolled 111 patients while Study 2 enrolled 58 patients.

- Key Inclusion Criteria:
  - Study 1:
    - 18 years of age or older
    - Confirmed diagnosis of acromegaly
    - Biochemically uncontrolled at time of randomization (including patients who were treatment-naïve, off acromegaly medications for at least 4 months before screening, or washed out of treatment during screening)
  - Study 2:
    - 18 years of age or older
    - Confirmed diagnosis of acromegaly
    - Previously biochemically controlled on a stable, effective dose of octreotide or lanreotide depot injections for at least 12 weeks
- Intervention:
  - In both studies, patients were randomized 1:1 to receive paltusotine or placebo once daily. In Study 2, the first dose of the study drug

was administered when the patient's next dose of octreotide or lanreotide was due.

- Primary Endpoint(s):
  - Study 1: Proportion of patients achieving biochemical control, defined as IGF-1 level ≤1x upper limit of normal (ULN) at week 24
  - Study 2: Proportion of patients with biochemical response maintenance, defined as IGF-1 ≤1x ULN at week 36
- Results:
  - Study 1: Biochemical control was achieved by 56% of patients who received paltusotine compared to 5% of patients who received placebo (P<0.0001).
  - Study 2: Biochemical response was maintained in 83% of patients who received paltusotine compared to 4% of patients who received placebo (P<0.0001).

Cost Comparison:

Product	Cost Per Unit	Cost Per Month⁺	Cost Per Year
Palsonify™ (paltusotine) 30mg tablet	**$402.75**	**$24,165.00**	**$289,980.00**
Signifor® LAR (pasireotide) 60mg vial	$21,758.90	$21,758.90	$282,865.70
Mycapssa® (octreotide DR) 20mg capsule	$126.16	$15,139.20	$181,670.40
octreotide acetate ER 20mg vial (generic)	$3,983.40	$7,966.80	$103,568.40
lanreotide acetate depot 120mg/0.5mL PFS (generic)	$8,493.12	$4,246.56	$55,205.28

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or Specialty Pharmaceutical Allowable Cost (SPAC).
⁺Cost per month based on the maximum FDA approved dose for each product: 60mg daily for Palsonify™, 60mg every 4 weeks for Signifor® LAR, 80mg daily for Mycapssa®, 40mg every 4 weeks for octreotide ER, and 120mg every 4 weeks for lanreotide depot
Unit = each capsule, tablet, vial, or mL
DR = delayed-release; ER = extended-release; PFS = prefilled syringe

Vykat™ XR (Diazoxide Choline ER) Product Summary[9,10]

Indication(s): Treatment of hyperphagia in adults and pediatric patients 4 years of age and older with PWS

How Supplied: 25mg, 75mg, and 150mg ER tablets

Dosing and Administration:

- Administered orally once daily based on weight:

Weight	Recommended Once Daily Dosage			
	Starting Dosage Weeks 1 and 2	Titration Dosage Weeks 3 and 4	Titration Dosage Weeks 5 and 6	Target Maintenance Dosage
20kg to <30kg	25mg	50mg	75mg	100mg
30kg to <40kg	75mg	150mg	150mg	150mg
40kg to <65kg	75mg	150mg	225mg	225mg
65kg to <100kg	150mg	225mg	300mg	375mg
100kg to <135kg	150mg	300mg	375mg	450mg
≥135kg	150mg	300mg	450mg	525mg

- Tablets should be swallowed whole and should not be split, crushed, or chewed.
- Vykat™ XR should not be substituted with diazoxide oral suspension because the pharmacokinetic profiles are different.
- Prior to initiating treatment, fasting plasma glucose and hemoglobin A1C (HbA1c) should be tested, and blood glucose should be optimized in patients who have hyperglycemia.
- Treatment with Vykat™ XR may need to be interrupted, or the dosage may need to be reduced due to elevations in fasting glucose or HbA1c or if fluid overload occurs.
- Dosage reductions are also necessary for concomitant use with strong CYP1A2 inhibitors.

Efficacy: The efficacy of Vykat™ XR was evaluated primarily in a 16-week, double-blind, placebo-controlled, randomized withdrawal study period which followed an open-label study period. A total of 77 patients, who had received diazoxide choline ER for a mean duration of 3.3 years (range: 2.5 to 4.5 years) during the initial open-label study period, were included in the randomized withdrawal study.

- Key Inclusion Criteria:
  - Genetically confirmed diagnosis of PWS
  - Presence of hyperphagia
- Intervention:
  - Patients were randomized 1:1 to continue their current dose of diazoxide choline ER or to receive placebo for 16 weeks
- Primary Endpoint:
  - Change from baseline in the hyperphagia questionnaire for clinical trials (HQ-CT) total score at week 16 (score ranges from 0 to 36, with higher scores indicating greater overall severity of hyperphagic and food-related behaviors)

- Results:
    - At week 16, the HQ-CT total score least squares mean change from baseline was 2.6 in the diazoxide choline ER group vs. 7.6 in the placebo group [difference: -5.0; 95% confidence interval (CI): -8.1, -1.8; P=0.0022], indicating that there was statistically significant worsening of hyperphagia in the placebo group when compared to the group which continued use of diazoxide choline ER.

Cost: The Wholesale Acquisition Cost (WAC) is $152.44 for each 25mg tablet, $457.32 for each 75mg tablet, and $914.64 for each 150mg tablet. For a member weighing 40kg using the target maintenance dose of 225mg once daily, this would result in an estimated cost of $41,158.80 per month or $493,905.60 per year. For a member weighing ≥135kg using the maximum target maintenance dose of 525mg once daily, this would result in an estimated cost of $96,037.20 per month or $1,152,446.40 per year.

Yuviwel® (Navepegritide) Product Summary[11,12]

Therapeutic Class: C-type natriuretic peptide (CNP) analog

Indication(s): To increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses

- This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

How Supplied: Supplied as a carton containing 4 kits; each kit contains:

- 1 single-dose vial (SDV) containing navepegritide as a lyophilized powder (1.3mg, 2.8mg, or 5.5mg)
- 1 prefilled diluent syringe containing 0.8mL or 1.1mL of sterile water for injection, USP
- 2 single use preparation needles (21 gauge)
- 1 single use injection syringe
- 1 single use injection needle (30 gauge)

Dosing and Administration:

- Dosing is based on body weight according to the following recommendations:

Body Weight	Weekly Dose	Injection Volume	Vial Strength for Reconstitution
8-9.9kg	0.88mg	0.4mL	1.3mg
10-13.4kg	1.2mg	0.55mL	
13.5-17.5kg	1.6mg	0.35mL	2.8mg
17.6-23kg	2.1mg	0.45mL	
23.1-30.5kg	2.8mg	0.6mL	
30.6-41.2kg	3.6mg	0.65mL	5.5mg
41.3-55.9kg	5mg	0.9mL	
56-73.5kg	6.6mg	1.2mL (use 2 kits; administer 0.6mL from each kit)	
73.6-90kg	8.8mg	1.6mL (use 2 kits; administer 0.8mL from each kit)	

- The concentration of navepegritide is 2.2mg/mL in a reconstituted 1.3mg vial; 4.6mg/mL in a reconstituted 2.8mg vial; and 5.5mg/mL in a reconstituted 5.5mg vial.
- Yuviwel® is administered once weekly by subcutaneous (sub-Q) injection into the abdominal region (2 inches from the belly button) or thighs. If a caregiver is administering Yuviwel®, sub-Q injection into the buttocks or back of the upper arm is also acceptable. Injection sites should be rotated.
- Yuviwel® should be discontinued upon confirmation of no further growth potential, indicated by closure of epiphyses.

Efficacy: The efficacy of Yuviwel® was evaluated primarily in a 52-week, randomized, double-blind, placebo-controlled trial which was followed by a single-arm 52-week open label extension (OLE) period. The trial enrolled a total of 84 patients, of which 57 received navepegritide and 27 received placebo.

- Key Inclusion Criteria:
  - Genetically confirmed diagnosis of achondroplasia
  - 2 to 11 years of age at time of screening
  - Naïve to treatment with growth-promoting agents
  - Open epiphyses
- Intervention:
  - Patients were randomized 2:1 to receive navepegritide or placebo once weekly for 52 weeks
- Primary Endpoint:
  - Annualized growth velocity (AGV) (cm/year) at week 52

- Results:
    - At week 52, the AGV was 5.9cm/year in the navepegritide group vs. 4.4cm/year in the placebo group [treatment difference: 1.5cm/year; 95% confidence interval (CI): 1.0, 1.9; P<0.0001].

Cost Comparison:

Product	Cost Per Vial	Cost Per 28 Days	Cost Per Year
Yuviwel® (navepegritide) 5.5mg vial (8 vials per 28 days)	**$9,581.25**	**$76,650.00**	**$996,450.00**
Yuviwel® (navepegritide) 5.5mg vial (4 vials per 28 days)	**$9,581.25**	**$38,325.00**	**$498,225.00**
Voxzogo® (vosoritide) 1.2mg vial (28 vials per 28 days)	$1,137.10	$31,838.80	$413,904.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Recommendations

The College of Pharmacy recommends the prior authorization of Palsonify™ (paltusotine), Vykat™ XR (diazoxide choline ER), and Yuviwel® (navepegritide) with the following criteria (shown in red):

Palsonify™ (Paltusotine) Approval Criteria:

1. An FDA approved diagnosis of acromegaly confirmed by 1 of the following:
    a. Serum growth hormone (GH) level >1ng/mL after a 2-hour oral glucose tolerance test (OGTT); or
    b. Elevated insulin-like growth factor 1 (IGF-1) (above the age and gender adjusted normal range); and
2. Member has had an inadequate response to surgery or is not a candidate for surgery; and
3. Member must be 18 years of age or older; and
4. Member must have a documented trial with long-acting injectable octreotide or lanreotide depot, which do not require prior authorization, with an inadequate response or a patient-specific, clinically significant reason why both of these are not appropriate for the member must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Mycapssa® (octreotide) and Signifor® LAR (pasireotide) must be provided; and
6. Must be prescribed by, or in consultation with, an endocrinologist; and
7. Initial approvals will be for the duration of 6 months. Reauthorization (for the duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment.

Vykat™ XR [Diazoxide Choline Extended-Release (ER)] Approval Criteria:

1. An FDA approved diagnosis of Prader-Willi syndrome (PWS) confirmed by chromosome analysis (results of genetic testing must be submitted); and
2. Member must be 4 years of age or older; and
3. Prescriber must confirm member has moderate to severe hyperphagia related to PWS; and
4. Must be prescribed by a geneticist, endocrinologist, psychiatrist, or other specialist with expertise in the treatment of PWS; and
5. The member's caregiver has implemented and intends to continue strategies to establish a food-secure environment (e.g., locked food storage); and
6. Prescriber must confirm the member is able to successfully swallow the number of tablets necessary to achieve the target maintenance dose; and
7. Prescriber must confirm the member does not have hepatic impairment or renal impairment; and
8. Fasting plasma glucose and hemoglobin A1c (HbA1c) must be evaluated prior to initiating treatment with Vykat™ XR; and
    a. For members with hyperglycemia, the prescriber must confirm the member's blood glucose has been optimized prior to initiating treatment; and
    b. Prescriber must agree to monitor blood glucose and HbA1c periodically during treatment; and
9. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Vykat™ XR, and agrees to modify the dose, if necessary; and
10. Member's recent weight (taken within the past month) must be provided to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for the duration of 6 months; and
12. Subsequent approvals (for the duration of 6 months) require all the following to be met:
    a. Prescriber must verify the member is tolerating and responding well to the medication as demonstrated by an improvement in hyperphagic symptoms; and
    b. Member has been adherent to therapy; and
    c. Member's recent weight (taken within the past month) must be provided to ensure the requested dose is still appropriate for member's weight.

Yuviwel® (Navepegritide) Approval Criteria:

1. Member must have an FDA approved indication of achondroplasia; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic mutation in the *FGFR3* gene; and
2. Member must be 2 years of age or older; and
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height (cm) and growth velocity (GV) (cm/year) must be provided; and
5. Yuviwel® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and
6. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing per package labeling; and
7. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Yuviwel®; and
8. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Voxzogo® (vosoritide) must be provided; and
9. A quantity limit of 4 kits per 28 days will apply; or
    a. For members weighing ≥56kg, a quantity limit override will be approved for 8 kits per 28 days; and
10. Initial and subsequent approvals will be for the duration of 6 months. For additional approval consideration:
    a. Member's current height must be provided and must demonstrate an improvement in GV from baseline; and
    b. Member's recent weight must be provided and dosing must be appropriate; and
    c. Member should be compliant; and
    d. Prescriber must verify member still has open epiphyses; and
11. Yuviwel® will not be approved following epiphyseal closure.

Additionally, the College of Pharmacy recommends the prior authorization of Daybue® Stix (trofinetide packet) with criteria similar to Daybue® (trofinetide oral solution) with the following changes (shown in red):

Daybue® (Trofinetide Oral Solution) and Daybue® Stix (Trofinetide Packet) Approval Criteria:

1. A diagnosis of typical Rett syndrome confirmed by all of the following:
    a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
        i. A period of regression followed by recovery or stabilization; and
        ii. Partial or complete loss of acquired purposeful hand skills; and

iii. Partial or complete loss of acquired spoken language; and
iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and

b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene; and

2. Member must be 2 years of age or older; and
3. Daybue® must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea, weight loss, and vomiting (including aspiration and aspiration pneumonia) associated with Daybue®, and will monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue®, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have severe renal impairment; and
   a. If the member has moderate renal impairment, the prescriber must agree to reduce the dose as required in the package labeling; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and
8. Requests for Daybue® Stix packets will require a patient-specific, clinically significant reason why the member cannot use Daybue® oral solution; and
9. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
10. The following quantity limits will apply:
    a. Oral Solution: A quantity limit of 3,600mL per 30 days will apply; or
    b. Packets: A quantity limit of 60 packets per 30 days will apply.

Next, the College of Pharmacy recommends updating the approval criteria for Skytrofa® (lonapegsomatropin-tcgd) and Sogroya® (somapacitan-beco) based on new FDA approved indications with the following changes (shown in red):

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
    a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; ~~and~~ or
    b. Adult GHD confirmed by 1 of the following:
        i. Insulin tolerance test (ITT) with peak growth hormone (GH) response <5ng/mL; or
        ii. Glucagon stimulation test (GST) with peak growth hormone (GH) response as follows:
            1. Member's recent body mass index (BMI) must be provided; and
            2. If BMI is ≤30kg/m^2: Peak GH response is ≤3ng/mL; or
            3. If BMI is >30kg/m^2: Peak GH response is ≤1ng/mL; or
        iii. ≥3 other pituitary hormone deficiencies (e.g., adrenal, thyroid, gonadal, vasopressin) with insulin-like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and
2. Member's weight must be ≥11.5kg; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
4. Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and
5. Initial approvals will be as follows:
    a. For pediatric members, initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the package labeling; ~~and~~ or
    b. For adult members, initial approvals will be for 0.7mg, 1.4mg, or 2.1mg per week depending on the member's age and oral estrogen use per package labeling; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year if not on adult dosing; and
    ~~e. Prescriber must verify member still has open epiphyses; and~~

f. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤ +2; and
g. For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and

7. ~~Skytrofa® will not be approved following epiphyseal closure. Skytrofa® is contraindicated in children with closed epiphyses.~~
8. A maximum approved dose of 6.3mg per week will apply for members with adult GHD.

Sogroya® (Somapacitan-beco) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
   a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting all the "Initial Approval" criteria for the member's specific diagnosis; or
   b. Adult GHD confirmed by 1 of the following:
      i. Insulin tolerance test (ITT) or glucagon test with a peak growth hormone (GH) response <3ng/mL; or
      ii. ≥3 pituitary hormone deficiencies and insulin like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; ~~and~~ or
   c. Idiopathic short stature (ISS) meeting all the "Initial Approval" criteria; or
   d. Noonan syndrome (NS) meeting all the "Initial Approval" criteria; or
   e. Small for gestational age (SGA) meeting all the "Initial Approval" criteria; and
2. Member must be 2.5 years of age or older; and
3. Sogroya® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member's baseline IGF-1 level and SDS must be provided; and
5. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
6. Prescriber must verify the member does not have active malignancy or active proliferative or severe non-proliferative diabetic retinopathy; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Sogroya®; and
8. Approval quantity will be based on the FDA approved dosing in accordance with the package labeling; and
9. Initial approvals will be for the duration of 6 months. For additional approval consideration:
   a. Dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and

   c. Member should be compliant; and
   d. Growth velocity (GV) should not be <2.5cm/year if not on adult dosing; and
   e. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤ +2; and
   f. For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and
10. If the member's diagnosis is ISS, NS, or SGA, treatment may continue until 1 of the following:
    a. Epiphyseal closure; or
    b. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
    c. GV <2.5cm/year; and
11. A maximum approved dose of 8mg per week will apply for members with adult GHD.

Lastly, the College of Pharmacy recommends updating the initial approval criteria for growth hormone for a diagnosis of ISS to be consistent with the FDA approved age range for Sogroya® (changes shown in red):

Idiopathic Short Stature Approval Criteria:

1. Initial Approval:
   a. Member must be ~~8~~ 2.5 years of age or older; and
   b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
   c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
   d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
   e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
   f. Member's growth chart and parental heights must be provided; and
      i. If the form is completed, a growth chart is not required; and
      ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:

a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment may continue until 1 of the following:
   i. Epiphyseal closure; or
   ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
   iii. GV <2.5cm/year; and
b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.

4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Epiphyses are open; and
   e. GV should not be <2.5cm/year.

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Appendix G

Vote to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel)

Oklahoma Health Care Authority
April 2026

Market News and Updates[1]

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

- **December 2025:** The FDA approved Waskyra™ (etuvetidigene autotemcel) as the first gene therapy for the treatment of Wiskott-Aldrich Syndrome (WAS) in adults and pediatric patients 6 months of age and older. Waskyra™ is manufactured from the patient's own CD34+ hematopoietic stem cells by transducing them with a lentiviral vector containing a functional copy of the *WAS* gene.

Waskyra™ (Etuvetidigene Autotemcel) Product Summary[2,3]

Therapeutic Class: Autologous hematopoietic stem cell-based gene therapy

Indication(s): Treatment of WAS in patients with a mutation in the *WAS* gene for whom hematopoietic stem cell transplant (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available

How Supplied: 1 to 8 infusion bags overall containing a suspension of 2 to 11.4 x 10^6 cells/mL (1.9 to 11.4 x 10^6 CD34+ cells/mL) in a cryopreservative solution

Dosing and Administration:

- Dosing is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight at the time of infusion
  - Minimum recommended dose is 7 x 10^6 CD34+ cells/kg
- Patients are required to undergo hematopoietic stem and progenitor cells (HSPC) mobilization followed by apheresis to obtain CD34+ cells for Waskyra™ manufacturing
- Reduced intensity conditioning is required before infusion of Waskyra™

Efficacy: The safety and efficacy of Waskyra™ were evaluated in a prospective, open-label, single-arm, multicenter clinical trial (N=8); an on-going, open-label, single-arm, multicenter trial (N=10); an expanded access program (N=3); and a Compassionate Use Program (N=6).

- Key Inclusion Criteria:
  - Diagnosis of WAS confirmed by *WAS* gene mutation and at least 1 of the following:
    - Severe *WAS* mutation
    - Absence of WASP expression
    - Severe clinical score (Zhu clinical score ≥3)
  - No HLA-matched sibling donor
  - Negative search for matched unrelated donor (10/10) or an adequate unrelated cord blood donor (5-6/6) within 4 to 6 months
- Intervention(s): Waskyra™ compared to 12-month pre-treatment outcomes
- Primary Endpoint(s):
  - Rate of severe infections during the 6- to 18-month period after Waskyra™ infusion compared with the 12-month pretreatment period
  - Rate of moderate or severe bleeding episodes during the 12-month period after Waskyra™ infusion compared with the 12-month pre-treatment period
- Results:
  - The rate of severe infections decreased from 2 infections per patient year observation (PYO) [95% confidence interval (CI): 1.5, 2.61] during the 12-month pre-treatment period to 0.2 infections per PYO (95% CI: 0.04, 0.40) during the 6- to 18-month post-treatment period.
  - The rate of moderate and severe bleeding events decreased from 2 events per PYO (95% CI: 1.5, 2.61) during the 12-month pre-treatment period to 0.8 events per PYO (95% CI: 0.49, 1.22) during the 12-month post-treatment period.

Cost: The Wholesale Acquisition Cost (WAC) of Waskyra™ is not currently available to allow for a cost analysis.

Recommendations

The College of Pharmacy recommends the prior authorization of Waskyra™ (etuvetidigene autotemcel) with the following criteria (shown in red):

Waskyra™ (Etuvetidigene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of Wiskott-Aldrich Syndrome (WAS); and
2. Diagnosis must be confirmed by molecular genetic testing confirming a mutation in the *WAS* gene (results of genetic testing must be submitted) and at least 1 of the following:
   a. Severe *WAS* mutation as indicated by molecular genetic testing; or
   b. Absence of WAS protein (WASP) expression in hematopoietic cells; or

    c. Severe Zhu clinical score of ≥3; and
3. Member must be male; and
4. Member must be 6 months of age or older; and
5. Must be prescribed by a geneticist, hematologist/oncologist, immunologist, or other specialist with expertise in the treatment of WAS and the administration of Waskyra™; and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched related stem cell donor; and
7. Member must not have any contraindications to the use of Waskyra™, including:
    a. Hypersensitivity to the active substance or to any of the excipients; and
    b. Previous treatment with hematopoietic stem cell transplantation (HSCT) within 6 months prior to screening or HSCT with evidence of residual donor cell; and
    c. Previous treatment with hematopoietic stem cell gene therapy; and
    d. Contraindications to the mobilization and the conditioning regimen; and
8. Prescriber must verify the member is eligible to undergo HSCT (i.e., HSCT must be appropriate for a member to be treated with Waskyra™); and
9. Prescriber must verify the member will be monitored for signs and symptoms of the following:
    a. Cytopenia for at least 8 weeks after treatment; and
    b. Engraftment failure after treatment; and
    c. Hepatic veno-occlusive diseases, including assessment of liver function tests for 1 month after infusion; and
    d. Infection before and after treatment with Waskyra™; and
10. Waskyra™ must be administered at a Waskyra™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific dose from receipt to storage to administration; and
11. Approvals will be for 1 dose per member per lifetime.

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Appendix H

Vote to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) and Update the Approval Criteria for the Dry Eye Disease (DED) Medications

Oklahoma Health Care Authority
April 2026

Market News and Updates[1]

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

- **May 2025:** The FDA approved Tryptyr® (acoltremon 0.003% ophthalmic solution) for the treatment of the signs and symptoms of DED.

Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Product Summary[2]

Therapeutic Class: Ophthalmic TRPM8 thermoreceptor agonist

Indication(s): Treatment of the signs and symptoms of DED

How Supplied: One carton contains 60 single dose vials (SDVs), each containing 0.4mL of Tryptyr®. One strip is comprised of 5 SDVs packaged in a foil pouch; the carton contains 12 foil pouches.

Dosing and Administration:

- 1 drop should be instilled in each eye twice daily (approximately 12 hours apart).
- Hands should be washed prior to use.
- The SDVs are for immediate use after opening and can be utilized for both eyes.
- Concomitant eye drops should be administered 5 minutes apart.
- Contact lenses should be removed prior to administration and reinserted 15 minutes later.

Efficacy: The efficacy of Tryptyr® was evaluated in 2 prospective, randomized, multi-center, double-masked, vehicle-controlled, parallel group studies (COMET-2 and COMET-3). Use of artificial tears was not allowed during the studies.

- Key Inclusion Criteria:
  - 30 years of age and older
  - Corneal fluorescein staining score of 2-15
  - Anesthetized Schirmer tear test (2-9mm)
  - Symptom Assessment iN Dry Eye (SANDE) score ≥50
  - Ocular Discomfort Score ≥50

- Intervention(s): Patients were randomized to Tryptyr® or vehicle in a 1:1 ratio and dosed twice a day for 90 days.
- Primary Endpoint(s): An increase of ≥10mm in a 5 minute unanesthetized Schirmer tear test score on day 14
- Results:
  - COMET-2: The primary endpoint was achieved in 42.6% of patients who received Tryptyr® vs. 8.2% of patients who received vehicle [difference: 34.4%; 95% confidence interval (CI): 26.9, 42.0; P<0.01].
  - COMET-3: The primary endpoint was achieved in 53.2% of patients who received Tryptyr® vs. 14.4% of patients who received vehicle (difference: 38.8%; 95% CI: 30.8, 46.8; P<0.01).

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Tryptyr® (acoltremon 0.003% sol) vial	**$14.07**	**$844.20***	**$10,130.40**
Miebo® (perfluorohexyloctane sol) multidose vial	$263.80	$791.40^Δ^	$9,496.80
Xiidra® (lifitegrast 5% sol) single-use container	$11.84	$710.40*	$8,524.80
cyclosporine 0.05% emu (generic Restasis®) vial	$1.80	$108.00*	$1,296.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the FDA approved dose of 1 drop twice daily in both eyes.
^Δ^Cost per 30 days is based on the FDA approved dose of 1 drop four times daily in both eyes.
Unit = each vial, mL, or single-use container
emu = emulsion; sol = solution

Recommendations

The College of Pharmacy recommends the prior authorization of Tryptyr® (acoltremon 0.003% ophthalmic solution) with the following criteria (shown in red):

Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to treat the signs and symptoms of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and

6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
7. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Additionally, the College of Pharmacy recommends to designate Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials as brand preferred based on net costs with the following criteria (shown in red):

Cyclosporine 0.05% Ophthalmic Emulsion (Generic Restasis® Single-Use Vials) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials must be provided.

Lastly, the College of Pharmacy recommends updating the Cequa® (cyclosporine 0.09% ophthalmic solution), Eysuvis® (loteprednol etabonate 0.25% ophthalmic suspension), Miebo® (perfluorohexyloctane ophthalmic solution), Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion), Tyrvaya® (varenicline nasal spray), Vevye® (cyclosporine 0.1% ophthalmic solution), and Xiidra® (lifitegrast 5% ophthalmic solution) approval criteria for clarity and based on net costs (changes shown in red):

Cequa® (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in members with keratoconjunctivitis sicca (dry eye); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
7. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Eysuvis® (Loteprednol Etabonate 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. Member must be 18 years of age or older; and

3. ~~A documented trial of intermittent or regular artificial tear use within the past 3 months; and~~
4. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
5. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
6. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which ~~is~~ are available without a prior authorization, must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids ~~including Lotemax® (loteprednol 0.5% suspension)~~ must be provided; and
8. Member must not have any contraindications to Eysuvis®; and
9. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Miebo® (Perfluorohexyloctane Ophthalmic Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use ~~Tryptyr® (acoltremon ophthalmic solution) and~~ Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of ~~12~~ 3mL per 30 days will apply.

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® in the individual dosage formulation (single-use vials), which is available without a prior authorization, must be provided; and
2. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided.

Tyrvaya® (Varenicline Nasal Spray) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 18 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per product) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. ~~A patient-specific, clinically significant reason why the member cannot use all available ophthalmic preparations for the treatment of DED must be provided; and~~
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of 8.4mL (2 bottles) per 30 days will apply.

Vevye® (Cyclosporine 0.1% Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use ~~and~~ Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of 2mL per 50 days will apply.

Xiidra® (Lifitegrast 5% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 17 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and

3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per trial) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A quantity limit of 2 vials per day will apply.

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[1] Alcon. Alcon Announces FDA Approval of Tryptyr® (Acoltremon Ophthalmic Solution) 0.003% for the Treatment of the Signs and Symptoms of Dry Eye Disease. Available online at: https://investor.alcon.com/news-and-events/press-releases/news-details/2025/Alcon-Announces-FDA-Approval-of-TRYPTYR-acoltremon-ophthalmic-solution-0-003-for-the-Treatment-of-the-Signs-and-Symptoms-of-Dry-Eye-Disease/default.aspx. Issued 05/28/2025. Last accessed 03/24/2026.

[2] Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Prescribing Information. Liquidia Technologies. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217370s000lbl.pdf. Last revised 05/2025. Last accessed 03/24/2026.

Appendix I

Vote to Prior Authorize Zolymbus™ (Bimatoprost 0.01% Gel) and Update the Approval Criteria for the Glaucoma Medications

Oklahoma Health Care Authority
April 2026

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

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

- **September 2025:** The FDA approved Zolymbus™ (bimatoprost ophthalmic 0.01% gel) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). It was approved through the 505(b)(2) pathway and was found to be non-inferior to bimatoprost 0.01% solution during a 12-week trial. Zolymbus™ is preservative free and is administered once daily. The cost information for Zolymbus™ (bimatoprost ophthalmic 0.01% gel) is currently not available.
- **January 2026:** The FDA approved a supplemental New Drug Application (sNDA) for iDose® TR (travoprost) to allow for re-administration of iDose® TR in patients who maintain a healthy cornea, as defined by corneal endothelial cell density parameters. The long-term safety data showed no clinically significant corneal endothelial cell loss observed through 3 years across clinical trials. Additionally, the data from the iDose® TR exchange trial showed a second administration and removal of iDose® TR implant was safe and well tolerated, over a 12-month evaluation period.

Recommendations

The College of Pharmacy recommends the following changes to the current Glaucoma Medications Product Based Prior Authorization (PBPA) category based on the new FDA approval and net costs (changes shown in red):

1. The prior authorization of Zolymbus™ (bimatoprost 0.01% gel) and placement into the Special PA Tier; and
2. Moving Betimol® (timolol 0.5%) from Tier-2 to the Special PA Tier; and
3. Moving Istalol® (timolol maleate 0.5%) from the Special PA Tier to Tier-2.

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Alpha-2 Adrenergic Agonists		
brimonidine (Alphagan® 0.2%)	apraclonidine (Iopidine® 0.5%, 1%)	brimonidine (Alphagan-P® 0.15%)

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
brimonidine (Alphagan® P 0.1%) – **Brand Preferred**		
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		
betaxolol (Betoptic-S® 0.25%)	betaxolol (Betoptic® 0.5%)	**timolol (Betimol® 0.5%)**
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	~~**timolol maleate (Istalol® 0.5%)**~~
carteolol (Ocupress® 1%)	~~**timolol (Betimol® 0.5%)**~~	timolol maleate (Timoptic® in Ocudose® 0.25%, 0.5%)
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)	**timolol maleate (Istalol® 0.5%)**	
levobunolol (Betagan® 0.5%)	timolol maleate (Timoptic-XE® 0.25%, 0.5%)	
timolol maleate (Timoptic® 0.25%, 0.5%)		
Carbonic Anhydrase Inhibitors		
acetazolamide (Diamox® 500mg caps; 125mg, 250mg tabs)⁺	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	methazolamide (Neptazane® 25mg, 50mg tabs)⁺
brinzolamide (Azopt® 1%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
dorzolamide (Trusopt® 2%)		
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)		
Cholinergic Agonists/Cholinesterase Inhibitors		
pilocarpine (Isopto® Carpine 1%, 2%, 4%)		
Prostaglandin Analogs		
bimatoprost (Lumigan® 0.01%)	bimatoprost (Lumigan® 0.03%)	**bimatoprost gel (Zolymbus™ 0.01%)**
latanoprost (Xalatan® 0.005%)		latanoprost (Iyuzeh™ 0.005%)
netarsudil/latanoprost (Rocklatan®)		latanoprostene bunod (Vyzulta® 0.024%)

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
tafluprost (Zioptan® 0.0015%) – **Brand Preferred**		
travoprost (Travatan-Z® 0.004%) – **Brand Preferred**		
Rho Kinase Inhibitors		
netarsudil (Rhopressa® 0.02%)		
netarsudil/latanoprost (Rocklatan®)		

*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).
⁺Indicates available oral medications.
Please note: Combination products are included in both applicable pharmaceutical classes; therefore, combination products are listed twice in the tier chart.
caps = capsules; PA = prior authorization; tabs = tablets

The College of Pharmacy also recommends updating the prior authorization criteria for iDose® TR (travoprost intracameral implant) based on the FDA label update (changes shown in red):

iDose® TR (Travoprost Intracameral Implant) Approval Criteria:

1. An FDA approved indication to reduce intraocular pressure (IOP) in members with open-angle glaucoma (OAG) or ocular hypertension (OHT); and
2. Member must be 18 years of age or older; and
3. iDose® TR must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires iDose® TR and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Durysta® (bimatoprost intracameral implant) must be provided; and
6. ~~The affected eye has not received prior treatment with iDose® TR; and~~
7. Member has no contraindications to iDose® TR; and
8. A quantity limit of (1) iDose® TR 75mcg implant per eye per ~~lifetime~~ year will apply; and
9. For reauthorization, the prescriber must verify the member is an appropriate candidate for re-administration of iDose® TR based on corneal endothelial cell density parameters defined in the package labeling.

[1] Zolymbus™ (Bimatoprost)—New Drug Approval. *OptumRx*®. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval-zolymbus-091125.pdf. Issued 09/09/2025. Last accessed 03/17/2026.
[2] U.S. Food and Drug Administration (FDA). Zolymbus™ (Bimatoprost) Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/217307Orig1s000ltr.pdf. Issued 09/09/2025. Last accessed 03/17/2026.
[3] Zolymbus™ (Bimatoprost) Prescribing Information. Thea Pharma Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217307s000lbl.pdf. Last revised 09/2025. Last accessed 03/17/2026.
[4] Glaukos. Glaukos Announces US FDA Approval of NDA Supplement Allowing for Re-Administration of iDose® TR. Available online at: https://investors.glaukos.com/news/news-details/2026/Glaukos-Announces-US-FDA-Approval-of-NDA-Supplement-Allowing-for-Re-Administration-of-iDose-TR/default.aspx. Issued 01/28/2026. Last accessed 03/17/2026.
[5] iDose® TR (Travoprost Intracameral Implant) Prescribing Information. Glaukos Corp. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/218010s004lbl.pdf. Last revised 01/2026. Last accessed 03/17/2026.

Appendix J

Vote to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) and Update the Approval Criteria for the Topical Antibiotic Products

Oklahoma Health Care Authority
April 2026

Recommendations

The College of Pharmacy recommends the prior authorization of Clindesse® (clindamycin phosphate 2% vaginal cream) with the following criteria based on net costs (changes shown in red):

Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) and Xaciato® (Clindamycin 2% Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient specific, clinically significant reason why the member cannot use Cleocin® (clindamycin 2% vaginal cream)~~, Clindesse® (clindamycin phosphate 2% vaginal cream),~~ and Cleocin® vaginal ovules (clindamycin phosphate 2.5g vaginal suppositories), which are available without a prior authorization, must be provided~~.~~; and
3. Requests for Clindesse® will also require a patient specific, clinically significant reason why the member cannot use Xaciato®.

Appendix K

Vote to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib) and Update the Approval Criteria for the Leukemia and Lymphoma Medications

Oklahoma Health Care Authority
April 2026

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

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

- **December 2023:** The FDA approved Phyrago™ (dasatinib) for the treatment of multiple indications for adults with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) or Ph+ acute lymphoblastic leukemia (ALL). In August 2025, the FDA approved additional indications for the treatment of pediatric patients 1 year of age and older with Ph+ ALL or Ph+ CML. Cycle Pharma announced the commercial United States launch of Phyrago™ in October 2025. Phyrago™ was FDA approved through the 505(b)(2) pathway based primarily on the existing safety and efficacy data of Sprycel® (dasatinib). Unlike Sprycel®, Phyrago™ may be administered concomitantly with proton pump inhibitors (PPIs) or histamine-2 (H_2) receptor antagonists.
- **August 2024:** The FDA approved Lymphir™ (denileukin diftitox-cxdl) for the treatment of adult patients with relapsed or refractory Stage I-III cutaneous T-cell lymphoma (CTCL) after at least 1 prior systemic therapy. The manufacturer announced the commercial launch of Lymphir™ in December 2025.
- **February 2025:** The FDA approved Nilotinib D-Tartrate capsules through the 505(b)(2) approval pathway based primarily on the existing safety and efficacy data of Tasigna® (nilotinib). Nilotinib D-Tartrate is indicated for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase and for the treatment of adult patients with chronic phase and accelerated phase Ph+ CML resistant to or intolerant to prior therapy that included imatinib. It is available as oral capsules containing nilotinib d-tartrate in the equivalent of 50mg, 150mg, and 200mg of nilotinib.
- **June 2025:** The FDA approved a new indication for Monjuvi® (tafasitamab-cxix), in combination with lenalidomide and rituximab, for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

- **June 2025:** The FDA announced the removal of the Risk Evaluation and Mitigation Strategies (REMS) programs for all currently approved bispecific B-cell maturation antigen (BCMA)- and CD19-directed autologous chimeric antigen receptor (CAR) T-cell immunotherapies, including Breyanzi® (lisocabtagene maraleucel), Kymriah® (tisagenlecleucel), Tecartus® (brexucabtagene autoleucel), and Yescarta® (axicabtagene ciloleucel). The FDA determined that the REMS were no longer necessary to ensure that the benefits of these therapies outweigh their risks and to minimize the burden on the health care delivery system.
- **October 2025:** The FDA approved a new indication for Gazyva® (obinutuzumab) for the treatment of adult patients with active lupus nephritis who are receiving standard therapy.
- **October 2025:** The FDA approved a new indication for Revuforj® (revumenib) for the treatment of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation in adult and pediatric patients 1 year of age and older who have no satisfactory alternative treatment options.
- **November 2025:** The FDA approved Komzifti™ (ziftomenib) for the treatment of adult patients with relapsed or refractory AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options.
- **November 2025:** The FDA approved a new indication for Epkinly® (epcoritamab-bysp), in combination with lenalidomide and rituximab, for the treatment of adult patients with relapsed or refractory FL.
- **December 2025:** The FDA granted traditional approval and an updated indication for Jaypirca® (pirtobrutinib) for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have previously been treated with a covalent Bruton tyrosine kinase (BTK) inhibitor.
- **December 2025:** The FDA approved a new indication for Breyanzi® (lisocabtagene maraleucel) for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 2 prior lines of systemic therapy.
- **December 2025:** The FDA granted accelerated approval to Lunsumio VELO™ (mosunetuzumab-axgb), a new subcutaneous (sub-Q) formulation of mosunetuzumab-axgb, for the treatment of adult patients with relapsed or refractory FL after 2 or more lines of systemic therapy.
- **February 2026:** The FDA approved an updated label for Yescarta® (axicabtagene ciloleucel) to remove the previous *Limitations of Use* which specified that it was not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.

News:

- **March 2026:** Ipsen, the manufacturer of Tazverik® (tazemetostat), announced the voluntary withdrawal of Tazverik® for all indications, effective immediately, based on risk of secondary hematologic malignancies observed in an ongoing clinical trial. Additionally, Ipsen is discontinuing all active clinical trials and expanded access programs for tazemetostat. Tazverik® was granted accelerated approval by the FDA for treatment of epithelioid sarcoma and FL.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for ALL:
  - Allow for the use of blinatumomab in combination with a tyrosine kinase inhibitor (TKI) for frontline consolidation or induction if the patient is not a candidate for multi-agent chemotherapy
  - Allow for the use of ponatinib in combination with blinatumomab for Ph+ ALL
- The NCCN guidelines for B-cell lymphomas:
  - Allow for the use of ibrutinib in patients with B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma] who are not candidates for CAR T-cell therapy or have no intention of proceeding to transplant
  - Removed recommendations for use of ibrutinib in patients with gastric or nongastric mucosa-associated lymphoid tissue (MALT) lymphoma, nodal or splenic MZL diagnosis
  - Allow for the combination of brentuximab and nivolumab; however, the recommendation is based on a lower level of evidence.
- The NCCN guidelines for multiple myeloma allow for the use of venetoclax in combination with daratumumab or daratumumab/ hyaluronidase-fihj in multiple myeloma and light chain amyloidosis for patients with t(11;14) translocation.
- The NCCN guidelines for CLL/SLL allow for the use of venetoclax in combination with acalabrutinib with or without obinutuzumab as first line therapy.
- The NCCN guidelines for T-cell lymphomas allow for the use of mogamulizumab-kpkc, used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) in members with no intention to proceed to transplant.

Komzifti™ (Ziftomenib) Product Summary[24]

Therapeutic Class: Menin inhibitor

Indication(s): Treatment of adult patients with relapsed or refractory AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options

How Supplied: 200mg oral capsules

Dosing and Administration: The recommended dose is 600mg orally once daily, continued until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is $538.89 per capsule which results in an estimated cost of $48,500.10 per month or $582,001.20 per year based on recommended dosing.

Lunsumio VELO™ (Mosunetuzumab-axgb) Product Summary[25]

Therapeutic Class: Bispecific CD20-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory FL after 2 or more lines of systemic therapy

- This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied:

- 5mg/0.5mL solution in a single-dose vial (SDV)
- 45mg/mL solution in an SDV

Dosing and Administration:

- Administered in 21-day treatment cycles by sub-Q injection
- <u>Cycle 1:</u> 5mg on day 1, 45mg on day 8, and 45mg on day 15
- <u>Cycle 2 (and subsequent cycles):</u> 45mg on day 1

Cost: The WAC is $3,227.37 for the 5mg vial and $29,046.35 for the 45mg vial. This would result in a cost of $61,320.07 for the first cycle and $29,046.35 for the second and subsequent cycles based on recommended dosing. This results in an estimated cost of $526,061.67 for a year of treatment.

Lymphir™ (Denileukin Diftitox-cxdl) Product Summary[26]

Therapeutic Class: Interleukin-2 (IL-2)-receptor-directed cytotoxin

Indication(s): Treatment of adult patients with relapsed or refractory Stage I-III CTCL after at least 1 prior systemic therapy

How Supplied: Lyophilized powder in a 300mcg SDV

Dosing and Administration: The recommended dose is 9mcg/kg administered as an intravenous (IV) infusion over 60 minutes on days 1-5 of a 21-day treatment cycle, continued until disease progression or unacceptable toxicity.

Cost: The WAC is $3,630 per vial. For a member weighing 75kg, this would result in an estimated cost of $54,450 per cycle or $925,650 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Komzifti™ (ziftomenib) and Lymphir™ (denileukin diftitox-cxdl), with the following criteria (shown in red):

Komzifti™ (Ziftomenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of AML; and
2. Disease is relapsed or refractory; and
3. Disease is positive for a susceptible nucleophosmin 1 (*NPM1*) mutation; and
4. Member has no satisfactory alternative treatment options; and
5. Member is 18 years of age or older.

Lymphir™ (Denileukin Diftitox-cxdl) Approval Criteria [Cutaneous T-Cell Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory stage I-III cutaneous T-cell lymphoma; and
2. Member must be 18 years of age or older; and
3. Expression of CD25 on ≥20% of malignant cells by immunohistochemistry (IHC); and
4. Has received at least 1 prior systemic therapy.

Next, the College of Pharmacy recommends the prior authorization of Nilotinib D-Tartrate, Lunsumio VELO™ (mosunetuzumab-axgb), and Phyrago™ (dasatinib) with criteria similar to Danziten® (nilotinib tartrate), Lunsumio™ (mosunetuzumab-axgb), and Sprycel® (dasatinib), respectively (changes shown in red):

Danziten® (Nilotinib Tartrate) and Nilotinib D-Tartrate Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
    a. Newly diagnosed chronic, accelerated, or blast phase CML; or

   b. Philadelphia chromosome positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy; or
   c. Post-hematopoietic stem cell transplant; and
3. A patient-specific, clinically significant reason the member cannot use Tasigna® (nilotinib) must be provided.

Lunsumio™ (Mosunetuzumab-axgb) and Lunsumio VELO™ (Mosunetuzumab-axgb) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:
1. Diagnosis of FL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:
1. Diagnosis of Ph+ ALL; and
2. Member must have 1 of the following:
   a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
   b. Maintenance therapy including:
      i. As a single agent if unfit for additional therapies; or
      ii. As a single agent if member previously received blinatumomab plus a tyrosine kinase inhibitor (TKI); or
      iii. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
      iv. Post-hematopoietic stem cell transplantation; or
   c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy; and
3. Member does not have the following mutations of BCR-ABL1: T315I/A, F317L/V/I/C, or V299L; and
4. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:
1. Diagnosis of CML; and
2. Member must have 1 of the following:
   a. Chronic, accelerated, or blast phase CML; or
   b. Post-hematopoietic stem cell transplantation; and
3. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – GIST; and
2. Used for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease; and
3. Used as second-line therapy as single agent; and
4. Member has progressive disease after treatment with avapritinib; and
5. PDGFRA exon 18 mutations that are insensitive to imatinib (including D842V); and
6. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Next, the College of Pharmacy recommends updating the approval criteria for Epkinly® (epcoritamab-bysp), Gazyva® (obinutuzumab), Jaypirca® (pirtobrutinib), Monjuvi® (tafasitamab-cxix), and Revuforj® (revumenib) based on recent FDA approvals (changes shown in red):

Epkinly® (Epcoritamab-bysp) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed or refractory ~~follicular lymphoma (FL) or diffuse large B-cell lymphoma (~~DLBCL~~)~~ not otherwise specified, including DLBCL arising from indolent lymphomas and/or high-grade B-cell lymphomas; and
2. Has received ≥2 lines of systemic therapy.

Epkinly® (Epcoritamab-bysp) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of relapsed or refractory FL; and
2. Used in 1 of the following settings:
   a. Has received ≥2 lines of systemic therapy; and
      i. Used as a single agent; or
   b. Has received ≥1 line of systemic therapy; and
      i. Used in combination with lenalidomide and rituximab.

Gazyva® (Obinutuzumab) Approval Criteria [Lupus Nephritis (LN) Diagnosis]:

1. An FDA approved indication for the treatment of active LN in members who are receiving standard therapy; and
2. Member must be 18 years of age or older; 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. Azathioprine; or
   c. Mycophenolate; or
   d. Cyclophosphamide; or

    e. Hydroxychloroquine/chloroquine; and
4. Will not be approved for combination use with other biologic therapies (e.g., anifrolumab, belimumab).

Jaypirca® (Pirtobrutinib) Approval Criteria [Chronic Lymphocytic/Small Lymphocytic Lymphoma (CLL/SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. ~~As second-line or subsequent therapy following resistance or intolerance to prior covalent Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor; or~~
3. Disease is relapsed or refractory; and
4. Previously treated with a covalent Bruton's kinase (BTK) inhibitor or a BCL-2 inhibitor; or
5. Demonstrates histologic (Richter) transformation to diffuse large B-cell lymphoma (DLBCL).

Monjuvi® (Tafasitamab-cxix) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of classic FL; and
2. Member must be 18 years of age or older; and
3. Used as second line or later line of therapy (no response, relapsed, or progressive disease); and
4. Used in combination with lenalidomide and rituximab; and
5. Member has received at least 1 prior systemic therapy including an anti-CD20 monoclonal antibody.

Revuforj® (Revumenib) Approval Criteria [Acute Leukemia Diagnosis]:

1. Diagnosis of acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL); and
2. Disease is relapsed or refractory; and
3. Must meet 1 of the following:
    a. Leukemia is positive for a lysine methyltransferase 2A gene (KMT2A) translocation; ~~and~~ or
    b. Susceptible nucleophosmin 1 (*NPM1*) mutation with no satisfactory alternative treatment options; and
4. Member is 1 year of age or older; and
5. Member's recent weight (kg) must be provided; and
    a. For members weighing <40kg, the member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug.

Next, the College of Pharmacy recommends updating the approval criteria for Breyanzi® (lisocabtagene maraleucel), Kymriah® (tisagenlecleucel), Tecartus® (brexucabtagene autoleucel), and Yescarta® (axicabtagene

ciloleucel) based on the removal of the REMS requirements, other FDA approvals, and net costs (changes shown in red):

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Burton tyrosine kinase (BTK) inhibitor and a B cell lymphoma-2 (BCL-2) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Follicular Lymphoma Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
5. ~~A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) are not appropriate for the member must be provided; and~~
6. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Large B Cell Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma; and
    a. One of the following:
        i. Refractory disease to frontline chemoimmunotherapy; or
        ii. Relapse within 12 months of frontline chemoimmunotherapy; or

   iii. Relapse within 12 months of frontline chemoimmunotherapy and member is not eligible for hematopoetic stem cell transplantation (HSCT) due to comorbidity or age; or
   iv. Relapse or refractory disease after 2 or more lines of systemic therapy; and
2. Member does not have primary central nervous system (CNS) lymphoma; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
4. ~~A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene) is not appropriate for the member must be provided.~~
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
5. ~~A patient-specific, clinically significant reason why Tecartus® (brexucabtagene autoleucel) is not appropriate for the member must be provided; and~~
6. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Marginal Zone Lymphoma (MZL) Diagnosis]:

1. Diagnosis of MZL; and
2. Disease is relapsed or refractory; and
3. Member has received at least 2 prior lines of systemic therapy; and
4. Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
5. Approvals will be for 1 dose per member per lifetime.

Kymriah® (Tisagenlecleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Members must meet all of the following:
    a. B-cell precursor ALL; and
    b. Member must be 25 years of age or younger; and
    c. Refractory or in second or later relapse:
        i. Philadelphia chromosome negative (Ph-) ALL: Must be refractory or with ≥2 relapses; or
        ii. Philadelphia chromosome positive (Ph+) ALL: Must have failed ≥2 tyrosine kinase inhibitors (TKIs); and
    d. Therapies to consider prior to tisagenlecleucel if appropriate: Clinical trial, multi-agent chemotherapy with or without hematopoietic cell transplantation (HCT), blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation); and
2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities~~, and must comply with the Kymriah Risk Evaluation and Mitigation Strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities~~, and must comply with the Kymriah Risk Evaluation and Mitigation Strategy (REMS) requirements~~; and
7. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of acute lymphoblastic leukemia (ALL); and
2. Relapsed or refractory disease; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must

be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
4. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Lymphoma Diagnosis]:

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

Yescarta® (Axicabtagene Ciloleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Member must be 18 years of age or older; and
3. Relapsed or refractory disease used in 1 of the following settings; and
    a. After 2 or more lines of therapy; or
    b. After 1 line of therapy, if member is refractory to first-line chemotherapy or relapses within 12 months of first-line chemotherapy; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
5. ~~For large B-cell lymphoma (including DLBCL, high grade B-cell lymphoma, and DLBCL arising from FL), member must not have primary central nervous system lymphoma.~~
6. Approvals will be for 1 dose per member per lifetime.

The College of Pharmacy also recommends updating the approval criteria for Adcetris® (brentuximab vedotin), Blincyto® (blinatumomab), Calquence® (acalabrutinib), Iclusig® (ponatinib), Imbruvica® (ibrutinib), Poteligeo® (mogamulizumab-kpkc), and Venclexta® (venetoclax) based on NCCN recommendations (changes shown in red):

Adcetris® (Brentuximab Vedotin) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High Grade Lymphoma Diagnosis]:

1. Diagnosis of DLBCL or high grade lymphoma; and
2. As a single agent; and
   a. CD30+ disease; and
   b. For DLBCL relapsed/refractory disease in non-autologous stem cell transplant (SCT) candidates or non-candidates for chimeric antigen receptor (CAR) T-cell therapy; or
3. Used in combination with lenalidomide and a rituximab product; and
   a. CD30+ disease; and
   b. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
   c. Ineligible for autologous hematopoietic stem cell transplantation (HSCT) or CAR T-cell therapy.~~; or~~
4. ~~Used in combination with nivolumab; and~~
   a. ~~CD30+ disease; and~~
   b. ~~Relapsed or refractory primary mediastinal large B-cell lymphoma.~~

Blincyto® (Blinatumomab) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Philadelphia chromosome negative (Ph-) ALL; and
   a. Member must be 1 month of age or older; and
   b. Used in 1 of the following settings:
      i. As consolidation therapy as a component of multiphase chemotherapy; or
      ii. As consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance minimal residual disease positive (MRD+) following a complete response to induction; or
      iii. As maintenance therapy in combination with mercaptopurine, vincristine, methotrexate, and prednisone (POMP) as a component of maintenance; or
      iv. For management of relapsed/refractory Ph- ALL; or
2. Diagnosis of Philadelphia chromosome positive (Ph+) ALL; and
   a. Member must be 1 month of age or older; and
   b. Used in 1 of the following settings:
      i. In combination with a tyrosine kinase inhibitor (TKI) as either frontline consolidation or induction if not a candidate for multiagent chemotherapy; or
      ii. With or without a TKI as consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance MRD+ following a complete response to induction; or

        iii. As maintenance therapy in combination with POMP as a component of maintenance if refractory to TKIs; or
        iv. For management of relapsed/refractory Ph+ ALL after failure of 2 TKIs.

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. Used as a single agent; or
3. In combination with obinutuzumab and/or venetoclax.

Iclusig® (Ponatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Used in 1 of the following settings:
    a. Newly diagnosed Ph+ ALL; and
        i. Used in combination with chemotherapy; or
        ii. Used in combination with blinatumomab; or
        iii. Used in combination with corticosteroids or as single agent in those unfit for chemotherapy; or
    b. Maintenance therapy either as a single agent or in combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
    c. Relapsed/refractory disease either as a single agent, in combination with chemotherapy not previously given, or in patients with T315I mutations.

Imbruvica® (Ibrutinib) Approval Criteria [B-Cell Lymphomas Diagnosis]:

1. Diagnosis of B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma]; and
2. As second-line or subsequent therapy; and
3. Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant.

~~**Imbruvica® (Ibrutinib) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis or Acquired Immunodeficiency Syndrome (AIDS)-Related B-Cell Lymphoma Diagnosis]:**~~

1. ~~Diagnosis of non-germinal center DLBCL; and~~
2. ~~As second-line or subsequent therapy; and~~
3. ~~Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant.~~

~~**Imbruvica® (Ibrutinib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:**~~

1. ~~Diagnosis of gastric or nongastric MALT lymphoma, nodal or splenic MZL; and~~
2. ~~As second-line or subsequent therapy for refractory or progressive disease.~~

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Adult T-Cell Leukemia/Lymphoma (ATLL) Diagnosis]:

1. Diagnosis of ATLL; and
2. Used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP); and
   a. No intention to proceed to transplant; or
3. As a single-agent in relapsed/refractory disease.

Venclexta® (Venetoclax) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. As first-line therapy in combination with acalabrutinib and/or obinutuzumab for a maximum duration of 12 months; or
3. As first-line therapy in combination with ibrutinib; or
4. Relapsed/refractory disease in combination with obinutuzumab, rituximab, or as a single agent.

Venclexta® (Venetoclax) Approval Criteria [Systemic Light Chain Amyloidosis Diagnosis]

1. Diagnosis of relapsed/refractory systemic light chain amyloidosis; and
2. Presence of t(11;14) translocation; and
3. Be used as a single agent; or
4. In combination with dexamethasone; or
5. In combination with daratumumab.

Venclexta® (Venetoclax) Approval Criteria [Multiple Myeloma Diagnosis]

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

Lastly, the College of Pharmacy recommends removing the criteria and SoonerCare coverage for Tazverik® (tazemetostat) based on the withdrawal of the medication from the market by the manufacture (changes shown in red):

~~**Tazverik® (Tazemetostat) Approval Criteria [Epitheloid Sarcoma Diagnosis]:**~~

1. ~~Diagnosis of metastatic or locally advanced epithelioid sarcoma; and~~
2. ~~Member is not eligible for complete resection; and~~
3. ~~Member must be 16 years of age or older.~~

~~**Tazverik® (Tazemetostat) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

1. ~~Diagnosis of FL; and~~
2. ~~Treatment of adult members with relapsed/refractory disease; and~~
3. ~~Must meet 1 of the following:~~
    a. ~~Subsequent therapy and EZH2 mutation positive after 2 or more prior systemic therapies; or~~
    b. ~~Second line therapy irrespective of EZH2 mutation status for older or infirm members with indications for treatment where other options are not expected to be tolerable; or~~
    c. ~~Third line and/or subsequent therapy (and not previously given) irrespective of EZH2 mutation status in members with indications for treatment.~~

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Appendix L

Fiscal Year 2025 Annual Review of Multiple Sclerosis (MS) Medications

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

The current prior authorization criteria for the MS medications can be found in the *Recommendations* section at the end of this report.

Utilization of MS 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	220	1,497	$9,913,759.35	$6,622.42	$220.78	49,971	44,904
Aetna	26	53	$413,581.96	$7,803.43	$269.79	1,816	1,533
Humana	45	111	$951,639.39	$8,573.33	$291.82	4,454	3,261
OCH	26	65	$334,747.87	$5,149.97	$178.34	1,351	1,877
2024 Total	**240**	**1,726**	**$11,613,728.57**	**$6,728.70**	**$225.18**	**57,592**	**51,575**
Fiscal Year 2025							
FFS	117	849	$5,207,520.90	$6,133.71	$199.87	29,105	26,054
Aetna	37	227	$1,879,687.58	$8,280.56	$265.61	5,978	7,077
Humana	70	479	$3,612,490.32	$7,541.73	$246.15	17,963	14,676
OCH	54	275	$1,968,348.88	$7,157.63	$214.25	8,473	9,187
2025 Total	**254**	**1,830**	**$12,668,047.68**	**$6,922.43**	**$222.27**	**61,519**	**56,994**
% Change	**5.80%**	**6.00%**	**9.10%**	**2.90%**	**-1.30%**	**6.80%**	**10.50%**
Change	**14**	**104**	**$1,054,319.11**	**$193.73**	**-$2.91**	**3,927**	**5,419**

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.

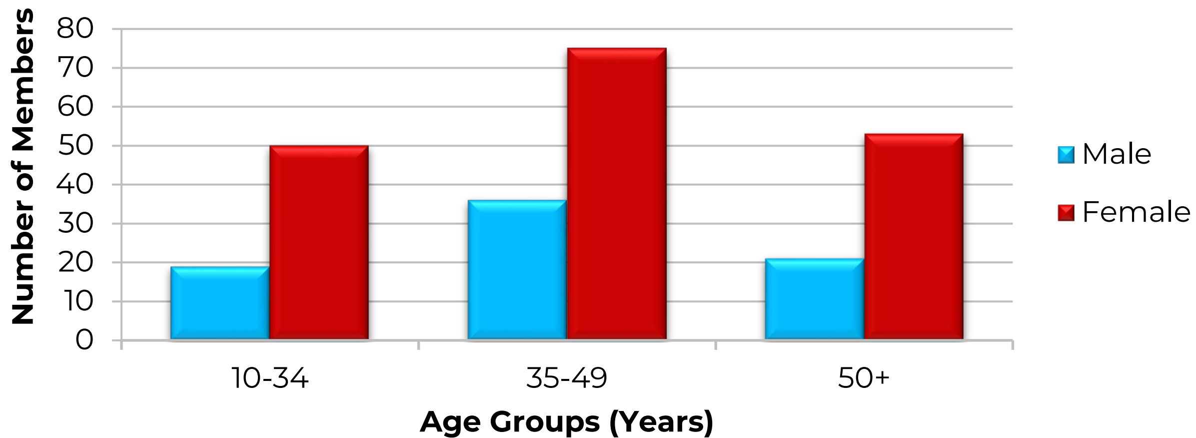
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	118	302	$5,819,547.49	$19,270.02	2.56
Aetna	1	1	$35,256.00	$35,256.00	1
Humana	0	0	$0.00	$0.00	0
OCH	2	2	$42,525.00	$21,262.50	1
2024 Total	**118**	**305**	**$5,897,328.49**	**$19,335.50**	**2.58**
Fiscal Year 2025					
FFS	75	187	$3,830,779.50	$20,485.45	2.49
Aetna	14	20	$431,525.33	$21,576.27	1.43
Humana	28	57	$1,048,324.84	$18,391.66	2.04
OCH	21	40	$1,042,176.10	$26,054.40	1.9
2025 Total	**133**	**304**	**$6,352,805.77**	**$20,897.39**	**2.29**
% Change	**12.71%**	**-0.33%**	**7.72%**	**8.08%**	**-11.57%**
Change	**15**	**-1**	**$455,477.28**	**$1,561.88**	**-0.3**

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

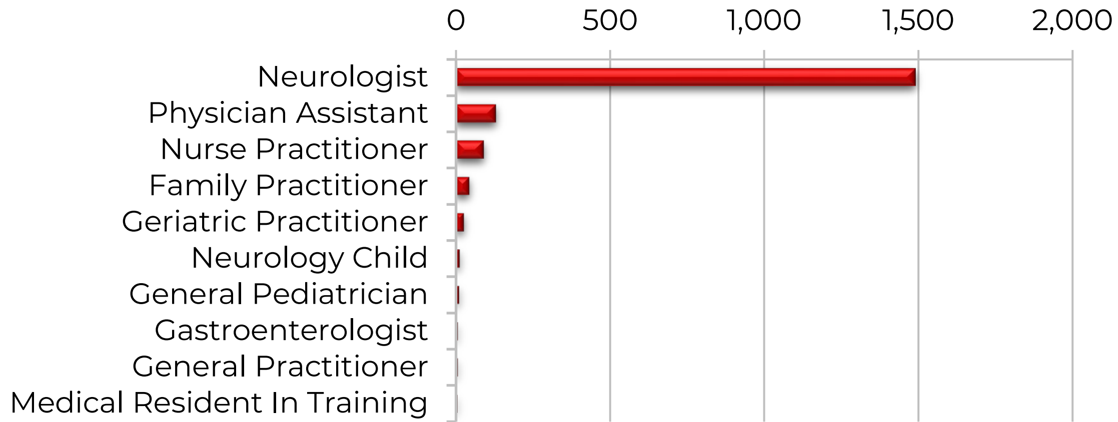
- Aggregate drug rebates collected during fiscal year 2025 for the MS medications totaled $9,556,472.64.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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



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

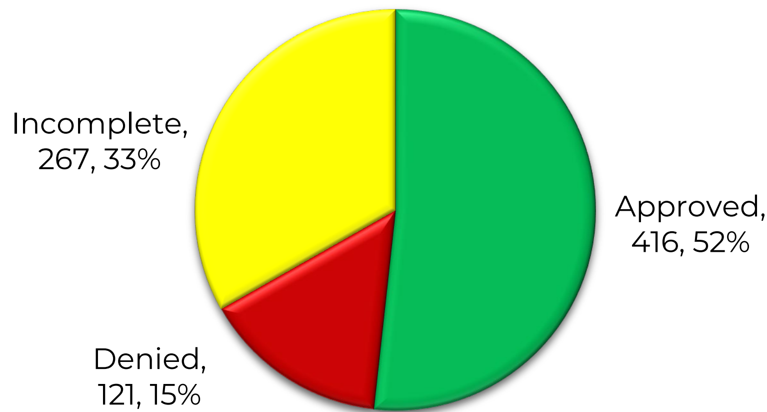
Top Prescriber Specialties of MS Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of MS Medications

There were 804 prior authorization requests submitted for MS 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	293	50%	233	40%	60	10%	**586**
Aetna	42	64%	13	20%	11	17%	**66**
Humana	38	76%	0	0%	12	24%	**50**
OCH	43	42%	21	21%	38	37%	**102**
Total	**416**	**52%**	**267**	**33%**	**121**	**15%**	**804**

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

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

Anticipated Patent Expiration(s):

- Gilenya® (fingolimod capsules): September 2032
- Vumerity® (diroximel fumarate capsules): October 2033
- Aubagio® (teriflunomide tablets): August 2034
- Bafiertam® (monomethyl fumarate capsules): February 2035
- Tecfidera® (dimethyl fumarate capsules): November 2035
- Tascenso ODT® [fingolimod orally disintegrating tablets (ODT)]: January 2036
- Mayzent® (siponimod tablets): April 2036
- Zeposia® (ozanimod capsules): September 2038
- Mavenclad® (cladribine tablets): September 2041
- Ponvory® (ponesimod tablets): October 2042

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

- **August 2025:** The FDA updated the labeling for all anti-CD20 B-cell depleting therapies, including Briumvi® (ublituximab-xiiy), Kesimpta® (ofatumumab), Ocrevus® (ocrelizumab), and Ocrevus Zunovo® (ocrelizumab/hyaluronidase-ocsq), to include information on the risks of liver injury associated with anti-CD20 therapy use. The new labeling included updates to *Assessments Prior to First Dose* and the *Warnings and Precautions* sections of the package labeling for each product. These updates are based on information from the post marketing setting that showed reports of clinically significant liver injury, without findings of viral hepatitis, that included markedly elevated serum hepatic enzymes with elevated total bilirubin occurring weeks to months after administration. The labeling now recommends liver function tests should be obtained prior to treatment initiation and monitoring for signs and symptoms of hepatic injury during treatment.
- **January 2026:** The FDA updated the labeling for Briumvi® (ublituximab-xiiy) to include postmarketing experience of progressive multifocal leukoencephalopathy (PML) in patients treated with Briumvi®. The new labeling included updates to the *Adverse Reactions* and *Warnings and Precautions* sections of the package labeling. All anti-CD20 monoclonal antibodies include a *Warnings and Precautions* section for the potential risk of developing PML in patients treated with these therapies.

News:

- **November 2025:** Sandoz announced the launch of Tyruko® (natalizumab-sztn), a biosimilar to Tysabri® (natalizumab). Tyruko® was approved by the FDA in 2023 for the same indications as Tysabri®.

- **November 2025:** Teva launched an AB-rated generic of Mavenclad® (cladribine) oral tablets for the treatment of relapsing MS (RMS), to include relapsing-remitting disease and active secondary progressive disease, in adults.

Pipeline:

- **Briumvi® (Ublituximab-xiiy):** Briumvi® is an anti-CD20 monoclonal antibody currently FDA approved for the treatment of RMS and is administered as an intravenous (IV) infusion. Briumvi® is being studied in the Phase 3 ENHANCE trial evaluating a consolidated day 1 and 15 dosing schedule. Patients were randomized into 1 of 2 arms: 600mg of Briumvi® on day 1 followed by a placebo infusion on day 15 and 450mg of Briumvi® at week 24 or 150mg of Briumvi® on day 1 followed by 450mg on day 15 and at week 24. The primary endpoint of the randomized portion of the study is noninferior exposure with respect to area under the curve (AUC) at week 16. Enrollment has been completed for this trial, and it is currently ongoing. Additionally, a Phase 3 trial evaluating a subcutaneous formulation of Briumvi® is currently enrolling.
- **Fenebrutinib:** Fenebrutinib is an investigational Bruton's tyrosine kinase (BTK) inhibitor being studied for the treatment of RMS and primary progressive MS (PPMS). The Phase 3 FENhance 1 and FENhance 2 trials showed statistically significant reductions in annualized relapse rates (ARR) by 51% and 59%, respectively, when compared to teriflunomide in patients with RMS. The Phase 3 FENtrepid trial met the primary endpoint of non-inferiority to ocrelizumab in reducing disability progression in patients with PPMS. Based on the data from the 3 trials, regulatory submission is anticipated in 2026.
- **Tolebrutinib:** Tolebrutinib is an investigational BTK inhibitor being studied for the treatment of non-relapsing secondary progressive MS (nrSPMS). Tolebrutinib was previously given a Prescription Drug User Fee Act (PDUFA) target date of December 8, 2025, however the FDA issued a complete response letter (CRL) for tolebrutinib based on the risk of severe drug-induced liver injury and uncertainties of benefit in disease subpopulations. Sanofi stated they plan to continue to work with the FDA to move forward with tolebrutinib.

Recommendations

The College of Pharmacy recommends the following changes to the MS medications approval criteria (changes shown in red):

1. Updating the MS interferon medications, Aubagio® (teriflunomide), Bafiertam® (monomethyl fumarate), Briumvi® (ublituximab-xiiy), Gilenya® (fingolimod), Kesimpta® (ofatumumab), Mayzent® (siponimod),

Ocrevus® (ocrelizumab), Ocrevus Zunovo® (ocrelizumab/hyaluronidase-ocsq), Ponvory® (ponesimod), Tascenso ODT® (fingolimod ODT), Tecfidera® (dimethyl fumarate), Tyruko® (natalizumab-sztn), Tysabri® (natalizumab), Vumerity® (diroximel fumarate), and Zeposia® (ozanimod) approval criteria based on clinical practice and to require all recommended clinical monitoring appropriate to the package labeling; and
2. Updating the Mavenclad® (cladribine) approval criteria based on clinical practice and designating it as brand preferred; and
3. Updating the Copaxone® (glatiramer acetate) approval criteria based on clinical practice and net costs.

Multiple Sclerosis Interferon Medications	
Tier-1	**Tier-2**
interferon β - 1a (Avonex®)	interferon β - 1a (Rebif®)
interferon β - 1b (Betaseron®)	interferon β - 1b (Extavia®)
peginterferon β - 1a (Plegridy®)	

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).

Multiple Sclerosis (MS) Interferon Medications Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of MS, or secondary progressive forms of MS; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Authorization of Tier-2 medications requires previous failure of preferred Tier-1 medication(s) defined as:
   a. Occurrence of an exacerbation after 6 months; or
   b. Significant increase in magnetic resonance imaging (MRI) lesion after 6 months; or
   c. Adverse reactions or intolerable side effects; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. ~~Compliance will be checked for continued approval every 6 months.~~
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Ampyra® (Dalfampridine) Approval Criteria:

1. An FDA approved indication to improve walking in adult members with multiple sclerosis (MS); and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Kurtzke Expanded Disability Status Scale (EDSS) score between 3 and 7.5; and

4. Initial approvals will be for the duration of 90 days. If the member has responded well to treatment and the prescriber states that the member has shown improvement or the drug was effective, the member may receive authorization for 1 year; and
5. A quantity limit of 60 tablets for 30 days will apply.
6. Ampyra® may be used with other MS therapies.

Aubagio® (Teriflunomide) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. ~~All of the following will be required for initiation of treatment:~~
    a. ~~Verification that female members are not pregnant and are currently using reliable contraception; and~~
    b. ~~Verification that the member has no active infection(s); and~~
    c. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
    d. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
    e. ~~Blood pressure (BP) measurement and verification that BP is being monitored; and~~
    f. ~~Verification that the member does not have tuberculosis (TB), or completion of standard medical treatment for members with TB; and~~
5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Aubagio®; and
6. Prescriber must confirm that the member does not have any contraindications for use of teriflunomide; and
7. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must be willing to use effective contraception during treatment with Aubagio® and until plasma concentrations are <0.02mcg/mL after discontinuing treatment; and
8. ~~Initial approvals of Aubagio® will be for 6 months, after which time all of the following will be required for further approval:~~
    a. ~~Medication compliance; and~~
    b. ~~Repeat CBC and verification that counts are acceptable to the prescriber; and~~

    c. ~~Repeat LFTs and verification that levels are acceptable to the prescriber; and~~
    d. ~~Verification that female members are not pregnant and will continue using reliable contraception; and~~
    e. ~~Verification that BP and signs of renal failure are being monitored; and~~

9. ~~Compliance will be checked for continued approval every 6 months; and~~
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
11. A quantity limit of 30 tablets per 30 days will apply.

Bafiertam® (Monomethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. Prescriber must confirm that the member does not have any contraindications for use of monomethyl fumarate; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Bafiertam®; and
7. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
8. ~~Complete blood counts (CBC), including lymphocyte count, and verification that levels are acceptable to the prescriber; and~~
9. ~~Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and~~
10. Intolerable adverse effects associated with a trial of Tecfidera® (dimethyl fumarate) and Vumerity® (diroximel fumarate) that are not expected to occur with Bafiertam® or a patient-specific, clinically significant reason why trials of Tecfidera® and Vumerity® are not appropriate for the member must be provided; and
11. ~~Verification that CBC, including lymphocyte count, levels are acceptable to the prescriber in addition to compliance will be required for continued approval every 6 months; and~~

12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 4 capsules per day will apply.

Briumvi® (Ublituximab-xiiy) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Briumvi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Briumvi® will be administered; and
    a. Briumvi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Briumvi® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver ~~must~~ will be trained on the proper storage of Briumvi®; and
5. Prescriber must confirm that member will be monitored for 1 hour following the first 2 infusions and as indicated for subsequent infusions; and
6. Prescriber must confirm that the member does not have any contraindications for use of ublituximab-xiiy; and
7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Briumvi®; and
8. ~~Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating Briumvi® therapy and member does not have active HBV; and~~
9. Verification from the prescriber that member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving Briumvi® therapy and for 6 months after the last infusion of Briumvi®; and

12. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Copaxone® (Glatiramer Acetate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must verify that the member has no history of hypersensitivity reactions, including anaphylaxis, to glatiramer acetate and verify that the member ~~has been~~ will be counseled on the symptoms of anaphylaxis and instructed to seek immediate medical care should anaphylaxis symptoms occur; and
5. ~~Approvals for the 40mg strength of Copaxone® will require a patient-specific, clinically significant reason why the member cannot use the 20mg strength; and~~
6. ~~Approvals for the generic formulation of either strength of Copaxone®, including Glatopa®, will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and~~
7. Brand name Copaxone® 20mg/mL is preferred. Requests for the 20mg/mL generic formulation, including Glatopa®, and the 40mg strength will require a patient-specific, clinically significant reason why the member cannot use brand name Copaxone® 20mg/mL; and
8. ~~Compliance will be checked for continued approval every 6 months.~~
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Gilenya® (Fingolimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and

5. ~~Member must not have any contraindications for use of Gilenya® including:~~
   a. ~~Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
   b. ~~Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
   c. ~~Baseline QTc interval ≥500msec; and~~
   d. ~~Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs; and~~
6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Gilenya® as per package labeling, including:~~
   a. ~~Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and~~
   b. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
   c. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
   d. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
   e. ~~Skin examination and verification that member will be monitored throughout therapy; and~~
   f. ~~Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Gilenya®; and~~
7. Prescriber must confirm that the member does not have any contraindications for use of fingolimod; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Gilenya®; and
9. Verification from the prescriber that member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must be willing to use effective contraception during treatment with Gilenya® and for at least 2 months after discontinuing treatment; and

~~12. Compliance will be checked for continued approval every 6 months.~~
13. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Kesimpta® (Ofatumumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that the member does not have any contraindications for use of ofatumumab; and
5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Kesimpta®; and
6. ~~The prescriber must verify Hepatitis B virus (HBV) screening is performed before the first dose of Kesimpta® and the member does not have an active HBV infection; and~~
7. ~~Prescriber must agree to monitor quantitative serum immunoglobulin level before, during, and after discontinuation of treatment with Kesimpta® until B-cell repletion; and~~
8. Prescriber must verify the member has no active infection(s); and
9. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
10. Prescriber must verify the first injection of Kesimpta® will be administered by a health care professional prepared to manage injection-related adverse reactions; and
11. Kesimpta® must be shipped via cold chain supply and the member or member's caregiver ~~must~~ will be trained on the proper storage and subcutaneous (sub-Q) administration of Kesimpta®; and
12. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of treatment with Kesimpta®; and
13. Female members of reproductive potential must use an effective method of contraception during treatment and for 6 months after stopping Kesimpta®; and
14. A quantity limit of 1 syringe or prefilled Sensoready® Pen per month will apply. Initial dosing titration will be approved for a quantity limit override upon meeting Kesimpta® approval criteria; and
15. ~~Compliance will be checked for continued approval every 6 months.~~

16. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Lemtrada® (Alemtuzumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
    a. Lemtrada® must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. The prescriber must agree that the member will be monitored for 2 hours after each infusion; and
4. The prescriber must agree to monitor complete blood counts (CBC) with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of Lemtrada®; and
5. The prescriber must agree that baseline and yearly skin examinations will be performed while the member is utilizing Lemtrada® therapy; and
6. Member, prescriber, pharmacy, and health care facility must all enroll in the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program and maintain enrollment throughout therapy.

Mavenclad® (Cladribine) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Requests for use in patients with clinically isolated syndrome (CIS) will not generally be approved; and
3. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
6. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and

7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Mavenclad®; and
8. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
9. Prescriber must confirm member does not have an active malignancy; and
10. Prescriber must confirm that female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
11. Prescriber must attest that female and male members of reproductive potential plan to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; and
12. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
13. Verification from the prescriber that member has no active infection(s); and
14. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
15. 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
16. Mavenclad® is brand preferred. Requests for generic cladribine will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
17. Quantity limits according to package labeling will apply; and
18. Approvals will be for 1 year of therapy (1 treatment course/2 cycles) at a time. Lifetime approval duration will be limited to a maximum of 2 treatment courses according to package labeling.

Mayzent® (Siponimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Member must have been assessed for CYP2C9 genotype:
   a. Members with a CYP2C9*3/*3 genotype will not generally be approved; or
   b. Members with a CYP2C9*1/*3 or *2/*3 genotype will not be approved for doses exceeding 1mg per day; or

   c. All other genotypes CYP2C9 *1/*1, *1/*2, or *2/*2 will be approved for 2mg per day; and
5. ~~Member must not have any contraindication for use of siponimod including:~~
   a. ~~CYP2C9*3/*3 genotype; or~~
   b. ~~Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or Class III/IV HF in the last 6 months; or~~
   c. ~~Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Mayzent® as per package labeling, including:~~
   a. ~~Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and~~
   b. ~~Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring~~
   c. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
   d. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
   e. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
   f. ~~Skin examination and verification that member will be monitored throughout therapy; and~~
   g. ~~Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Mayzent®; and~~
7. Prescriber must confirm that the member does not have any contraindications for use of siponimod; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Mayzent®; and
9. Member must not have received prior treatment with alemtuzumab; and
10. Verification from the prescriber that member has no active infection(s); and
11. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and

12. Verification from the prescriber that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree AV block (Mobitz type I), or a history of HF or MI will be monitored following the first dose for a minimum of 6 hours; and
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. Female members of reproductive potential must be willing to use effective contraception during treatment with Mayzent® and for at least 10 days after discontinuing treatment; and
15. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
16. ~~Compliance will be checked for continued approval every 6 months; and~~
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
18. Quantity limits according to package labeling will apply.

Ocrevus® (Ocrelizumab) and Ocrevus Zunovo® (Ocrelizumab/ Hyaluronidase-ocsq) Approval Criteria:

1. An FDA approved diagnosis of primary progressive forms of multiple sclerosis (MS) or relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease modifying therapies; and
4. Ocrevus® and Ocrevus Zunovo® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion/injection reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how the requested product will be administered; and
    a. Ocrevus® and Ocrevus Zunovo® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Ocrevus® and Ocrevus Zunovo® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver ~~must~~ will be trained on the proper storage of the requested product; and
5. Prescriber must confirm that member will be monitored appropriately per package labeling after each infusion or injection; and

6. ~~Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating ocrelizumab therapy and member does not have active HBV; and~~
7. Prescriber must confirm that the member does not have any contraindications for use of ocrelizumab; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for the requested product; and
9. Verification from the prescriber that member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving ocrelizumab therapy and for 6 months after the last dose infusion of ocrelizumab; and
12. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Ponvory® (Ponesimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree atrioventricular (AV) block (Mobitz type I), or a history of heart failure (HF) or myocardial infarction (MI) will be monitored following the first dose for a minimum of 4 hours; and
5. ~~Member must not have any contraindications for use of Ponvory® including:~~
   a. ~~MI, unstable angina, stroke, transient ischemic attack (TIA), decompensated HF requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
   b. ~~Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Ponvory® as per package labeling, including:~~

a. ~~Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and~~
b. ~~Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring~~
c. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
d. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
e. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
f. ~~Skin examination and verification that member will be monitored throughout therapy; and~~
g. ~~Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Ponvory®; and~~

7. Prescriber must confirm that the member does not have any contraindications for use of ponesimod; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Ponvory®; and
9. Member must not have received prior treatment with alemtuzumab; and
10. Verification from the prescriber that the member has no active infection(s); and
11. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
12. ~~Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and~~
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. Female members of reproductive potential must be willing to use effective contraception during treatment with Ponvory® and for at least 1 week after discontinuing treatment; and
15. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
16. ~~Compliance will be checked for continued approval every 6 months; and~~
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents

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

18. A quantity limit of 30 tablets per 30 days will apply for the 20mg tablet. A quantity limit of 14 tablets per 14 days will apply for the Ponvory® starter pack.

Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
5. ~~Member must not have any contraindications for use of Tascenso ODT® including:~~
    a. ~~Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
    b. ~~Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
    c. ~~Baseline QTc interval ≥500msec; and~~
    d. ~~Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs; and~~
6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Tascenso ODT® as per package labeling, including:~~
    a. ~~Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and~~
    b. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
    c. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
    d. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
    e. ~~Skin examination and verification that member will be monitored throughout therapy; and~~

~~f. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Tascenso ODT®; and~~

7. Prescriber must confirm that the member does not have any contraindications for use of fingolimod; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Tascenso ODT®; and
9. Verification from the prescriber that member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must be willing to use effective contraception during treatment with Tascenso ODT® and for at least 2 months after discontinuing treatment; and
12. A patient-specific, clinically significant reason why the member cannot use Gilenya® (fingolimod) capsules must be provided; and
13. ~~Compliance will be checked for continued approval every 6 months.~~
14. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Tecfidera® (Dimethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of multiple sclerosis (MS), or secondary progressive forms of MS in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no active infection(s); and
5. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Tecfidera®; and

7. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
8. ~~Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and~~
9. ~~Compliance will be checked for continued approval every 6 months; and~~
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
11. A quantity limit of 60 tablets per 30 days will apply.

Tyruko® (Natalizumab-sztn) and Tysabri® (Natalizumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, or Crohn's disease in adults; and
2. For a diagnosis of MS, the following criteria will apply:
    a. Prescriber must be a neurologist or an advanced care practitioner with a supervising physician who is a neurologist; and
    b. Approvals will not be granted for concurrent use with other disease-modifying therapies; or
3. For a diagnosis of Crohn's disease, the following criteria will apply:
    a. Treatment with at least 2 different first-line therapeutic categories for Crohn's disease that have failed to yield an adequate clinical response, or a patient-specific, clinically significant reason why the member cannot use all available first- and second-line alternatives must be provided; and
4. For Tyruko®, a patient-specific, clinically significant reason why the member cannot use Tysabri® 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
5. For Tyruko®, prescriber, infusion center, and member must enroll in the Risk Evaluation and Mitigation Strategy (REMS) program; and
6. For Tysabri®, prescriber, infusion center, and member must enroll in the TOUCH Prescribing Program; and
7. ~~Compliance will be checked for continued approval every 6 months.~~
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Vumerity® (Diroximel Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
6. ~~Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and~~
7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Vumerity®; and
8. Verification from the prescriber that member does not have moderate or severe renal impairment; and
9. Verification from the prescriber that the member ~~has been~~ will be counseled on proper administration of Vumerity® including caloric and fat intake limits at the time of dosing; and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. ~~Compliance will be checked for continued approval every 6 months; and~~
12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 120 capsules per 30 days will apply.

Zeposia® (Ozanimod) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following in adults:
   a. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; or
   b. Moderately to severely active ulcerative colitis (UC); and
2. For the diagnosis of MS:
   a. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
   b. Approvals will not be granted for concurrent use with other disease-modifying therapies; and

~~3. Member must not have any contraindications for use of Zeposia® including:~~
   ~~a. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
   ~~b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; or~~
   ~~c. Have severe untreated sleep apnea; or~~
   ~~d. Concurrent use of monoamine oxidase inhibitors (MAOIs); and~~
~~4. Verification from the prescriber that all baseline assessments have been completed prior to initiating Zeposia® as per package labeling, including:~~
   ~~a. Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and~~
   ~~b. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and~~
   ~~c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
   ~~d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
   ~~e. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
   ~~f. Skin examination and verification that member will be monitored throughout therapy; and~~
   ~~g. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and~~
5. Prescriber must confirm that the member does not have any contraindications for use of ozanimod; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Zeposia®; and
7. Member must not have received prior treatment with alemtuzumab; and
8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and

10. Member must not be concurrently using strong CYP2C8 inhibitors/ inducers; and
11. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
12. Female members of reproductive potential must be willing to use effective contraception during treatment with Zeposia® and for at least 3 months after discontinuing treatment; and
13. For the diagnosis of MS, member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; or
14. For the diagnosis of UC, member must have had an inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators (e.g., 6-mercaptopurine, azathioprine), and a biologic [e.g., tumor necrosis factor (TNF) blocker]. Tier structure applies; and
15. ~~Compliance will be checked for continued approval every 6 months; and~~
16. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
17. A quantity limit of 30 capsules per 30 days will apply.

Utilization Details of MS Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OFATUMUMAB PRODUCTS						
KESIMPTA INJ 20MG/0.4ML	584	86	$5,240,170.93	$8,972.90	6.79	41.37%
SUBTOTAL	**584**	**86**	**$5,240,170.93**	**$8,972.90**	**6.79**	**41.37%**
DALFAMPRIDINE PRODUCTS						
DALFAMPRIDINE TAB 10MG ER	256	34	$9,926.76	$38.78	7.53	0.08%
AMPYRA TAB 10MG	12	1	$52,242.09	$4,353.51	12	0.41%
SUBTOTAL	**268**	**35**	**$62,168.85**	**$231.97**	**7.66**	**0.49%**
DIROXIMEL FUMARATE PRODUCTS						
VUMERITY CAP 231MG	205	30	$1,801,617.15	$8,788.38	6.83	14.22%
SUBTOTAL	**205**	**30**	**$1,801,617.15**	**$8,788.38**	**6.83**	**14.22%**
GLATIRAMER ACETATE PRODUCTS						
COPAXONE INJ 40MG/ML	79	11	$458,344.53	$5,801.83	7.18	3.62%
COPAXONE INJ 20MG/ML	61	12	$416,960.12	$6,835.41	5.08	3.29%
GLATIRAMER INJ 40MG/ML	33	5	$41,912.98	$1,270.09	6.6	0.33%
GLATOPA INJ 40MG/ML	5	3	$6,675.68	$1,335.14	1.67	0.05%
SUBTOTAL	**178**	**31**	**$923,893.31**	**$5,190.41**	**5.74**	**7.29%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TERIFLUNOMIDE PRODUCTS						
TERIFLUNOMIDE TAB 14MG	111	20	$3,465.40	$31.22	5.55	0.03%
AUBAGIO TAB 14MG	41	6	$386,972.94	$9,438.36	6.83	3.05%
TERIFLUNOMIDE TAB 7MG	19	6	$512.18	$26.96	3.17	0.00%
SUBTOTAL	**171**	**32**	**$390,950.52**	**$2,286.26**	**5.34**	**3.09%**
FINGOLIMOD PRODUCTS						
FINGOLIMOD CAP 0.5MG	97	13	$22,952.94	$236.63	7.46	0.18%
GILENYA CAP 0.5MG	33	7	$357,081.09	$10,820.64	4.71	2.82%
TASCENSO ODT 0.25MG	8	1	$83,475.20	$10,434.40	8	0.66%
TASCENSO ODT 0.5MG	8	1	$83,475.20	$10,434.40	8	0.66%
SUBTOTAL	**146**	**22**	**$546,984.43**	**$3,746.47**	**6.64**	**4.32%**
DIMETHYL FUMARATE PRODUCTS						
DIMETHYL FUM CAP 240MG DR	62	12	$4,396.25	$70.91	5.17	0.03%
TECFIDERA CAP 240MG	14	2	$133,634.81	$9,545.34	7	1.05%
DIMETHYL FUM CAP 120MG DR	9	6	$964.74	$107.19	1.5	0.01%
DIMETHYL FUM CAP STR PAK	3	3	$596.73	$198.91	1	0.00%
SUBTOTAL	**88**	**23**	**$139,592.53**	**$1,586.28**	**3.83**	**1.10%**
INTERFERON BETA-1A PRODUCTS						
AVONEX PEN KIT 30MCG	35	4	$287,277.04	$8,207.92	8.75	2.27%
REBIF REBIDOSE INJ 44MCG/0.5ML	10	1	$105,000.51	$10,500.05	10	0.83%
REBIF REBIDOSE INJ 22MCG/0.5ML	7	1	$74,884.96	$10,697.85	7	0.59%
SUBTOTAL	**52**	**6**	**$467,162.51**	**$8,983.89**	**8.67**	**3.69%**
OZANIMOD PRODUCTS						
ZEPOSIA CAP 0.92MG	34	5	$308,631.78	$9,077.41	6.8	2.44%
ZEPOSIA CAP STR PAK	1	1	$2,085.72	$2,085.72	1	0.02%
SUBTOTAL	**35**	**6**	**$310,717.50**	**$8,877.64**	**5.83**	**2.45%**
NATALIZUMAB PRODUCTS						
TYSABRI INJ 300MG/15ML	28	4	$202,911.28	$7,246.83	7	1.60%
SUBTOTAL	**28**	**4**	**$202,911.28**	**$7,246.83**	**7**	**1.60%**
OCRELIZUMAB PRODUCTS						
OCREVUS INJ 300MG/10ML	21	12	$852,303.65	$40,585.89	1.75	6.73%
SUBTOTAL	**21**	**12**	**$852,303.65**	**$40,585.89**	**1.75**	**6.73%**
INTERFERON BETA-1B PRODUCTS						
BETASERON INJ 0.3MG	21	2	$201,185.52	$9,580.26	10.5	1.59%
SUBTOTAL	**21**	**2**	**$201,185.52**	**$9,580.26**	**10.5**	**1.59%**
CLADRIBINE PRODUCTS						
MAVENCLAD 7-PAK 10MG	4	3	$302,624.42	$75,656.11	1.33	2.39%
MAVENCLAD 10-PAK 10MG	3	2	$320,219.23	$106,739.74	1.5	2.53%
MAVENCLAD 5-PAK 10MG	2	1	$104,073.62	$52,036.81	2	0.82%
MAVENCLAD 9-PAK 10MG	2	2	$187,324.66	$93,662.33	1	1.48%
MAVENCLAD 8-PAK 10MG	2	2	$169,718.44	$84,859.22	1	1.34%
MAVENCLAD 6-PAK 10MG	1	1	$64,850.47	$64,850.47	1	0.51%
SUBTOTAL	**14**	**11**	**$1,148,810.84**	**$82,057.92**	**1.27**	**9.07%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SIPONIMOD PRODUCTS						
MAYZENT TAB 2MG	9	1	$88,068.82	$9,785.42	9	0.70%
MAYZENT STR PAK	1	1	$1,010.15	$1,010.15	1	0.01%
SUBTOTAL	**10**	**2**	**$89,078.97**	**$8,907.90**	**5**	**0.70%**
UBLITUXIMAB PRODUCTS						
BRIUMVI INJ 150MG/6ML	9	4	$290,499.69	$32,277.74	2.25	2.29%
SUBTOTAL	**9**	**4**	**$290,499.69**	**$32,277.74**	**2.25**	**2.29%**
TOTAL	**1,830**	**254***	**$12,668,047.68**	**$6,922.43**	**7.2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; ER = extended-release; FUM = fumarate; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; STR = starter; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OCREVUS INJ 300MG/10ML (J2350)	166	106	$5,085,630.94	$30,636.33	1.57
TYSABRI INJ 300MG/15ML (J2323)	117	16	$831,478.68	$7,106.66	7.31
BRIUMVI INJ 150MG/6ML (J2329)	21	11	$435,696.15	$20,747.44	1.91
TOTAL	**304**	**133**	**$6,352,805.77**	**$20,897.39**	**2.29**

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

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Appendix M

Fiscal Year 2025 Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj)

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

Utilization data for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Mektovi® (binimetinib), Opdivo® (nivolumab), Qvantig™ (nivolumab/hyaluronidase-nvhy), Tafinlar® (dabrafenib), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) and approval criteria for indications other than lung cancer can be found in the December 2025 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Cyramza® (ramucirumab) and approval criteria for indications other than lung cancer can be found in the January 2026 DUR Board packet. Cyramza® is reviewed annually with the gastrointestinal cancer medications. Utilization data for Datroway® (datopotamab deruxtecan-dlnk) and Enhertu® (fam-trastuzumab deruxtecan-nxki) and approval criteria for indications other than lung cancer can be found in the September 2025 DUR Board packet. These medications are reviewed annually with the breast cancer medications.

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

1. Diagnosis of recurrent or metastatic NSCLC; and
    a. Anaplastic lymphoma kinase (ALK) positivity; and
    b. First-line or recurrent setting; and
    c. As a single agent only; or
2. Diagnosis of resected NSCLC (tumors ≥4cm or node positive); and
    a. ALK positivity; and
    b. Used as adjuvant treatment; and
    c. As a single agent only.

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

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. As a single agent.

Augtyro™ (Repotrectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. *ROS1*-positive; and
3. Used as a single agent.

Augtyro™ (Repotrectinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of solid tumor(s) that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion; and
2. Locally advanced or metastatic or where surgical resection is likely to result in severe morbidity; and
3. Member must be 12 years of age or older; and
4. Progressed following treatment or have no satisfactory alternative therapy; and
5. Used as a single agent.

Axtle™ (Pemetrexed; J9292), Pemfexy® (Pemetrexed; J9304), and Pemrydi RTU® (Pemetrexed; J9324) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed; J9305), pemetrexed ditromethamine (J9323), and other preferred pemetrexed 25mg/mL solution products (J9294 - Hospira, J9296 - Accord, J9297 – Sandoz, J9314 - Teva, J9322 - Bluepoint) that do not require prior authorization must be provided.

Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, unresectable or metastatic NSCLC; and
2. Neuregulin 1 (*NRG1*) gene fusion-positive; and
3. Disease progression on or after prior systemic therapy; and
4. Used as single agent.

Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Pancreatic Cancer Diagnosis]:

1. Diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma; and
2. Neuregulin 1 (*NRG1*) gene fusion-positive; and
3. Disease progression on or after prior systemic therapy; and
4. Used as single agent.

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

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

Cosela® (Trilaciclib) Approval Criteria [Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. Member is undergoing myelosuppressive chemotherapy with 1 of the following:
   a. Platinum (carboplatin or cisplatin) and etoposide-containing regimen; or
   b. Topotecan-containing regimen.

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

1. Diagnosis of metastatic NSCLC; and
2. First-line in combination with erlotinib; and
   a. Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation; or
3. Subsequent therapy for metastatic disease; and
   a. In combination with docetaxel.

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.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Unresectable or metastatic NSCLC; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member must have received a prior systemic therapy.

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

1. Diagnosis of NSCLC in adults; and
2. Recurrent, advanced, or metastatic disease; and
3. Rearranged during transfection (RET) fusion-positive tumor; and
4. As a single agent.

Gavreto® (Pralsetinib) Approval Criteria [Thyroid Cancer Diagnosis]:

1. Adult and pediatric members 12 years of age and older; and
2. Diagnosis of advanced or metastatic disease with:
    a. RET fusion-positive thyroid cancer requiring systemic therapy and member is radioactive iodine-refractory (if radioactive iodine is appropriate); and
3. As a single agent.

Gilotrif® (Afatinib) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of head and neck cancer; and
2. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
3. Non-nasopharyngeal cancer must be 1 of the following:
    a. Newly diagnosed T4b, any N, M0 disease, unresectable nodal disease with no metastases, or for members who are unfit for surgery and have a performance status (PS) of 3; or
    b. Metastatic (M1) disease at initial presentation, recurrent/persistent disease with distant metastases, or unresectable locoregional recurrence or second primary with prior radiation therapy (RT) and PS of 0 to 2; or
    c. Unresectable locoregional recurrence without prior RT and PS of 3; and
4. As a single agent only.

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

1. Diagnosis of metastatic NSCLC; and
2. For first-line therapy, meeting the following:
    a. Epidermal growth factor receptor (EGFR) mutation detected; and
    b. As a single agent only; or
3. For second-line therapy, meeting the following:
    a. Progressed following platinum-based chemotherapy; and
    b. As a single agent or in combination with cetuximab in members with a known sensitizing EGFR mutation who are T790M negative.

Imdelltra® (Tarlatamab-dlle) Approval Criteria [Extensive Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. Member has disease progression on or after platinum-based chemotherapy; and
3. Healthcare facilities must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities.

Imfinzi® (Durvalumab) Approval Criteria [Biliary Tract Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic biliary tract cancer; and

2. Used in combination with gemcitabine and cisplatin.

Imfinzi® (Durvalumab) Approval Criteria [Bladder Cancer Diagnosis]:
1. Diagnosis of muscle invasive bladder cancer; and
2. Used in combination with gemcitabine and cisplatin as neoadjuvant treatment for 4 cycles; and
3. Followed by single-agent adjuvant treatment following radical cystectomy for up to 8 additional cycles.

Imfinzi® (Durvalumab) Approval Criteria [Endometrial Cancer Diagnosis]:
1. Diagnosis of primary advanced (FIGO measurable stage III/newly diagnosed stage IV) or recurrent endometrial cancer; and
2. Mismatch repair deficient (dMMR); and
3. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance.

Imfinzi® (Durvalumab) Approval Criteria [Extensive-Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:
1. Diagnosis of ES-SCLC; and
2. In combination with etoposide and either cisplatin or carboplatin followed by single agent maintenance.

Imfinzi® (Durvalumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:
1. Diagnosis of unresectable HCC; and
2. Used in combination with tremelimumab-actl; or
3. As a single agent.

Imfinzi® (Durvalumab) Approval Criteria [Limited-Stage Small Cell Lung Cancer (LS-SCLC) Diagnosis]:
1. Diagnosis of LS-SCLC; and
2. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; and
3. Used as single agent.

Imfinzi® (Durvalumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of resectable (tumors ≥4cm and/or node positive) NSCLC; and
   a. Used in combination with platinum-containing chemotherapy as neoadjuvant treatment before surgery, followed by single agent durvalumab as adjuvant treatment after surgery; and
   b. No epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements; or
2. Diagnosis of unresectable stage II or III non-small cell lung cancer (NSCLC); and

   a. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; or
3. Diagnosis of metastatic NSCLC; and
   a. No EGFR mutation or ALK genomic tumor aberrations; and
   b. Used in combination with tremelimumab-actl and platinum-based chemotherapy.

Imjudo® (Tremelimumab-actl) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:
1. Diagnosis of unresectable HCC; and
2. Used in combination with durvalumab; and
3. Will be approved for a maximum of 1 dose per treatment plan per member.

Imjudo® (Tremelimumab-actl) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of metastatic NSCLC; and
2. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or *ROS1* mutations; and
3. Used in combination with durvalumab and platinum-based chemotherapy; and
4. Will be approved for a maximum of 5 doses per treatment plan per member.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Mesothelioma Diagnosis]:
1. Diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma; and
2. Used as first-line therapy in adult members; and
3. Used in combination with pemetrexed and platinum chemotherapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Metastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of metastatic NSCLC; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression as follows:
   a. As a single agent, first-line: ≥1%; or
   b. First-line in combination: No expression required; or
   c. As a single agent, second-line: ≥1%; and
4. Member meets 1 of the following:

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

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

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

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

1. Diagnosis of metastatic SCLC; and

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

Krazati® (Adagrasib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:
1. Diagnosis of locally advanced or metastatic CRC; and
2. Presence of KRAS G12C mutation; and
3. Member has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
4. Used in combination with cetuximab or panitumumab; or
    a. Used as a single agent if unable to tolerate epidermal growth factor receptor (EGFR) inhibitor due to toxicity.

Krazati® (Adagrasib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Presence of KRAS G12C mutation in tumor or plasma specimen as determined by an FDA approved test; and
3. Member has received at least 1 prior systemic therapy; and
4. As a single agent.

Lazcluze® (Lazertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations; and
3. Used as first-line treatment in combination with amivantamab.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of advanced, unresectable, or metastatic NSCLC; and
2. Used in the first-line setting; and
3. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or *ROS1* mutations; and
4. Used in 1 of the following settings:
    a. Used as a single agent; and
        i. High programmed death ligand 1 (PD-L1) expression [tumor proportion score (TPS) ≥50%]; or
    b. Used in combination with platinum-based chemotherapy; and
        i. No requirement for PD-L1 expression; or
    c. Used as continuation maintenance therapy following first line therapy with cemiplimab; and
        i. Used in combination with pemetrexed; or
        ii. Used as a single agent.

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

1. Diagnosis of metastatic NSCLC; and
2. Tumor expresses anaplastic lymphoma kinase (ALK) translocation; and
3. As a single agent as first-line therapy; or
4. As a single agent as second-line therapy following disease progression on either alectinib or ceritinib; or
5. As a single agent as third-line or greater therapy following disease progression on crizotinib and 1 other ALK inhibitor (i.e., ceritinib, alectinib).

Lumakras® (Sotorasib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic CRC; and
2. Presence of KRAS G12C mutation; and
3. Member has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
4. Used in combination with cetuximab or panitumumab; or
    a. Used as a single agent if unable to tolerate epidermal growth factor receptor (EGFR) inhibitor due to toxicity.

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

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Presence of *KRAS G12C* mutation; and
3. Disease has progressed on at least 1 prior systemic therapy; and
4. As a single agent.

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

1. Diagnosis of refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type BRAF NSCLC; and
3. In combination with dabrafenib.

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

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

Opdivo® (Nivolumab) Approval Criteria [Mesothelioma Diagnosis]:

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

3. Used in combination with ipilimumab.

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

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

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

1. Must meet 1 of the following criteria:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease is progressive on initial chemotherapy; and
2. Used as a single agent; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and

4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Rearranged during transfection (RET) fusion-positive tumor; and
3. As a single agent.

Retevmo® (Selpercatinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of locally advanced or metastatic solid tumor; and
2. Member must be 2 years of age or older; and
3. Rearranged during transfection (RET) gene fusion; and
    a. Disease has progressed on or following prior systemic treatment; or
    b. There are no satisfactory alternative treatment options; and
4. As a single agent.

Retevmo® (Selpercatinib) Approval Criteria [Thyroid Cancer Diagnosis]:

1. Adult and pediatric members 2 years of age and older; and
2. As a single agent; and
3. Diagnosis of advanced or metastatic disease with either:
    a. Rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) requiring systemic therapy; or
    b. RET fusion-positive thyroid cancer requiring systemic therapy and member is radioactive iodine-refractory (if radioactive iodine is appropriate).

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

1. Diagnosis of metastatic NSCLC; and
2. *ROS1*-positive; and
3. As a single agent.

Rozlytrek® (Entrectinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of solid tumors; and
2. Member must be older than 1 month of age; and
3. Neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation; and
4. Metastatic or not a surgical candidate; and
5. Progressed following treatment or have no satisfactory alternative therapy.
6. As a single agent.

Rybrevant® (Amivantamab-vmjw) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and

2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
    a. As first-line therapy in combination with carboplatin and pemetrexed; or
    b. As a single agent in disease that has progressed on or after platinum-based chemotherapy; or
3. Tumor exhibits EGFR exon 19 deletion or exon 21 L858R mutations; and
    a. As first-line therapy in combination with lazertinib; or
    b. As subsequent therapy in combination with carboplatin and pemetrexed after progression on an EGFR tyrosine kinase inhibitor.

Tabrecta® (Capmatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and
3. As a single agent.

Tafinlar® (Dabrafenib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
    a. Not indicated for wild-type BRAF NSCLC; and
3. As a single agent or in combination with trametinib.

Tagrisso® (Osimertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of NSCLC; and
    a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; and
    b. As a single agent; or
2. Diagnosis of locally advanced, unresectable (stage III) NSCLC; and
    a. EGFR exon 19 deletions or exon 21 L858R mutations; and
    b. As single agent; and
    c. Disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy; or
3. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease; or
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and
    c. As a single agent; or
4. Diagnosis of locally advanced or metastatic non-squamous NSCLC; and
    a. Used as first-line treatment; and
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and

c. Used in combination with pemetrexed and platinum-based (cisplatin or carboplatin) chemotherapy.

Tarceva® (Erlotinib) Approval Criteria [Bone Cancer – Chordoma Diagnosis]:

1. Diagnosis of bone cancer – chordoma; and
2. Recurrent disease; and
3. As a single agent only.

Tarceva® (Erlotinib) Approval Criteria [Kidney Cancer Diagnosis]:

1. Diagnosis of advanced papillary renal cell carcinoma; and
2. Non-clear cell histology; and
3. Relapsed disease or surgically unresectable stage IV disease; and
4. Used in combination with bevacizumab.

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

1. Diagnosis of NSCLC; and
2. Recurrent or metastatic disease; and
3. Epidermal growth factor receptor (EGFR) mutation detected; and
4. As a single agent only.

Tarceva® (Erlotinib) Approval Criteria [Pancreatic Adenocarcinoma Diagnosis]:

1. Diagnosis of pancreatic adenocarcinoma; and
2. ECOG performance status of 0 or 1; and
3. Locally advanced, unresectable disease or metastatic disease; and
4. In combination with gemcitabine.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Alveolar Soft Part Sarcoma (ASPS) Diagnosis]:

1. Diagnosis of unresectable or metastatic ASPS; and
2. Member must be 2 years of age or older for Tecentriq®; or
3. Member must be 18 years of age or older for Tecentriq Hybreza®.

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

1. Diagnosis of advanced unresectable or metastatic HCC disease; and
2. Used in combination with bevacizumab; and
3. Member has not received prior systemic therapy; and
4. Member must be 18 years of age or older.

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

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

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of non-squamous NSCLC; and
    a. First-line therapy for metastatic disease; and
    b. The member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, BRAF, MET exon 14 skipping mutation, or RET mutations; and
    c. Used in combination with bevacizumab, paclitaxel, and carboplatin (maximum of 6 cycles) or in combination with paclitaxel (protein bound) and carboplatin; and
    d. Atezolizumab and bevacizumab may be continued after the above combination in members without disease progression (applies to the bevacizumab/paclitaxel/carboplatin regimen); or
2. Diagnosis of NSCLC; and
    a. For first-line therapy for metastatic disease:
        i. Used as a single-agent; and
        ii. Member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, BRAF, MET exon 14 skipping, or RET mutations; and
        iii. High programmed death ligand-1 (PD-L1) expression determined by 1 of the following:
            1. PD-L1 stained ≥50% of tumor cells (TC≥50%); or
            2. PD-L1 stained tumor-infiltrating immune cells (IC) covering ≥10% of the tumor area (IC≥10%); or
    b. For subsequent therapy for metastatic disease, meets the following:
        i. Used as a single-agent only; or
3. Diagnosis of stage II or IIIA NSCLC; and
    a. Member has undergone resection and completed platinum-based chemotherapy; and
    b. PD-L1 expression of ≥1% of tumor cells; and
4. Member must be 18 years of age or older.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. First-line therapy; and
3. Extensive-stage disease; and
4. Atezolizumab must be used in combination with carboplatin and etoposide; and
5. Member must be 18 years of age or older.

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

1. Diagnosis of advanced, metastatic, or unresectable NSCLC; and
2. Mesenchymal-epithelial transition (MET) exon 14 skipping positive tumor; and
3. As a single agent.

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

1. Diagnosis of metastatic NSCLC; and
2. Member has not received prior epidermal growth factor receptor (EGFR) therapy for metastatic disease; and
3. Members must meet 1 of the following:
    a. EGFR exon 19 deletion; or
    b. Exon 21 L858R substitution mutation; and
4. As a single agent.

Xalkori® (Crizotinib) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL) Diagnosis]:

1. Members 1 year of age or older:
    a. Diagnosis of systemic ALCL that is anaplastic lymphoma kinase (ALK)-positive; and
    b. Relapsed or refractory disease; and
2. As a single agent.

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

1. Diagnosis of metastatic NSCLC; and
2. First-line or subsequent therapy; and
3. Anaplastic lymphoma kinase (ALK) or *ROS1*-positive; or
4. MET amplification; and
5. As a single agent only.

Xalkori® (Crizotinib) Approval Criteria [Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) Diagnosis]:

1. Diagnosis of soft tissue sarcoma – IMT; and
2. Member must be 1 year of age or older; and
1. Anaplastic lymphoma kinase (ALK) positive; and
2. Used as a single agent only.

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

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

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
    a. Used for first-line therapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Used in 1 of the following settings:
        i. Used in combination with nivolumab and member has programmed death ligand 1 (PD-L1) ≥1% expression; or
        ii. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy.

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

1. Refractory or metastatic disease; and
2. BRAF V600E or V600K mutation; and
    a. Not indicated for wild-type BRAF NSCLC; and
3. As a single agent.

Zepzelca® (Lurbinectedin) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Used following disease progression on or after platinum-based chemotherapy.

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

1. Diagnosis of metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. As a single agent only.

Zykadia® (Ceritinib) Approval Criteria [Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT) with Anaplastic Lymphoma Kinase (ALK) Translocation Diagnosis]:

1. Diagnosis of soft tissue sarcoma – IMT; and
2. ALK positivity; and
3. As a single agent only.

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 Lung Cancer Medications: Fiscal Year 2025

The following utilization data includes medications indicated for lung cancer; however, the data does not differentiate between lung cancer and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	25	162	$2,611,738.87	$16,121.84	$547.42	18,698	4,771
Aetna	3	7	$140,326.35	$20,046.62	$668.22	690	210
Humana	4	12	$221,844.58	$18,487.05	$616.23	2,040	360
OCH	3	4	$84,136.28	$21,034.07	$701.14	150	120
2024 Total	**27**	**185**	**$3,058,046.08**	**$16,529.98**	**$559.98**	**21,578**	**5,461**
Fiscal Year 2025							
FFS	15	69	$1,098,519.01	$15,920.57	$542.48	7,275	2,025
Aetna	5	29	$620,650.85	$21,401.75	$713.39	3,330	870
Humana	5	46	$818,639.54	$17,796.51	$595.81	6,840	1,374
OCH	10	27	$501,879.65	$18,588.14	$631.30	1,875	795
2025 Total	**31**	**171**	**$3,039,689.05**	**$17,775.96**	**$600.25**	**19,320**	**5,064**
% Change	**14.80%**	**-7.60%**	**-0.60%**	**7.50%**	**7.20%**	**-10.50%**	**-7.30%**
Change	**4**	**-14**	**-$18,357.03**	**$1,245.98**	**$40.27**	**-2,258**	**-397**

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	146	920	$5,935,608.18	$6,451.75	6.3
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	5	9	$71,046.00	$7,894.00	1.8
2024 Total	**147**	**929**	**$6,006,654.18**	**$6,465.72**	**6.32**
Fiscal Year 2025					
FFS	135	740	$3,790,187.43	$5,121.87	5.48
Aetna	31	120	$434,575.40	$3,621.46	3.87
Humana	17	39	$165,417.60	$4,241.48	2.29
OCH	36	169	$823,351.98	$4,871.91	4.69
2025 Total	**201**	**1,068**	**$5,213,532.41**	**$4,881.58**	**5.31**
% Change	**36.73%**	**14.96%**	**-13.20%**	**-24.50%**	**-15.98%**
Change	**54**	**139**	**-$793,121.77**	**-$1,584.14**	**-1.01**

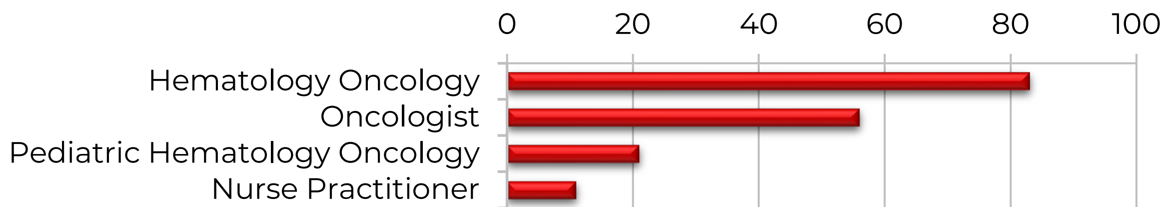
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect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

- Aggregate drug rebates collected during fiscal year 2025 for lung cancer medications totaled $3,659,071.57.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

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

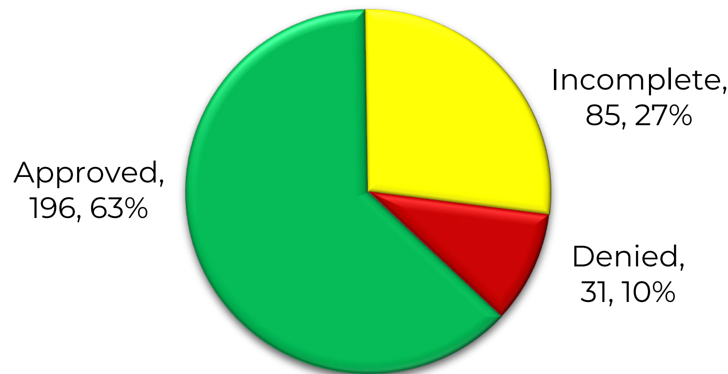
Top Prescriber Specialties of Lung Cancer Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Lung Cancer Medications

There were 312 prior authorization requests submitted for lung cancer medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (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.

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	156	62%	78	31%	17	7%	251
Aetna	6	100%	0	0%	0	0%	6
Humana	17	81%	0	0%	4	19%	21
OCH	17	50%	7	21%	10	29%	34
Total	196	63%	85	27%	31	10%	312

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]

Anticipated Patent Expiration(s):

- Xalkori® (crizotinib): November 2029
- Tepmetko® (tepotinib): March 2030
- Gilotrif® (afatinib): January 2031
- Vizimpro® (dacomitinib): September 2032
- Ibtrozi™ (taletrectinib): June 2033
- Alecensa® (alectinib): April 2035
- Tabrecta® (capmatinib): July 2035
- Hyrnuo® (sevabertinib): October 2035
- Alunbrig® (brigatinib): November 2035
- Pemfexy® (pemetrexed): February 2036
- Augtyro™ (repotrectinib): July 2036
- Ensacove™ (ensartinib): June 2037
- Zykadia® (ceritinib): December 2037
- Rozlytrek® (entrectinib): July 2038
- Lorbrena® (lorlatinib): October 2038
- Retevmo® (selpercatinib): April 2039
- Zepzelca® (lurbinectedin): May 2040
- Lumakras® (sotorasib): September 2040
- Cosela® (trilaciclib): November 2040
- Hernexeos® (zongertinib): July 2041
- Lazcluze® (lazertinib): August 2041
- Gavreto® (pralsetinib): July 2042
- Tagrisso® (osimertinib): November 2042
- Krazati® (adagrasib): August 2043

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

- **December 2024:** The FDA approved Ensacove™ (ensartinib) for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test who have not previously

received an ALK-inhibitor. According to the FDA's National Drug Code (NDC) Directory, Ensacove™ began being marketed in April 2025.

- **May 2025:** The FDA granted accelerated approval to Emrelis™ (telisotuzumab vedotin-tllv) for the treatment of adult patients with locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.
- **June 2025:** The FDA approved Ibtrozi™ (taletrectinib) for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC.
- **June 2025:** The FDA approved Avgemsi™ (gemcitabine) through the 505(b)(2) pathway based on prior studies utilizing Gemzar® (gemcitabine). Avgemsi™ is supplied as a solution for intravenous (IV) use in multiple-dose vials available in 1g/26.3mL and 2g/52.6mL strengths.
- **August 2025:** The FDA granted accelerated approval to Hernexeos® (zongertinib) for the treatment of adult patients with unresectable or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy. In February 2026, the FDA granted accelerated approval for an updated indication for Hernexeos®, removing the requirement that patients have received prior systemic therapy.
- **October 2025:** The FDA approved Tecentriq® (atezolizumab) and Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs), in combination with Zepzelca® (lurbinectedin), for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase-tqjs, and carboplatin plus etoposide.
- **November 2025:** The FDA granted accelerated approval to Hyrnuo® (sevabertinib) for the treatment of adult patients with locally advanced or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
- **November 2025:** The FDA approved an age expansion for Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs) for the treatment of pediatric patients 12 years of age and older who weigh ≥40kg with unresectable or metastatic alveolar soft part sarcoma (ASPS). Previously, Tecentriq Hybreza® was only FDA approved for this indication in adults.
- **November 2025:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with fluorouracil, leucovorin, oxaliplatin, and

docetaxel (FLOT) chemotherapy as neoadjuvant and adjuvant treatment, followed by single agent durvalumab, for the treatment of adult patients with resectable gastric or gastroesophageal junction (GEJ) adenocarcinoma.
- **December 2025:** The FDA approved Rybrevant Faspro™ (amivantamab/hyaluronidase-lpuj), a new subcutaneous (sub-Q) formulation of amivantamab, for adult patients with NSCLC for all the same indications as the IV formulation of amivantamab.

Guideline Update(s):
- The National Comprehensive Cancer Network (NCCN) guidelines for NSCLC allow for the use of erlotinib in patients with metastatic disease who have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as a single agent or in combination with ramucirumab (if T790M mutation negative).

Emrelis™ (Telisotuzumab Vedotin-tllv)) Product Summary[16]

Therapeutic Class: C-Met-directed antibody and microtubule inhibitor conjugate

Indication(s): Treatment of adult patients with locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.
- This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: Lyophilized powder in 20mg and 100mg single-dose vials (SDVs)

Dosing and Administration:
- The recommended dose is 1.9mg/kg (up to a maximum of 190mg for patients weighing ≥100kg) every 2 weeks until disease progression or unacceptable toxicity.
- Each dose should be administered as an IV infusion over 30 minutes.

Cost: The Wholesale Acquisition Cost (WAC) is $13,980 per 100mg SDV and $2,796 per 20mg SDV. For a member weighing 80kg, this would result in an estimated cost of $44,736 per 28 days or $581,568 per year based on recommended dosing. At maximum dose, this would result in an estimated cost of $55,920 per 28 days or $726,960 per year.

Ensacove™ (Ensartinib) Product Summary[17]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with ALK-positive locally advanced or metastatic NSCLC as detected by an FDA-approved test who have not previously received an ALK-inhibitor.

How Supplied: 25mg and 100mg oral capsules

Dosing and Administration:

- The recommended dose is 225mg orally once daily with or without food, continued until disease progression or unacceptable toxicity.

Cost: The WAC is $310.52 per 100mg capsule and $77.60 per 25mg capsule. This would result in an estimated cost of $20,959.20 per month or $251,510.40 per year based on recommended dosing.

Hernexeos® (Zongertinib) Product Summary[18]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with unresectable or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-authorized test.

- 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 a confirmatory trial.

How Supplied: 60mg oral tablets

Dosing and Administration: The recommended dosage is based on body weight, as follows:

- <90kg: 120mg once daily with or without food
- ≥90kg: 180mg once daily with or without food
- Dosing should continue until disease progression or unacceptable toxicity.
- Dosage adjustments may be necessary based on adverse reactions or drug interactions. If concomitant use with strong CYP3A4 inducers cannot be avoided, increased doses up to 360mg once daily may be required.

Cost: The WAC is $361.12 per tablet. For a member weighing <90kg, this would result in an estimated cost of $21,667.20 per month or $260,006.40 per year based on recommended dosing. For a member weighing ≥90kg, this would result in an estimated cost of $32,500.80 per month or $390,009.60 per year.

Hyrnuo® (Sevabertinib) Product Summary[19]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with locally advanced or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.

- This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

How Supplied: 10mg oral tablets

Dosing and Administration:

- The recommended dose is 20mg orally twice daily with food, continued until disease progression or unacceptable toxicity.

Cost: The WAC is $200 per tablet. This would result in an estimated cost of $24,000 per month or $288,000 per year based on recommended dosing.

Ibtrozi™ (Taletrectinib) Product Summary[20]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC

How Supplied: 200mg oral capsules

Dosing and Administration:

- The recommended dosage is 600mg [using (3) 200mg capsules] orally once daily on an empty stomach (no food intake at least 2 hours before and 2 hours after taking Ibtrozi™) until disease progression or unacceptable toxicity.

Cost: The WAC is $347.30 per capsule. This would result in an estimated cost of $31,257 per month or $375,084 per year based on recommended dosing.

Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) Product Summary[21]

Therapeutic Class: Combination of amivantamab, a bispecific EGFR-directed and MET receptor-directed antibody, and hyaluronidase, an endoglycosidase

Indication(s): Indicated for all of the same all of the same indications for NSCLC as the IV formulation of Rybrevant®

How Supplied: Available as SDVs in the following combinations:

- 1,600mg amivantamab/20,000 units hyaluronidase per 10mL solution
- 2,240mg amivantamab/28,000 units hyaluronidase per 14mL solution
- 2,400mg amivantamab/30,000 units hyaluronidase per 15mL solution
- 3,520mg amivantamab/44,000 units hyaluronidase per 22mL solution

Dosing and Administration:

- Rybrevant Faspro™ should be administered as a sub-Q injection in the abdomen over approximately 5 minutes.
- The recommended dose and frequency depends on whether Rybrevant Faspro™ is used in combination with carboplatin and pemetrexed, in combination with lazertinib, or as a single agent.
- Rybrevant Faspro™ should be continued until disease progression or unacceptable toxicity.
- Please see the full *Prescribing Information* for specific dosing information.

Cost: The WAC is $1,238.27 per mL. For a member weighing 80kg and receiving 2,240mg/28,000 units (14mL) every 2 weeks, this would result in an estimated cost of $34,671.56 per 28 days or $450,730.28 per year.

Cost Comparison: Gemcitabine Products

Product	Cost Per 200mg	Cost Per 21 Days*	Cost Per Year
Avgemsi™ (gemcitabine) (J9184)	**$390.00**	**$8,580.00**	**$145,860.00**
gemcitabine (Accord) (J9196)	$5.29	$116.38	$1,978.46
gemcitabine (generic Gemzar®) (J9201)	$3.59	$78.98	$1,342.66

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS).

*Cost per 21 days based on a dose of 1,250mg/m^2 on days 1 and 8 of each 21-day cycle for a member with a body surface area (BSA) of 1.73m^2 (using a total of 2,200mg per dose).

Recommendations

The College of Pharmacy recommends the prior authorization of Emrelis™ (telisotuzumab vedotin-tllv), Ensacove™ (ensartinib), Hernexeos® (zongertinib), Hyrnuo® (sevabertinib), and Ibtrozi™ (taletrectinib) based on recent FDA approval with the following criteria (shown in red):

Emrelis™ (Telisotuzumab Vedotin-tllv) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent, advanced, or metastatic non-squamous NSCLC; and

2. Disease with high c-Met/MET protein overexpression, defined as ≥50% of tumor cells with strong staining [immunohistochemistry (IHC) 3+]; and
3. Epidermal growth factor receptor (EGFR) wild-type; and
4. Member has received prior systemic therapy; and
5. ECOG performance status of 0-2; and
6. Used as a single agent; and
7. Member must be 18 years of age or older.

Ensacove™ (Ensartinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positive; and
3. Used as a single agent; and
4. Member has not previous received an ALK inhibitor.

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

1. Diagnosis of non-squamous NSCLC; and
2. Disease is unresectable or metastatic; and
3. Disease is positive for HER2 (ERBB2) tyrosine kinase domain activating mutation; and
4. Member must be 18 years of age or older.

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

1. Diagnosis of non-squamous NSCLC; and
2. Disease is locally advanced or metastatic; and
3. Disease is positive for HER2 (ERBB2) tyrosine kinase domain activating mutations; and
4. Member has received prior systemic therapy; and
5. Member is 18 years of age or older.

Ibtrozi™ (Taletrectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
2. Disease is locally advanced or metastatic; and
3. Disease is positive for *ROS1* rearrangements; and
4. Members is 18 years of age or older.

Next, the College of Pharmacy also recommends the prior authorization of Rybrevant Faspro™ (amivantamab/hyaluronidase-lpuj) with criteria similar to Rybrevant® (amivantamab-vmjw) with the following changes (shown in red):

Rybrevant® (Amivantamab-vmjw) and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
   a. As first-line therapy in combination with carboplatin and pemetrexed; or
   b. As a single agent in disease that has progressed on or after platinum-based chemotherapy; or
3. Tumor exhibits EGFR exon 19 deletion or exon 21 L858R mutations; and
   a. As first-line therapy in combination with lazertinib; or
   b. As subsequent therapy in combination with carboplatin and pemetrexed after progression on an EGFR tyrosine kinase inhibitor.

The College of Pharmacy also recommends the prior authorization of Avgemsi™ (gemcitabine) based on net costs with the following criteria (shown in red):

Avgemsi™ (Gemcitabine; J9184) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Gemzar® (gemcitabine – J9201) and other preferred gemcitabine products (J9196 – Accord) that do not require prior authorization must be provided.

Next, the College of Pharmacy recommends updating the Imfinzi® (durvalumab), Tecentriq® (atezolizumab), Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs), and Zepzelca® (lurbinectedin) approval criteria based on new FDA approvals (changes shown in red):

Imfinzi® (Durvalumab) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of gastric or GEJ adenocarcinoma; and
2. Disease is resectable; and
3. Disease is positive for programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1 or tumor area positivity (TAP) ≥1%; and
4. Used as perioperative treatment, where:
   a. Used in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy as neoadjuvant and adjuvant treatment; and
   b. Used as single agent maintenance therapy following combination therapy with FLOT chemotherapy; and
5. Member is 18 years of age or older.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/Hyaluronidase-tqjs) Approval Criteria [Alveolar Soft Part Sarcoma (ASPS) Diagnosis]:

1. Diagnosis of unresectable or metastatic ASPS; and
2. Member must be 2 years of age or older for Tecentriq®; or
3. Member must be ~~18~~ 12 years of age or older and weigh ≥40kg for Tecentriq Hybreza®.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/Hyaluronidase-tqjs) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. A diagnosis of SCLC; and
2. ~~First-line therapy; and~~
3. Extensive-stage disease; and
4. ~~Atezolizumab must be used in combination with carboplatin and etoposide; and~~
5. Used in 1 of the following settings:
   a. Used as primary treatment in combination with carboplatin and etoposide; or
   b. Used as first-line maintenance treatment for disease that has not progressed on or after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase, carboplatin, and etoposide; and
      i. Maintenance treatment is given in combination with lurbinectedin or as a single agent; and
6. Member must be 18 years of age or older.

Zepzelca® (Lurbinectedin) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. A diagnosis of ~~metastatic~~ SCLC; and
2. Used in 1 of the following settings:
   a. Disease is metastatic; and
      i. Used as subsequent therapy following disease progression on or after platinum-based chemotherapy; or
   b. Disease is extensive-stage; and
      i. Used as first-line maintenance treatment for disease that has not progressed on or after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase, carboplatin, and etoposide; and
      ii. Maintenance treatment is given in combination with atezolizumab or atezolizumab/hyaluronidase; and
3. Member must be 18 years of age or older.

Next, the College of Pharmacy recommends updating the Tarceva® (erlotinib) approval criteria based on NCCN guideline recommendations (changes shown in red):

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

1. Diagnosis of NSCLC; and
2. Recurrent or metastatic disease; and
3. Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation detected; and
4. As a single agent ~~only.~~; or
5. In combination with ramucirumab (if T790M mutation negative).

Utilization Details of Lung Cancer Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SELPERCATINIB PRODUCTS						
RETEVMO TAB 80MG	16	3	$269,658.94	$16,853.68	5.33	8.87%
RETEVMO TAB 160MG	11	2	$259,997.91	$23,636.17	5.5	8.55%
RETEVMO CAP 80MG	11	4	$203,503.91	$18,500.36	2.75	6.69%
RETEVMO TAB 120MG	6	1	$137,913.82	$22,985.64	6	4.54%
RETEVMO TAB 40MG	5	1	$109,655.38	$21,931.08	5	3.61%
RETEVMO CAP 40MG	4	1	$90,436.00	$22,609.00	4	2.98%
SUBTOTAL	**53**	**12**	**$1,071,165.96**	**$20,210.68**	**4.42**	**35.24%**
ALECTINIB PRODUCTS						
ALECENSA CAP 150MG	38	4	$723,386.20	$19,036.48	9.5	23.80%
SUBTOTAL	**38**	**4**	**$723,386.20**	**$19,036.48**	**9.5**	**23.80%**
OSIMERTINIB PRODUCTS						
TAGRISSO TAB 80MG	24	9	$407,893.54	$16,995.56	2.67	13.42%
TAGRISSO TAB 40MG	10	3	$206,034.85	$20,603.49	3.33	6.78%
SUBTOTAL	**34**	**12**	**$613,928.39**	**$18,056.72**	**2.83**	**20.20%**
ADAGRASIB PRODUCTS						
KRAZATI TAB 200MG	17	5	$334,630.16	$19,684.13	3.4	11.01%
SUBTOTAL	**17**	**5**	**$334,630.16**	**$19,684.13**	**3.4**	**11.01%**
ENTRECTINIB PRODUCTS						
ROZLYTREK CAP 200MG	9	1	$137,027.10	$15,225.23	9	4.51%
SUBTOTAL	**9**	**1**	**$137,027.10**	**$15,225.23**	**9**	**4.51%**
ERLOTINIB PRODUCTS						
ERLOTINIB TAB 100MG	9	1	$1,295.19	$143.91	9	0.04%
SUBTOTAL	**9**	**1**	**$1,295.19**	**$143.91**	**9**	**0.04%**
SOTORASIB PRODUCTS						
LUMAKRAS TAB 320MG	4	1	$84,509.88	$21,127.47	4	2.78%
LUMAKRAS TAB 120MG	2	1	$5,301.84	$2,650.92	2	0.17%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**6**	**2**	**$89,811.72**	**$14,968.62**	**3**	**2.95%**
AFATINIB PRODUCTS						
GILOTRIF TAB 30MG	2	1	$23,606.34	$11,803.17	2	0.78%
GILOTRIF TAB 40MG	1	1	$11,803.17	$11,803.17	1	0.39%
SUBTOTAL	**3**	**2**	**$35,409.51**	**$11,803.17**	**1.5**	**1.16%**
DACOMITINIB PRODUCTS						
VIZIMPRO TAB 45MG	2	1	$33,034.82	$16,517.41	2	1.09%
SUBTOTAL	**2**	**1**	**$33,034.82**	**$16,517.41**	**2**	**1.09%**
TOTAL	**171**	**31***	**$3,039,689.05**	**$17,775.96**	**5.52**	**100%**

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

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
GEMCITABINE J9201	315	56	$5,256.26	$16.69	5.63
DURVALUMAB J9173	222	53	$2,433,165.03	$10,960.20	4.19
PEMETREXED J9305	181	34	$52,461.90	$289.84	5.32
ATEZOLIZUMAB J9022	174	46	$1,852,514.66	$10,646.64	3.78
GEMCITABINE J9196	54	12	$3,679.31	$68.14	4.5
LURBINECTEDIN J9223	46	10	$503,203.20	$10,939.20	4.6
PEMETREXED J9294	29	4	$1,979.50	$68.26	7.25
TRILACICLIB J1448	22	4	$41,922.00	$1,905.55	5.5
TARLATAMAB-DLLE J9026	11	1	$168,538.50	$15,321.68	11
AMIVANTAMAB-VMJW J9061	8	1	$68,916.75	$8,614.59	8
PEMETREXED J9297	3	1	$91.80	$30.60	3
TREMELIMUMAB-ACTL J9347	2	2	$81,303.00	$40,651.50	1
PEMETREXED J9322	1	1	$500.50	$500.50	1
TOTAL	**1,068**	**201**	**$5,213,532.41**	**$4,881.58**	**5.31**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2025 = 07/01/204 to 06/30/2025

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Appendix N

Fiscal Year 2025 Annual Review of Attention-Deficit/ Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution)

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

<table>
<tr><th colspan="4">ADHD Medications</th></tr>
<tr><th>Tier-1*</th><th>Tier-2*</th><th>Tier-3*</th><th>Special PA</th></tr>
<tr><td colspan="3">Amphetamine</td><td rowspan="7">amphetamine (Evekeo®)Δ

amphetamine ODT (Evekeo ODT®)Δ

amphetamine/ dextroamphetamine ER (Mydayis®)Δ

dextroamphetamine (Dexedrine®)Δ

dextroamphetamine soln (ProCentra®)Δ

dextroamphetamine (Xelstrym®)Δ

dextroamphetamine (Zenzedi®)Δ

methamphetamine (Desoxyn®)Δ

methylphenidate ER 72mgΔ

methylphenidate ER ODT (Cotempla XR-ODT®)Δ

methylphenidate ER (Relexxii®)Δ</td></tr>
<tr><td colspan="3">Short-Acting</td></tr>
<tr><td>amphetamine/ dextroamphetamine (Adderall®)</td><td></td><td></td></tr>
<tr><td colspan="3">Long-Acting</td></tr>
<tr><td>amphetamine/ dextroamphetamine ER (Adderall XR®)</td><td>dextroamphetamine ER (Dexedrine Spansules®)

lisdexamfetamine cap (Vyvanse®)+</td><td>amphetamine ER ODT (Adzenys XR-ODT®)Δ

amphetamine ER susp and tab (Dyanavel® XR)Δ

lisdexamfetamine chew tab (Vyvanse®)Δ</td></tr>
<tr><td colspan="3">Methylphenidate
Short-Acting</td></tr>
<tr><td>dexmethylphenidate (Focalin®)

methylphenidate tab and soln (Methylin®)Δ

methylphenidate (Ritalin®)</td><td></td><td></td></tr>
</table>

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Long-Acting			methylphenidate chew tab (Methylin®)Δ methylphenidate ER chew tab (QuilliChew ER®)Δ
dexmethylphenidate ER (Focalin XR®) methylphenidate ER (Concerta®) methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)	methylphenidate ER (Aptensio XR®) methylphenidate ER (Daytrana®)Δ methylphenidate ER susp (Quillivant XR®)Δ methylphenidate ER (Ritalin LA®)	methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ	clonidine ER susp (Onyda™ XR)Δ	viloxazine (Qelbree®)Δ

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
⁺Unique criteria applies for the diagnosis of binge eating disorder (BED). Other tier trial requirements do not apply for a diagnosis of BED.
ΔUnique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 180 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. For Daytrana® patches, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and

4. For Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. Kapvay® Approval Criteria:
    a. An FDA approved diagnosis; and
    b. A previously failed trial (within the last 180 days) with a long-acting Tier-1 stimulant or non-stimulant unless contraindicated, that did not yield adequate results.
6. Vyvanse® Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
    a. An FDA approved diagnosis of moderate-to-severe BED; and
    b. Member must be 18 years of age or older; and
    c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
    d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
    e. A quantity limit of 30 capsules per 30 days will apply; and
    f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
4. For Adzenys XR-ODT® and Dyanavel® XR oral suspension, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. Onyda™ XR Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and

    c. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
    d. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Kapvay® (clonidine ER tablet) must be provided.
6. For Vyvanse® chewable tablet, a patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
    a. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Cotempla XR-ODT®, Evekeo ODT®, QuilliChew ER®, and Xelstrym® Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Mydayis® Approval Criteria:
    a. A covered diagnosis; and
    b. Member must be 13 years of age or older; and

   c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and
   c. Previously failed trial (within the last 180 days) with atomoxetine or any ADHD medication, unless contraindicated, that did not yield adequate results; and
      i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or any ADHD medications within the past 180 days of claims history; and
   d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
   e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
   f. Quantity limits will apply based on FDA-approved dosing.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted psychiatrist.
3. For Methylin® oral solution, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
   a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
   b. Absence of cataplexy; and
   c. Multiple sleep latency test (MSLT) results showing 1 of the following:
      i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
      ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and

   d. At least 1 of the following:
      i. MSLT showing mean sleep latency ≤8 minutes; or
      ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
   e. Insufficient sleep syndrome has been ruled out; and
   f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and
2. Diagnosis must be confirmed by a sleep specialist; and
3. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
   a. Tier-1 stimulant; or
   b. Tier-2 stimulant; or
   c. Nuvigil® (armodafinil); or
   d. Provigil® (modafinil); or
   e. Clarithromycin; and
4. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
5. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
   a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Sunosi® (solriamfetol), Wakix® (pitolisant), Xyrem® (sodium oxybate), or Xywav® (calcium/magnesium/ potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with Tier-1 and Tier-2 stimulants from different chemical categories, Provigil® (modafinil), and Nuvigil® (armodafinil), unless contraindicated, that did not yield adequate results; and
   a. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and

3. Additionally, use of Xywav® (calcium/ magnesium/potassium/sodium oxybates) requires a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Xyrem®; and
   a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided; and
4. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
5. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Utilization of ADHD and Narcolepsy Medications: Fiscal Year 2025

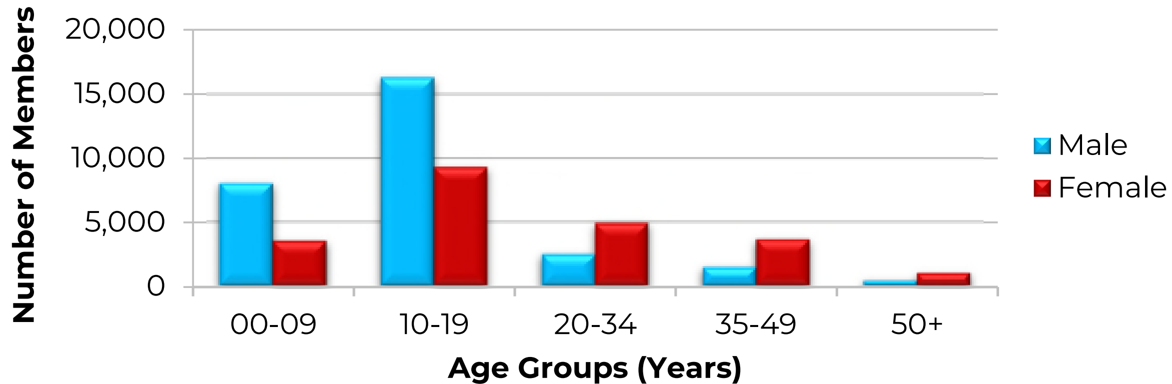
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

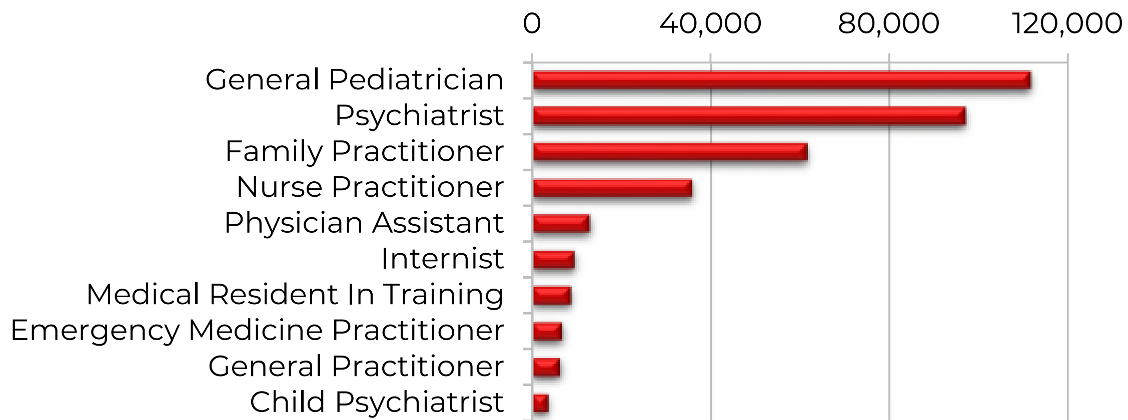
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	47,776	301,861	$47,272,301.16	$156.60	$5.16	10,774,211	9,160,184
Aetna	6,135	14,588	$2,051,602.52	$140.64	$4.65	531,209	441,650
Humana	6,380	15,170	$2,326,722.28	$153.38	$5.08	547,174	458,385
OCH	10,010	24,775	$2,992,364.92	$120.78	$3.99	867,642	750,570
2024 Total	**50,895**	**356,394**	**$54,642,990.88**	**$153.32**	**$5.05**	**12,720,236**	**10,810,789**
Fiscal Year 2025							
FFS	20,954	123,830	$16,520,816.10	$133.42	$4.34	4,518,720	3,802,955
Aetna	10,338	64,942	$8,760,200.15	$134.89	$4.46	2,354,092	1,965,080
Humana	10,471	65,086	$9,705,829.96	$149.12	$4.91	2,371,647	1,978,263
OCH	16,063	112,616	$14,407,483.11	$127.93	$4.15	4,046,856	3,469,308
2025 Total	**50,777**	**366,474**	**$49,394,329.32**	**$134.78**	**$4.40**	**13,291,315**	**11,215,606**
% Change	**-0.20%**	**2.80%**	**-9.60%**	**-12.10%**	**-12.90%**	**4.50%**	**3.70%**
Change	**-118**	**10,080**	**-$5,248,661.56**	**-$18.54**	**-$0.65**	**571,079**	**404,817**

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

- Aggregate drug rebates collected during fiscal year 2025 for ADHD and narcolepsy medications totaled $34,949,753.96.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

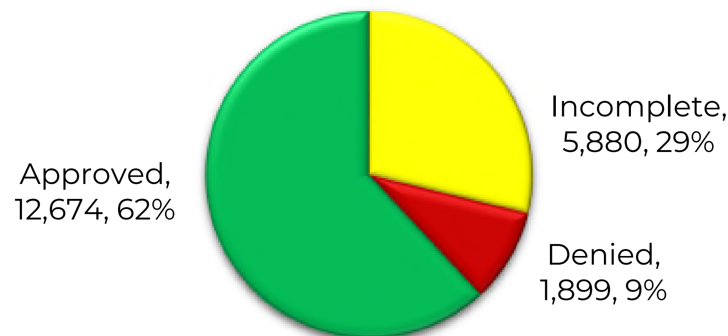
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.





Prior Authorization of ADHD and Narcolepsy Medications

There were 20,453 prior authorization requests submitted for ADHD and narcolepsy medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	7,272	58%	4,716	37%	627	5%	12,615
Aetna	1,934	70%	420	15%	395	14%	2,749
Humana	87	49%	0	0%	90	51%	177
OCH	3,381	69%	744	15%	787	16%	4,912
Total	12,674	62%	5,880	29%	1,899	9%	20,453

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

Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available for the SoonerCare fee-for-service (FFS) population and can be scheduled by calling 1-405-522-7597.
- **Care Management (Including Behavioral Health):** Additional services are available for SoonerCare members, including Behavioral Health Care Management, through the member's SoonerCare (FFS) or SoonerSelect (managed care) health plan.
- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care management for chronic and complex medical conditions at: https://medicine.okstate.edu/echo/.
- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/.
- **Statewide Psychiatry Access, Resources, and Knowledge (SPARK):** SPARK provides services directly to primary care providers (PCPs) who deliver pediatric mental health care in the primary care setting and can be found online at: https://okspark.org. Provider-to-provider services include telephone consultation, enhanced mental health education, referral assistance, medication management assistance, diagnostic decision making, in-office interventions, and family engagement. Many of the learning opportunities also provide Category 1-A Continuing Medical Education (CME).

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

Anticipated Patent Expiration(s):

- Wakix® (pitolisant tablet): March 2030
- Quillivant XR® (methylphenidate ER suspension): February 2031
- Jornay PM® (methylphenidate ER capsule): March 2032
- Adzenys XR-ODT® [amphetamine ER orally disintegrating tablet (ODT)]: June 2032
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Qelbree® (viloxazine ER capsule): April 2035
- Dyanavel® XR (amphetamine ER suspension): September 2036
- Evekeo ODT® (amphetamine ODT): March 2037
- Azstarys® (serdexmethylphenidate/dexmethylphenidate capsule): December 2037
- Cotempla XR-ODT® (methylphenidate ER ODT): January 2038
- Dyanavel® XR (amphetamine ER tablet): February 2040
- Arynta™ (lisdexamfetamine oral solution): August 2040
- Xywav® (calcium/magnesium/potassium/sodium oxybates oral solution): February 2041
- Onyda™ XR (clonidine ER suspension): July 2041
- Xelstrym® (dextroamphetamine transdermal system): January 2042
- Sunosi® (solriamfetol tablet): December 2042

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

- **June 2025:** The FDA approved Arynta™ (lisdexamfetamine oral solution) through the 505(b)(2) pathway based on prior studies utilizing Vyvanse® (lisdexamfetamine) capsules. A pharmacokinetic study demonstrated comparable bioavailability between Arynta™ and lisdexamfetamine capsules. Azurity Pharmaceuticals has announced that Arynta™ will be available in mid-2026.
- **March 2026:** The FDA approved Atoncy™ (atomoxetine oral solution) through the 505(b)(2) pathway based on prior studies utilizing Strattera® (atomoxetine) capsules. No clinically significant differences in pharmacokinetics of atomoxetine were observed after administration of Atoncy™ and atomoxetine capsules under fasted conditions.

Pipeline:

- **Centanafadine (EB-1020):** Centanafadine is an investigational norepinephrine, dopamine, and serotonin reuptake inhibitor (NDSRI) that is being evaluated for the treatment of ADHD. Phase 3 studies of centanafadine have demonstrated significant improvements in ADHD symptoms, relative to placebo, in children, adolescents, and adults. In January 2026, Otsuka announced the FDA has accepted their New

Drug Application (NDA) for centanafadine and has assigned a Prescription Drug User Fee Act (PDUFA) target date of July 24, 2026.

- **CTx-1301 (Dexmethylphenidate):** CTx-1301 is an investigational, once-daily formulation of dexmethylphenidate which utilizes proprietary technology to deliver 3 timed releases of medication throughout the day with the goal of achieving rapid onset of action and entire active-day duration. In October 2025, Cingulate announced the FDA has accepted their NDA for CTx-1301 for the treatment of ADHD in children and adults and has assigned a PDUFA target date of May 31, 2026.
- **Oveporexton (TAK-861):** Oveporexton is an investigational orexin receptor 2 (OX2R)-selective agonist that is being evaluated for the treatment of narcolepsy type 1 (NT1). In February 2026, Takeda announced the FDA has accepted their NDA for oveporexton for priority review and has assigned a PDUFA target date within the third quarter of 2026.
- **TRN-257 (Sodium Oxybate):** TRN-257 is an investigational formulation of sodium oxybate which is being evaluated for the treatment of narcolepsy and idiopathic hypersomnia. TRN-257 is being developed as a low-sodium option which can be administered with once-nightly dosing. In December 2025, Tris Pharma announced the FDA has accepted their NDA for TRN-257 for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy and for the treatment of idiopathic hypersomnia in adults and has assigned a PDUFA target date of June 20, 2026.

Arynta™ (Lisdexamfetamine Oral Solution) Product Summary[10,11]

Therapeutic Class: Central nervous system (CNS) stimulant

Indication(s):

- Treatment of ADHD in adults and pediatric patients 6 years and older
- Treatment of moderate to severe binge eating disorder (BED) in adults
- **Limitation(s) of Use:**
  - Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
  - Arynta™ is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Arynta™ for the treatment of obesity have not been established.

How Supplied: 10mg/mL oral solution in a 30mL, 60mL, 90mL, 100mL, or 120mL bottle

Dosing and Administration:

- The recommended dosing is the same as the recommended dosing for Vyvanse® (lisdexamfetamine) capsules and chewable tablets. The recommended initial dose is 30mg and the maximum recommended dose is 70mg regardless of indication.
- Arynta™ should be taken orally once daily in the morning, with or without food, using the oral dosing syringe and bottle adapter provided. Afternoon doses should be avoided because of the potential for insomnia.
- Any remaining medication should be discarded 30 days after first opening the bottle.

Efficacy: The efficacy of Arynta™ was based primarily on the existing data from studies utilizing lisdexamfetamine capsules. Arynta™ was determined to have comparable bioavailability to lisdexamfetamine capsules.

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Arynta™ (lisdexamfetamine) 10mg/mL sol - 120mL bottle	**$2.75**	**$577.50**	**$6,930.00**
Vyvanse® (lisdexamfetamine) 70mg cap	$12.35	$370.50	$4,446.00
Vyvanse® (lisdexamfetamine) 60mg chewable tab	$12.35	$370.50	$4,446.00
lisdexamfetamine 60mg chewable tab (generic)	$4.86	$145.80	$1,749.60
lisdexamfetamine 70mg cap (generic)	$2.88	$86.40	$1,036.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the use of 1 capsule/tablet daily or 7mL (70mg) daily for the solution.
Unit = each capsule, tablet, or mL
cap = capsule; sol = solution; tab = tablet

Atoncy™ (Atomoxetine Oral Solution) Product Summary[12]

Therapeutic Class: Selective norepinephrine reuptake inhibitor (SNRI)

Indication(s): Treatment of ADHD in adults and pediatric patients 6 years of age and older as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with ADHD

How Supplied: 4mg/mL grape-flavored oral solution in a 100mL bottle

Dosing and Administration:

- The recommended dosing for Atoncy™ is the same as the recommended dosing for Strattera® (atomoxetine) capsules.
- Atoncy™ may be administered either as a single daily dose in the morning or as evenly divided doses in the morning and late afternoon/early evening.

- <u>Pediatric patients weighing <70kg:</u>
  - The recommended starting dose is 0.5mg/kg/day.
  - The maximum recommended dose is 1.4mg/kg/day or 100mg/day, whichever is less.
- <u>Pediatric patients weighing ≥70kg and adults:</u>
  - The recommended starting dose is 40mg/day.
  - The maximum recommended dose is 100mg/day.
- Atoncy™ may be taken with or without food. Only the supplied syringe and bottle adapter should be used to measure and take Atoncy™.
- Any remaining medication should be discarded 45 days after first opening the bottle.

Efficacy: The efficacy of Atoncy™ was based primarily on the existing data from studies utilizing atomoxetine capsules. No clinically significant differences in pharmacokinetics of atomoxetine were observed after administration of Atoncy™ and atomoxetine capsules under fasted conditions.

Cost: The cost of Atoncy™ is not yet available.

Recommendations

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

1. Prior authorization of Arynta™ (lisdexamfetamine oral solution) and Atoncy™ (atomoxetine oral solution) and placement into the Special PA Tier with the additional criteria shown below; and
2. Separating the existing lisdexamfetamine binge eating disorder (BED) criteria and making additional updates to apply to all formulations and Tiers of lisdexamfetamine with the changes shown below; and
3. Moving Daytrana® (methylphenidate ER) patch from Tier-2 to Tier-3 based on net cost.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine (Evekeo®)Δ amphetamine ODT (Evekeo ODT®)Δ amphetamine/ dextroamphetamine ER (Mydayis®)Δ
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			

<table>
<tr><th colspan="4">ADHD Medications</th></tr>
<tr><th>Tier-1*</th><th>Tier-2*</th><th>Tier-3*</th><th>Special PA</th></tr>
<tr><td colspan="3">Long-Acting</td><td rowspan="7">dextroamphetamine (Dexedrine®)Δ

dextroamphetamine soln (ProCentra®)Δ

dextroamphetamine (Xelstrym®)Δ

dextroamphetamine (Zenzedi®)Δ

lisdexamfetamine soln (Arynta™)Δ

methamphetamine (Desoxyn®)Δ

methylphenidate ER 72mgΔ

methylphenidate ER ODT (Cotempla XR-ODT®)Δ

methylphenidate ER (Relexxii®)Δ

methylphenidate chew tab (Methylin®)Δ

methylphenidate ER chew tab (QuilliChew ER®)Δ</td></tr>
<tr><td>amphetamine/ dextroamphetamine ER (Adderall XR®)</td><td>dextroamphetamine ER (Dexedrine Spansules®)

lisdexamfetamine cap (Vyvanse®)+</td><td>amphetamine ER ODT (Adzenys XR-ODT®)Δ

amphetamine ER susp and tab (Dyanavel® XR)Δ

lisdexamfetamine chew tab (Vyvanse®)Δ</td></tr>
<tr><td colspan="3">Methylphenidate</td></tr>
<tr><td colspan="3">Short-Acting</td></tr>
<tr><td>dexmethylphenidate (Focalin®)

methylphenidate tab and soln (Methylin®)Δ

methylphenidate (Ritalin®)</td><td></td><td></td></tr>
<tr><td colspan="3">Long-Acting</td></tr>
<tr><td>dexmethylphenidate ER (Focalin XR®)

methylphenidate ER (Concerta®)

methylphenidate ER (Metadate CD®)

methylphenidate ER (Metadate ER®)

methylphenidate ER (Methylin ER®)

methylphenidate ER (Ritalin SR®)</td><td>methylphenidate ER (Aptensio XR®)

~~methylphenidate ER (Daytrana®)Δ~~

methylphenidate ER susp (Quillivant XR®)Δ

methylphenidate ER (Ritalin LA®)</td><td>methylphenidate ER (Daytrana®)Δ

methylphenidate ER (Jornay PM®)

serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)</td></tr>
<tr><td colspan="4">Non-Stimulants</td></tr>
<tr><td>atomoxetine (Strattera®)

guanfacine ER (Intuniv®)</td><td>clonidine ER (Kapvay®)Δ</td><td>clonidine ER susp (Onyda™ XR)Δ</td><td>atomoxetine soln (Atoncy™)Δ

viloxazine (Qelbree®)Δ</td></tr>
</table>

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
+Unique criteria applies for the diagnosis of binge eating disorder (BED). Other tier trial requirements do not apply for a diagnosis of BED.
ΔUnique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet;
ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution;
susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 180 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. ~~For Daytrana® patches, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and~~
4. For Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. Kapvay® Approval Criteria:
    a. An FDA approved diagnosis; and
    b. A previously failed trial (within the last 180 days) with a long-acting Tier-1 stimulant or non-stimulant unless contraindicated, that did not yield adequate results.
6. ~~Vyvanse® Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:~~
    a. ~~An FDA approved diagnosis of moderate-to-severe BED; and~~
    b. ~~Member must be 18 years of age or older; and~~
    c. ~~Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and~~
    d. ~~Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and~~
    e. ~~A quantity limit of 30 capsules per 30 days will apply; and~~
    f. ~~Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.~~

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and

3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
4. For Adzenys XR-ODT® and Dyanavel® XR oral suspension, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. For Daytrana® patches, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
6. Onyda™ XR Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and
    c. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
    d. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Kapvay® (clonidine ER tablet) must be provided.
7. ~~For~~ Vyvanse® Chewable Tablet Approval Criteria:
    a. For a diagnosis of binge eating disorder (BED), the member must meet the unique BED approval criteria; or
    b. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Arynta™ Approval Criteria:
    a. For a diagnosis of binge eating disorder (BED), the member must meet the unique BED approval criteria; or
    b. An FDA approved diagnosis; and

   c. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
   d. A patient-specific, clinically significant reason why the member cannot use lisdexamfetamine chewable tablets must be provided; and
   e. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Atoncy™ Approval Criteria:
   a. An FDA approved diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all lower-tiered stimulant and non-stimulant medications, including generic atomoxetine capsules, must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
3. Cotempla XR-ODT®, Evekeo ODT®, QuilliChew ER®, and Xelstrym® Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Desoxyn®, Dexedrine®, Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Methylin® Chewable Tablets Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
6. Mydayis® Approval Criteria:

    a. A covered diagnosis; and
    b. Member must be 13 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
7. Qelbree® Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and
    c. Previously failed trial (within the last 180 days) with atomoxetine or any ADHD medication, unless contraindicated, that did not yield adequate results; and
        i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or any ADHD medications within the past 180 days of claims history; and
    d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
    e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
    f. Quantity limits will apply based on FDA-approved dosing.

Arynta™ (Lisdexamfetamine Oral Solution) and Vyvanse® (Lisdexamfetamine Capsule or Chewable Tablet) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe BED; and
2. Member must be 18 years of age or older; and
3. ~~Vyvanse®~~ Lisdexamfetamine for the diagnosis of BED must be prescribed by a psychiatrist; and
4. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of ~~Vyvanse®~~ lisdexamfetamine for the treatment of obesity have not been established; and
7. For Vyvanse® chewable tablet:
    a. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
    b. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
5. For Arynta™:

a. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
b. A patient-specific, clinically significant reason why the member cannot use lisdexamfetamine chewable tablets must be provided; and
c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and

~~6. A quantity limit of 30 capsules per 30 days will apply; and~~
7. A maximum dose of 70mg per day will apply; and
8. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of ~~Vyvanse®~~ lisdexamfetamine.

Utilization Details of ADHD and Narcolepsy Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADHD MEDICATIONS						
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	18,814	5,083	$7,102,303.47	$377.50	3.7	14.38%
VYVANSE CAP 40MG	16,141	3,706	$6,097,118.65	$377.74	4.36	12.34%
VYVANSE CAP 20MG	14,393	4,395	$5,434,375.24	$377.57	3.27	11.00%
VYVANSE CAP 50MG	10,205	2,196	$3,847,799.01	$377.05	4.65	7.79%
VYVANSE CAP 10MG	6,586	2,468	$2,454,319.97	$372.66	2.67	4.97%
VYVANSE CAP 60MG	6,108	1,162	$2,301,067.45	$376.73	5.26	4.66%
VYVANSE CAP 70MG	4,159	695	$1,574,408.77	$378.55	5.98	3.19%
LISDEXAMFET CAP 30MG	909	521	$124,487.84	$136.95	1.74	0.25%
LISDEXAMFET CAP 40MG	868	439	$122,389.29	$141.00	1.98	0.25%
VYVANSE CHW 10MG	785	328	$293,946.17	$374.45	2.39	0.60%
VYVANSE CHW 20MG	701	227	$266,960.54	$380.83	3.09	0.54%
LISDEXAMFET CAP 20MG	624	385	$83,846.98	$134.37	1.62	0.17%
LISDEXAMFET CAP 50MG	574	286	$83,694.57	$145.81	2.01	0.17%
VYVANSE CHW 30MG	414	117	$151,656.05	$366.32	3.54	0.31%
LISDEXAMFET CAP 60MG	327	152	$50,177.49	$153.45	2.15	0.10%
LISDEXAMFET CAP 10MG	255	162	$35,603.12	$139.62	1.57	0.07%
LISDEXAMFET CAP 70MG	210	94	$33,429.86	$159.19	2.23	0.07%
VYVANSE CHW 40MG	125	33	$45,323.85	$362.59	3.79	0.09%
VYVANSE CHW 50MG	58	16	$20,729.20	$357.40	3.63	0.04%
LISDEXAMFET CHW 10MG	38	25	$9,234.82	$243.02	1.52	0.02%
LISDEXAMFET CHW 20MG	37	25	$8,872.82	$239.81	1.48	0.02%
LISDEXAMFET CHW 30MG	22	14	$5,279.58	$239.98	1.57	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFET CHW 40MG	10	3	$2,513.91	$251.39	3.33	0.01%
VYVANSE CHW 60MG	7	3	$1,717.20	$245.31	2.33	0.00%
LISDEXAMFET CHW 60MG	1	1	$260.35	$260.35	1	0.00%
SUBTOTAL	**82,371**	**15,212***	**$30,151,516.20**	**$366.05**	**5.41**	**61.04%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 20MG	12,588	2,516	$323,983.09	$25.74	5	0.66%
AMPHET/DEXTR TAB 10MG	11,886	3,028	$248,260.47	$20.89	3.93	0.50%
AMPHET/DEXTR TAB 5MG	7,292	2,067	$141,825.47	$19.45	3.53	0.29%
AMPHET/DEXTR CAP 20MG ER	6,069	1,805	$168,420.80	$27.75	3.36	0.34%
AMPHET/DEXTR TAB 30MG	5,994	1,089	$150,978.86	$25.19	5.5	0.31%
AMPHET/DEXTR CAP 30MG ER	5,810	1,227	$158,090.25	$27.21	4.74	0.32%
AMPHET/DEXTR CAP 10MG ER	5,661	1,982	$141,801.01	$25.05	2.86	0.29%
AMPHET/DEXTR CAP 15MG ER	4,196	1,262	$118,326.22	$28.20	3.32	0.24%
AMPHET/DEXTR TAB 15MG	3,965	952	$87,613.22	$22.10	4.16	0.18%
AMPHET/DEXTR CAP 25MG ER	2,596	633	$70,216.97	$27.05	4.1	0.14%
AMPHET/DEXTR CAP 5MG ER	1,619	711	$41,649.42	$25.73	2.28	0.08%
AMPHET/DEXTR TAB 7.5MG	791	199	$19,724.78	$24.94	3.97	0.04%
AMPHET/DEXTR TAB 12.5MG	363	100	$10,587.30	$29.17	3.63	0.02%
ADDERALL XR CAP 20MG	202	102	$45,165.84	$223.59	1.98	0.09%
ADDERALL XR CAP 30MG	113	53	$24,219.37	$214.33	2.13	0.05%
ADDERALL XR CAP 10MG	101	65	$21,530.12	$213.17	1.55	0.04%
ADDERALL XR CAP 25MG	99	36	$21,336.31	$215.52	2.75	0.04%
ADDERALL XR CAP 15MG	54	28	$12,193.38	$225.80	1.93	0.02%
ADDERALL TAB 10MG	37	15	$18,017.58	$486.96	2.47	0.04%
ADDERALL XR CAP 5MG	35	23	$7,566.13	$216.18	1.52	0.02%
AMPHET/DEXTR CAP 25MG ER	28	7	$7,207.21	$257.40	4	0.01%
AMPHET/DEXTR CAP 37.5 ER	27	8	$5,791.01	$214.48	3.38	0.01%
ADDERALL TAB 20MG	24	10	$14,646.85	$610.29	2.4	0.03%
ADDERALL TAB 15MG	21	7	$10,705.44	$509.78	3	0.02%
MYDAYIS CAP 25MG	13	4	$3,862.67	$297.13	3.25	0.01%
MYDAYIS CAP 50MG	11	2	$3,360.64	$305.51	5.5	0.01%
ADDERALL TAB 5MG	10	6	$4,201.81	$420.18	1.67	0.01%
MYDAYIS CAP 37.5MG	7	2	$2,101.41	$300.20	3.5	0.00%
ADDERALL TAB 30MG	6	5	$3,042.51	$507.09	1.2	0.01%
AMPHET/DEXTR CAP 50MG ER	4	4	$1,069.72	$267.43	1	0.00%
AMPHET/DEXTR CAP 12.5MG ER	3	3	$579.31	$193.10	1	0.00%
SUBTOTAL	**69,625**	**12,408***	**$1,888,075.17**	**$27.12**	**5.61**	**3.82%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	9,151	2,157	$165,515.80	$18.09	4.24	0.34%
METHYLPHENID TAB 5MG	7,904	2,208	$136,312.64	$17.25	3.58	0.28%
METHYLPHENID CAP 20MG CD	5,654	1,714	$288,223.28	$50.98	3.3	0.58%
METHYLPHENID TAB 36MG OSM	4,631	1,266	$159,260.90	$34.39	3.66	0.32%
METHYLPHENID CAP 30MG CD	4,444	1,220	$216,454.79	$48.71	3.64	0.44%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID TAB 20MG	4,078	802	$85,585.86	$20.99	5.08	0.17%
METHYLPHENID CAP 10MG CD	3,249	1,245	$145,014.67	$44.63	2.61	0.29%
METHYLPHENID TAB 54MG OSM	3,200	714	$111,385.24	$34.81	4.48	0.23%
METHYLPHENID CAP 40MG CD	3,182	767	$170,831.42	$53.69	4.15	0.35%
METHYLPHENID TAB 27MG OSM	3,034	1,060	$93,983.65	$30.98	2.86	0.19%
METHYLPHENID TAB 18MG OSM	2,973	1,278	$95,413.76	$32.09	2.33	0.19%
METHYLPHENID CAP 50MG CD	1,835	368	$99,056.15	$53.98	4.99	0.20%
METHYLPHENID TAB 20MG ER	1,293	361	$38,709.53	$29.94	3.58	0.08%
METHYLPHENID CAP 60MG CD	1,118	196	$68,251.20	$61.05	5.7	0.14%
METHYLPHENID SOL 5MG/5ML	1,071	319	$31,774.98	$29.67	3.36	0.06%
METHYLPHENID CAP 30MG LA	1,038	271	$79,415.80	$76.51	3.83	0.16%
METHYLPHENID CAP 20MG LA	960	285	$55,169.66	$57.47	3.37	0.11%
METHYLPHENID TAB 10MG ER	847	291	$19,709.10	$23.27	2.91	0.04%
METHYLPHENID CAP 40MG LA	746	158	$50,719.76	$67.99	4.72	0.10%
QUILLIVANT SUS 25MG/5ML	612	123	$264,153.48	$431.62	4.98	0.53%
METHYLPHENID SOL 10MG/5ML	535	117	$20,659.28	$38.62	4.57	0.04%
METHYLPHENID TAB 18MG ER	485	232	$14,982.84	$30.89	2.09	0.03%
CONCERTA TAB 36MG	484	148	$243,728.23	$503.57	3.27	0.49%
METHYLPHENID CAP 10MG LA	425	150	$51,538.92	$121.27	2.83	0.10%
CONCERTA TAB 27MG	325	106	$125,731.17	$386.87	3.07	0.25%
JORNAY PM CAP 60MG ER	325	69	$142,550.90	$438.62	4.71	0.29%
CONCERTA TAB 54MG	279	88	$120,098.13	$430.46	3.17	0.24%
APTENSIO XR CAP 40MG	265	52	$65,539.64	$247.32	5.1	0.13%
JORNAY PM CAP 40MG ER	257	65	$112,607.66	$438.16	3.95	0.23%
METHYLPHENID CAP 40MG XR	228	76	$30,472.94	$133.65	3	0.06%
CONCERTA TAB 18MG	223	91	$84,552.27	$379.16	2.45	0.17%
METHYLPHENID CAP 50MG XR	222	61	$32,591.91	$146.81	3.64	0.07%
JORNAY PM CAP 80MG ER	213	44	$93,715.88	$439.98	4.84	0.19%
JORNAY PM CAP 100MG ER	172	25	$76,949.73	$447.38	6.88	0.16%
METHYLPHENID CAP 30MG XR	167	77	$16,093.83	$96.37	2.17	0.03%
METHYLPHENID CAP 60MG XR	165	42	$25,874.03	$156.81	3.93	0.05%
APTENSIO XR CAP 30MG	126	47	$30,901.30	$245.25	2.68	0.06%
JORNAY PM CAP 20MG ER	124	48	$56,729.43	$457.50	2.58	0.11%
METHYLIN SOL 5MG/5ML	114	41	$4,776.65	$41.90	2.78	0.01%
METHYLPHENID TAB 72MG OSM	113	21	$59,801.34	$529.22	5.38	0.12%
APTENSIO XR CAP 50MG	101	24	$25,238.29	$249.88	4.21	0.05%
METHYLPHENID CAP 20MG XR	95	49	$17,680.23	$186.11	1.94	0.04%
METHYLPHENID TAB 54MG ER	90	47	$3,046.53	$33.85	1.91	0.01%
QUILLICHEW CHW 20MG ER	89	27	$32,060.28	$360.23	3.3	0.06%
DAYTRANA DIS 10MG/9HR	80	31	$14,544.83	$181.81	2.58	0.03%
DAYTRANA DIS 15MG/9HR	78	24	$14,343.04	$183.89	3.25	0.03%
METHYLPHENID CAP 15MG XR	77	32	$5,889.89	$76.49	2.41	0.01%
DAYTRANA DIS 30MG/9HR	72	21	$13,600.67	$188.90	3.43	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID TAB 36MG ER	70	50	$2,377.70	$33.97	1.4	0.00%
APTENSIO XR CAP 20MG	69	32	$16,755.60	$242.83	2.16	0.03%
APTENSIO XR CAP 60MG	62	21	$14,966.55	$241.40	2.95	0.03%
METHYLPHENID PAD 10MG/9HR	59	30	$16,408.29	$278.11	1.97	0.03%
METHYLPHENID PAD 20MG/9HR	57	15	$16,798.40	$294.71	3.8	0.03%
METHYLPHENID CAP 10MG XR	54	27	$5,534.82	$102.50	2	0.01%
METHYLPHENID TAB 27MG ER	52	40	$1,668.01	$32.08	1.3	0.00%
QUILLICHEW CHW 30MG ER	44	10	$16,942.84	$385.06	4.4	0.03%
DAYTRANA DIS 20MG/9HR	41	18	$7,546.38	$184.06	2.28	0.02%
METHYLPHENID PAD 15MG/9HR	40	14	$11,654.17	$291.35	2.86	0.02%
METHYLPHENID TAB 45MG OSM	36	9	$20,573.69	$571.49	4	0.04%
APTENSIO XR CAP 15MG	36	17	$9,054.50	$251.51	2.12	0.02%
QUILLICHEW CHW 40MG ER	33	7	$12,162.17	$368.55	4.71	0.02%
METHYLPHENID CHW 5MG	27	14	$2,237.67	$82.88	1.93	0.00%
METHYLPHENID TAB 63MG OSM	23	5	$13,354.24	$580.62	4.6	0.03%
METHYLPHENID PAD 30MG/9HR	23	9	$6,256.86	$272.04	2.56	0.01%
METHYLPHENID CHW 2.5MG	20	10	$1,312.46	$65.62	2	0.00%
APTENSIO XR CAP 10MG	14	9	$3,392.00	$242.29	1.56	0.01%
METHYLPHENID CAP 60MG LA	12	6	$3,155.83	$262.99	2	0.01%
METHYLIN SOL 10MG/5ML	12	7	$699.03	$58.25	1.71	0.00%
RITALIN LA CAP 10MG	10	6	$3,721.58	$372.16	1.67	0.01%
RITALIN TAB 20MG	9	5	$1,447.26	$160.81	1.8	0.00%
METHYLPHENID CHW 10MG	8	3	$1,238.85	$154.86	2.67	0.00%
RITALIN TAB 5MG	6	2	$332.13	$55.36	3	0.00%
RELEXXII TAB 72MG ER	5	2	$3,509.55	$701.91	2.5	0.01%
RELEXXII TAB 45MG ER	5	2	$3,237.40	$647.48	2.5	0.01%
RITALIN LA CAP 40MG	3	1	$1,177.93	$392.64	3	0.00%
RITALIN LA CAP 30MG	3	2	$1,150.59	$383.53	1.5	0.00%
COTEMPLA XR TAB 8.6MG	1	1	$503.22	$503.22	1	0.00%
RELEXXII TAB 54MG ER	1	1	$420.14	$420.14	1	0.00%
SUBTOTAL	**67,784**	**11,380***	**$4,110,831.37**	**$60.65**	**5.96**	**8.32%**
GUANFACINE PRODUCTS						
GUANFACINE TAB 2MG ER	18,216	4,374	$340,369.39	$18.69	4.16	0.69%
GUANFACINE TAB 1MG ER	15,754	5,131	$272,716.73	$17.31	3.07	0.55%
GUANFACINE TAB 3MG ER	11,790	2,373	$214,839.34	$18.22	4.97	0.43%
GUANFACINE TAB 4MG ER	8,960	1,504	$161,154.32	$17.99	5.96	0.33%
INTUNIV TAB 4MG	35	3	$9,920.29	$283.44	11.67	0.02%
INTUNIV TAB 3MG	31	4	$10,268.84	$331.25	7.75	0.02%
INTUNIV TAB 1MG	8	2	$2,149.42	$268.68	4	0.00%
INTUNIV TAB 2MG	6	2	$3,427.04	$571.17	3	0.01%
SUBTOTAL	**54,800**	**10,123***	**$1,014,845.37**	**$18.52**	**5.41**	**2.05%**
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	12,515	4,019	$357,584.00	$28.57	3.11	0.72%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ATOMOXETINE CAP 25MG	9,549	3,186	$240,593.81	$25.20	3	0.49%
ATOMOXETINE CAP 18MG	5,505	1,962	$148,419.98	$26.96	2.81	0.30%
ATOMOXETINE CAP 60MG	5,333	1,327	$135,543.36	$25.42	4.02	0.27%
ATOMOXETINE CAP 10MG	4,403	1,628	$112,628.13	$25.58	2.7	0.23%
ATOMOXETINE CAP 80MG	3,189	922	$98,856.11	$31.00	3.46	0.20%
ATOMOXETINE CAP 100MG	1,040	293	$32,632.49	$31.38	3.55	0.07%
STRATTERA CAP 40MG	26	10	$10,672.14	$410.47	2.6	0.02%
STRATTERA CAP 60MG	13	5	$5,481.79	$421.68	2.6	0.01%
STRATTERA CAP 18MG	12	3	$4,096.80	$341.40	4	0.01%
STRATTERA CAP 25MG	9	5	$4,078.25	$453.14	1.8	0.01%
STRATTERA CAP 80MG	3	3	$2,248.58	$749.53	1	0.00%
STRATTERA CAP 10MG	2	1	$1,538.44	$769.22	2	0.00%
SUBTOTAL	**41,599**	**9,672***	**$1,154,373.88**	**$27.75**	**4.3**	**2.34%**
DEXMETHYLPHENIDATE PRODUCTS						
FOCALIN XR CAP 10MG	6,444	1,888	$983,169.13	$152.57	3.41	1.99%
FOCALIN XR CAP 20MG	5,277	1,238	$827,381.13	$156.79	4.26	1.68%
DEXMETHYLPHE TAB 10MG	4,684	885	$105,410.21	$22.50	5.29	0.21%
DEXMETHYLPHE TAB 5MG	4,652	1,128	$98,144.87	$21.10	4.12	0.20%
FOCALIN XR CAP 15MG	4,503	1,266	$702,441.73	$155.99	3.56	1.42%
FOCALIN XR CAP 30MG	2,956	586	$448,162.90	$151.61	5.04	0.91%
FOCALIN XR CAP 25MG	2,561	517	$421,667.97	$164.65	4.95	0.85%
FOCALIN XR CAP 5MG	2,524	1,060	$370,247.22	$146.69	2.38	0.75%
DEXMETHYLPHE TAB 2.5MG	1,527	434	$25,407.23	$16.64	3.52	0.05%
FOCALIN XR CAP 40MG	1,223	191	$209,275.10	$171.12	6.4	0.42%
FOCALIN XR CAP 35MG	631	126	$108,492.33	$171.94	5.01	0.22%
DEXMETHYLPHE CAP 20MG ER	469	199	$24,021.57	$51.22	2.36	0.05%
DEXMETHYLPHE CAP 10MG ER	402	211	$17,658.57	$43.93	1.91	0.04%
DEXMETHYLPHE CAP 15MG ER	392	181	$14,714.28	$37.54	2.17	0.03%
DEXMETHYLPHE CAP 5MG ER	218	126	$8,797.56	$40.36	1.73	0.02%
DEXMETHYLPHE CAP 30MG ER	174	72	$8,745.92	$50.26	2.42	0.02%
DEXMETHYLPHE CAP 25MG ER	168	64	$11,505.21	$68.48	2.63	0.02%
DEXMETHYLPHE CAP 40MG ER	106	30	$4,444.22	$41.93	3.53	0.01%
FOCALIN TAB 5MG	54	25	$2,489.68	$46.11	2.16	0.01%
FOCALIN TAB 10MG	53	22	$3,564.19	$67.25	2.41	0.01%
DEXMETHYLPHE CAP 35MG ER	29	15	$2,263.75	$78.06	1.93	0.00%
FOCALIN TAB 2.5MG	9	4	$279.93	$31.10	2.25	0.00%
SUBTOTAL	**39,056**	**6,013***	**$4,398,284.70**	**$112.61**	**6.5**	**8.90%**
VILOXAZINE PRODUCTS						
QELBREE CAP 200MG ER	5,104	1,151	$2,597,338.82	$508.88	4.43	5.26%
QELBREE CAP 100MG ER	1,804	617	$667,406.78	$369.96	2.92	1.35%
QELBREE CAP 150MG ER	1,100	266	$591,497.77	$537.73	4.14	1.20%
SUBTOTAL	**8,008**	**1,586***	**$3,856,243.37**	**$481.55**	**5.05**	**7.81%**
CLONIDINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLONIDINE TAB 0.1MG ER	1,010	187	$28,419.88	$28.14	5.4	0.06%
ONYDA XR SUS 0.1MG/ML	7	2	$2,149.23	$307.03	3.5	0.00%
SUBTOTAL	**1,017**	**189***	**$30,569.11**	**$30.06**	**5.38**	**0.06%**
DEXMETHYLPHENIDATE/SERDEXMETHYLPHENIDATE PRODUCTS						
AZSTARYS CAP 39.2-7.8MG	194	51	$80,983.96	$417.44	3.8	0.16%
AZSTARYS CAP 52.3-10.4MG	157	26	$64,523.11	$410.98	6.04	0.13%
AZSTARYS CAP 26.1-5.2MG	69	27	$28,779.69	$417.10	2.56	0.06%
SUBTOTAL	**420**	**88***	**$174,286.76**	**$414.97**	**4.77**	**0.35%**
AMPHETAMINE PRODUCTS						
DYANAVEL XR TAB 15MG	50	13	$21,976.71	$439.53	3.85	0.04%
DYANAVEL XR SUS 2.5MG/ML	47	11	$18,753.97	$399.02	4.27	0.04%
DYANAVEL XR TAB 20MG	36	8	$15,952.86	$443.14	4.5	0.03%
DYANAVEL XR TAB 10MG	35	17	$15,468.83	$441.97	2.06	0.03%
DYANAVEL XR TAB 5MG	24	17	$5,340.80	$222.53	1.41	0.01%
AMPHETAMINE TAB 10MG	9	2	$211.60	$23.51	4.5	0.00%
ADZENYS XR TAB 9.4MG	8	1	$3,995.77	$499.47	8	0.01%
AMPHETAMINE TAB 5MG	1	1	$28.94	$28.94	1	0.00%
SUBTOTAL	**210**	**54***	**$81,729.48**	**$389.19**	**3.89**	**0.17%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	58	13	$4,442.79	$76.60	4.46	0.01%
DEXTROAMPHET TAB 10MG	37	13	$1,636.70	$44.24	2.85	0.00%
DEXTROAMPHET TAB 5MG	23	10	$643.26	$27.97	2.3	0.00%
DEXTROAMPHET CAP 10MG ER	20	13	$793.24	$39.66	1.54	0.00%
DEXTROAMPHET SOL 5MG/5ML	14	7	$2,118.04	$151.29	2	0.00%
DEXTROAMPHET TAB 30MG	11	1	$1,662.64	$151.15	11	0.00%
XELSTRYM PAD 4.5MG/9HR	8	4	$3,988.37	$498.55	2	0.01%
DEXTROAMPHET TAB 15MG	8	2	$2,380.64	$297.58	4	0.00%
DEXTROAMPHET TAB 20MG	6	4	$1,201.74	$200.29	1.5	0.00%
DEXTROAMPHET TAB 7.5MG	3	2	$575.44	$191.81	1.5	0.00%
XELSTRYM PAD 18MG/9HR	3	1	$1,499.31	$499.77	3	0.00%
DEXTROAMPHET CAP 5MG ER	3	2	$101.81	$33.94	1.5	0.00%
XELSTRYM PAD 13.5/9HR	2	2	$999.73	$499.87	1	0.00%
XELSTRYM PAD 9MG/9HR	1	1	$501.81	$501.81	1	0.00%
SUBTOTAL	**197**	**66***	**$22,545.52**	**$114.44**	**2.98**	**0.05%**
METHAMPHETAMINE PRODUCTS						
METHAMPHETAMINE TAB 5MG	1	1	$613.51	$613.51	1	0.00%
SUBTOTAL	**1**	**1***	**$613.51**	**$613.51**	**1**	**0.00%**
ADHD TOTAL	**365,088**	**50,493***	**$46,883,914.44**	**$128.42**	**7.23**	**94.92%**
NARCOLEPSY MEDICATIONS						
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	450	143	$10,939.48	$24.31	3.15	0.02%
MODAFINIL TAB 100MG	164	65	$3,201.60	$19.52	2.52	0.01%
PROVIGIL TAB 200MG	14	2	$48,856.06	$3,489.72	7	0.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PROVIGIL TAB 100MG	9	1	$13,991.90	$1,554.66	9	0.03%
SUBTOTAL	**637**	**203***	**$76,989.04**	**$120.86**	**3.14**	**0.16%**
ARMODAFINIL PRODUCTS						
ARMODAFINIL TAB 250MG	209	55	$7,189.11	$34.40	3.8	0.01%
ARMODAFINIL TAB 150MG	155	52	$4,755.01	$30.68	2.98	0.01%
ARMODAFINIL TAB 200MG	52	15	$1,632.45	$31.39	3.47	0.00%
NUVIGIL TAB 250MG	38	7	$35,943.60	$945.88	5.43	0.07%
NUVIGIL TAB 200MG	18	2	$19,451.97	$1,080.67	9	0.04%
ARMODAFINIL TAB 50MG	9	6	$208.17	$23.13	1.5	0.00%
SUBTOTAL	**481**	**127***	**$69,180.31**	**$143.83**	**3.79**	**0.14%**
SOLRIAMFETOL PRODUCTS						
SUNOSI TAB 150MG	90	20	$78,221.53	$869.13	4.5	0.16%
SUNOSI TAB 75MG	17	8	$14,717.14	$865.71	2.13	0.03%
SUBTOTAL	**107**	**23***	**$92,938.67**	**$868.59**	**4.65**	**0.19%**
PITOLISANT PRODUCTS						
WAKIX TAB 17.8MG	54	12	$650,080.06	$12,038.52	4.5	1.32%
WAKIX TAB 4.45MG	7	7	$13,310.10	$1,901.44	1	0.03%
SUBTOTAL	**61**	**12***	**$663,390.16**	**$10,875.25**	**5.08**	**1.34%**
CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES PRODUCTS						
XYWAV SOL 0.5GM/ML	56	13	$908,873.66	$16,229.89	4.31	1.84%
SUBTOTAL	**56**	**13***	**$908,873.66**	**$16,229.89**	**4.31**	**1.84%**
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	43	6	$682,426.63	$15,870.39	7.17	1.38%
SOD OXYBATE SOL 500MG/ML	1	1	$16,616.41	$16,616.41	1	0.03%
SUBTOTAL	**44**	**7***	**$699,043.04**	**$15,887.34**	**6.29**	**1.42%**
NARCOLEPSY TOTAL	**1,386**	**355***	**$2,510,414.88**	**$1,811.27**	**3.9**	**5.08%**
TOTAL	**366,474**	**50,777***	**$49,394,329.32**	**$134.78**	**7.22**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMPHET/DEXTR = amphetamine/dextroamphetamine; CAP = capsule; CHW = chewable tablet; DEXMETHYLPHE = dexmethylphenidate; DEXTROAMPHET = dextroamphetamine; DIS = patch; ER = extended-release; HR = hour; LA = long-acting; LISDEXAMFET = lisdexamfetamine; METHYLPHENID = methylphenidate; OSM = osmotic; SOD = sodium; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix O

Fiscal Year 2025 Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Voyxact® (Sibeprenlimab-szsi)

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

Utilization data for Fabhalta® (iptacopan) and approval criteria for indications other than primary IgAN can be found in the December 2025 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the Complement Inhibitors and Miscellaneous Immunomodulatory Agents.

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

1. An FDA approved indication to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy (can refer to a recent or historical biopsy); and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Filspari® (Sparsentan) Approval Criteria:

1. An FDA approved indication to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy; and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent), despite 3 months of maximal supportive care; and
6. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) prior to initiating treatment with Filspari®; and
8. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari®; and
9. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari®; and
10. If member is using antacids, they must agree to separate antacid and Filspari® administration by 2 hours; and
11. Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. A quantity limit of 30 tablets per 30 days will apply.

Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy; and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune

disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and

3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent); and
6. Member must be on a stable dose of a maximally-tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. Approval duration will be for 9 months. The safety and efficacy of Tarpeyo® have not been established beyond 9 months of treatment. For continued authorization consideration after 9 months of treatment, a patient-specific, clinically significant reason why a longer treatment duration is medically necessary for the member must be provided; and
8. A quantity limit of 120 capsules per 30 days will apply.

Vanrafia® (Atrasentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy; and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent), despite 3 months of maximal supportive care; and
6. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Females 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 2 weeks after the last dose of Vanrafia®; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Utilization of Primary IgAN 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	12	$188,314.92	$15,692.91	$523.10	1,440	360
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	2	4	$42,636.82	$10,659.20	$409.97	194	104
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**5**	**16**	**$230,951.74**	**$14,434.48**	**$497.74**	**1,634**	**464**
Fiscal Year 2025							
FFS	4	6	$72,826.19	$12,137.70	$492.07	418	148
Aetna	4	16	$228,481.75	$14,280.11	$492.42	1,184	464
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	1	1	$16,253.41	$16,253.41	$541.78	120	30
2025 Total	**8**	**23**	**$317,561.35**	**$13,807.02**	**$494.64**	**1,722**	**642**
% Change	**60.00%**	**43.80%**	**37.50%**	**-4.30%**	**-0.60%**	**5.40%**	**38.40%**
Change	**3**	**7**	**$86,609.61**	**-$627.46**	**-$3.10**	**88**	**178**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 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 Primary IgAN Medications (All Plans)

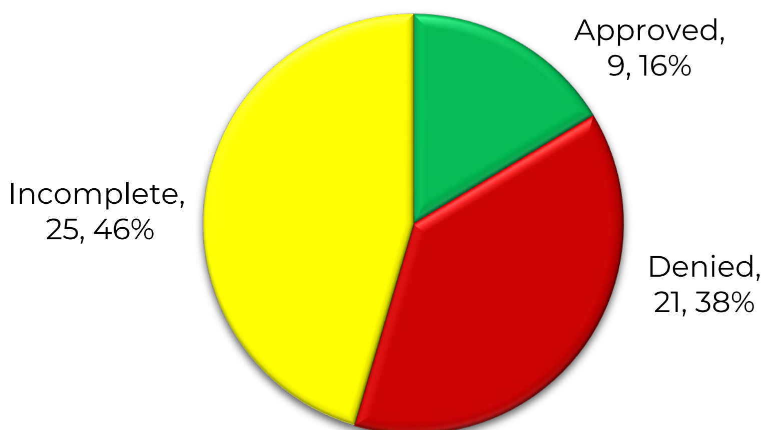
- Due to the limited number of members utilizing primary IgAN medications during fiscal year 2025, detailed demographic information could not be provided.

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

Prior Authorization of Primary IgAN Medications

There were 55 prior authorization requests submitted for primary IgAN 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	10%	18	62%	8	28%	29
Aetna	2	17%	5	42%	5	42%	12
Humana	1	50%	0	0%	1	50%	2
OCH	3	25%	2	17%	7	58%	12
Total	9	16%	25	46%	21	38%	55

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

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

Anticipated Patent Expiration(s):

- Filspari® (sparsentan): March 2030
- Vanrafia® (atrasentan): February 2041
- Fabhalta® (iptacopan): July 2041
- Tarpeyo® (budesonide DR capsule): January 2043

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

- **November 2025:** The FDA granted accelerated approval to Voyxact® (sibeprenlimab-szsi) for the reduction of proteinuria in adults with primary IgAN at risk for disease progression.

News:

- **October 2025:** In October 2025, the results of the Phase 3 APPLAUSE-IgAN clinical trial for Fabhalta® were announced, which showed that Fabhalta® demonstrated a statistically significant improvement in estimated glomerular filtration rate (eGFR) slope versus placebo over 2 years. Fabhalta® was initially approved through accelerated approval in August 2024 and based on the results of the clinical trial, Novartis, the makers of Fabhalta®, plans to submit for traditional approval in 2026.

- **February 2026:** In February 2026, the results of the Phase 3 ALIGN clinical trial for Vanrafia® were announced. The results showed in the Vanrafia®-treated group a difference of 2.39mL/min/1.73m^2 eGFR change from baseline versus placebo (2-sided P=0.057) at week 136, 4 weeks after the end of the study treatment. Vanrafia® was initially approved through accelerated approval in April 2025 and based on the results of the clinical trial, Novartis, the makers of Vanrafia®, plans to submit for traditional approval in 2026 despite the trial not meeting statistical significance.

Guideline Update(s):

- **Kidney Disease Improving Global Outcomes (KDIGO) Guideline Update:** KDIGO released a clinical practice update for the *Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV)* clinical practice guideline in October 2025, which replaced the guidelines from October 2021. Some of the key updates for IgAN included:
  - A diagnosis of IgAN can only be confirmed by a kidney biopsy and should be considered in all adults with proteinuria ≥0.5g/day (or equivalent) with a suspicion of IgAN. Once IgAN is confirmed, the patient should be assessed for secondary causes of IgAN.
  - The definition of a patient at risk of progressive loss of kidney function was changed from the prior definition of proteinuria >0.75-1g/day despite ≥90 days of optimized supportive care. The update now defines at risk patients as having proteinuria ≥0.5g/day (or equivalent), while on or off treatment for IgAN, and recommends treatment/additional treatment should be started in all cases.
  - The treatment goal is to reduce the rate of loss of kidney function <1mL/min per year for the rest of a patient's life. Urine protein excretion is the only validated biomarker to help guide clinical decision making and should be maintained at <0.5g/day (or equivalent), ideally at <0.3g/day (or equivalent), and multiple treatment strategies may be needed to achieve this goal.
  - The focus of management for most patients should be simultaneous to prevent or reduce IgA immune complex formation and immune complex-mediated glomerular injury [i.e., treatment with Tarpeyo® (budesonide delayed-release capsule)] as well as to manage the consequences of existing IgAN-induced nephron loss [i.e., treatment with lifestyle modifications, renin-angiotensin system inhibitors (RASi), and sodium-glucose cotransporter-2 (SGLT-2) inhibitors].

Pipeline:

- **Atacicept:** Atacicept is an investigational recombinant fusion protein that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) that binds to the cytokines B-cell activating factor (BAFF) and A PRoliferation-Inducing Ligand (APRIL). These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with IgAN. In January 2026, the FDA accepted a Biologics License Application (BLA) for atacicept for the treatment of adults with IgAN. The BLA, submitted under the accelerated approval pathway, was supported by data from the interim analysis of the ORIGIN 3 clinical trial which showed the percentage reduction from baseline in the 24-hour urine protein-to-creatine ratio (UPCR) was 45.7% in the atacicept group and 6.8% in the placebo group with a geometric mean between-group difference of 41.8% [95% confidence interval (CI): 28.9%, 52.3%; $P<0.001$]. If approved, atacicept will be available in an auto-injector for at-home self-administration for once-weekly subcutaneous (sub-Q) injection. Atacicept was given a Prescription Drug User Fee Act (PDUFA) target action date of July 7, 2026.
- **Filspari® (Sparsentan):** Filspari® is being studied for the treatment of focal segmental glomerulosclerosis (FSGS). FSGS is a rare proteinuric kidney disorder that is defined by progressive scarring of the kidney and often leads to kidney failure. There are currently no FDA approved medications for FSGS. A supplemental New Drug Application (sNDA) has been submitted to the FDA. In January 2026, Travere Therapeutics, the makers of Filspari®, announced the FDA extended the PDUFA date to April 13, 2026, after additional information was submitted to the FDA regarding the clinical benefit of Filspari® in FSGS.
- **Povetacicept:** Povetacicept is an engineered fusion protein and dual inhibitor of the BAFF and APRIL cytokines being studied to treat IgAN. In March 2026, the 36-week interim analysis results of the ongoing Phase 3 RAINER trial of povetacicept were announced. The trial met its primary objective. In the interim analysis population, patients treated with povetacicept achieved a 52.0% reduction from baseline in UPCR at week 36, with a statistically significant 49.8% UPCR reduction compared to placebo ($P<0.0001$). If approved, povetacicept would be available in a sub-Q auto-injector for at-home administration once every 4 weeks. Vertex, the makers of povetacicept, announced that the BLA submission should be completed by the end of March 2026. Povetacicept has been given priority review by the FDA.

Voyxact® (Sibeprenlimab-szsi) Product Summary[9]

Therapeutic Class: APRIL blocker

Indication(s): To reduce proteinuria in adults with primary IgAN at risk of disease progression

- This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Voyxact® slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

How Supplied: 400mg/2mL (200mg/mL) single-dose prefilled syringe

Dosing and Administration:

- The recommended dose of Voyxact® is 400mg injected sub-Q once every 4 weeks.

Efficacy: The efficacy of Voyxact® was studied in a randomized, double-blind, placebo-controlled, multicenter Phase 3 VISIONARY clinical trial.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Biopsy confirmed IgAN
  - eGFR ≥30mL/min/1.73m²
  - Proteinuria (defined as either UPCR based on 24-hour urine collections ≥0.75g/g or urine protein ≥1.0g/day)
  - Stable dose of maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) and/or angiotensin receptor blocker (ARB) with or without an SGLT-2 inhibitor
- Intervention: Randomized 1:1 to receive either Voyxact® or placebo injected sub-Q once every 4 weeks
- Primary Outcome: The primary endpoint was the percent reduction in UPCR at 9 months compared to baseline.
- Results: Voyxact® showed a 51% reduction in UPCR compared to placebo (96.5% CI: 43%, 58%; P<0.0001) at 9 months.

Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days	Cost Per Year
Voyxact® (sibeprenlimab-szsi) 400mg/2mL inj	**$15,000.00**	**$30,000.00**	**$390,000.00¥**
Fabhalta® (iptacopan) 200mg tablet	$799.31	$44,761.36	$581,897.68*

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet; inj = injection
¥Cost is based on the FDA approved dosing of 400mg/2mL injection sub-Q once every 4 weeks.
*Cost is based on the FDA approved dosing of 1 tablet twice daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Voyxact® (sibeprenlimab-szsi) with the following criteria (shown in red):

Voyxact® (Sibeprenlimab-szsi) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy (can refer to a recent or historical biopsy); and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent); and
6. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Voyxact®; and
7. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

The College of Pharmacy also recommends updating the Filspari® (sparsentan) and Vanrafia® (atrasentan) approval criteria for clarity and based on clinical practice (changes shown in red):

Filspari® (Sparsentan) Approval Criteria:

1. An FDA approved indication to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy (can refer to a recent or historical biopsy); and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and

5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent)~~, despite 3 months of maximal supportive care~~; and
6. ~~Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and~~
7. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
8. Prescriber must verify the member will ~~discontinue~~ not use ~~of~~ other renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) ~~prior to initiating treatment~~ concurrently with Filspari®; and
9. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari®; and
10. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari®; and
11. If member is using antacids, they must agree to separate antacid and Filspari® administration by 2 hours; and
12. Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
13. A quantity limit of 30 tablets per 30 days will apply.

Vanrafia® (Atrasentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy (can refer to a recent or historical biopsy); and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent)~~, despite 3 months of maximal supportive care~~; and

~~6. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II~~

~~receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and~~

7. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months alone, and member must agree to continue the use of an ACE or an ARB with Vanrafia™, unless contraindicated or intolerant; and
8. Females 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 2 weeks after the last dose of Vanrafia®; and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Lastly, the College of Pharmacy recommends updating the Tarpeyo® (budesonide delayed release capsule) approval criteria based on guideline updates and clinical practice (changes shown in red):

Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent); and
6. ~~Member must be on a stable dose of a maximally-tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and~~
7. Approval duration will be for 9 months. The safety and efficacy of Tarpeyo® have not been established beyond 9 months of treatment. For continued authorization consideration after 9 months of treatment, a patient-specific, clinically significant reason why a longer treatment duration is medically necessary for the member must be provided; and
8. A quantity limit of 120 capsules per 30 days will apply.

Utilization Details of Primary IgAN Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TARPEYO CAP 4MG	12	4	$207,904.92	$17,325.41	3	65.47%
FILSPARI TAB 400MG	8	3	$92,217.01	$11,527.13	2.67	29.04%
FILSAPRI TAB 200MG	3	2	$17,439.42	$5,813.14	1.5	5.49%
TOTAL	**23**	**8***	**$317,561.35**	**$13,807.02**	**2.88**	**100%**

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

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[7] Travere Therapeutics. Travere Therapeutics Announces FDA Extends Review of sNDA for Filspari® (Sparsentan) in FSGS. Available online at: https://ir.travere.com/press-releases/news-details/2026/Travere-Therapeutics-Announces-FDA-Extends-Review-of-sNDA-for-FILSPARI-sparsentan-in-FSGS/default.aspx. Issued 01/13/2026. Last accessed 03/11/2026.
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Appendix P

Fiscal Year 2025 Annual Review of Spinal Muscular Atrophy (SMA) Medications and 30-Day Notice to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve)

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1 (SMN1)* gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. For the tablet formulation, the member must be 2 years of age or older and weigh ≥20kg (recent weight measured within the last 3 months must be submitted); and
6. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
7. Pharmacy must confirm Evrysdi® oral solution will be constituted by a pharmacist prior to dispensing and must confirm Evrysdi® oral solution will be shipped via cold chain supply to adhere to the storage and handling requirements in the package labeling; and
8. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® formulations prior to administration of the first dose; and
9. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
10. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and

11. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
12. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
13. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
14. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and
15. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and
15. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
16. A quantity limit of 240mL per 36 days will apply.
17. For the oral solution, a quantity limit of 240mL per 36 days will apply and for the tablets, a quantity limit of 30 tablets per 30 days will apply.

Spinraza® (Nusinersen) Approval Criteria:

1. Diagnosis of spinal muscular atrophy (SMA):
    a. Type 1; or
    b. Type 2; or
    c. Type 3 with symptoms; and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam); and

7. Prescriber must verify platelet count, coagulation laboratory testing, and quantitative spot urine protein testing have been assessed at baseline, levels are acceptable to the prescriber, and levels will be monitored prior to each dose; and
8. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
    a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
9. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. Hammersmith Infant Neurological Exam (HINE); or
    b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
    c. Upper Limb Module (ULM) Test; or
    d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
10. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment:
    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or
    d. HFMSE; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. Only (1) 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric members younger than 2 years of age; and
2. Member must have reached full-term gestational age prior to Zolgensma® infusion; and
3. Molecular genetic testing to confirm biallelic mutations in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
4. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
5. Zolgensma® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner

with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests and platelet counts at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Zolgensma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Zolgensma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam) or Spinraza® (nusinersen) following Zolgensma® infusion (current authorizations for risdiplam or nusinersen will be discontinued upon Zolgensma® approval); and
11. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
12. Only 1 Zolgensma® infusion will be approved per member per lifetime.

Utilization of SMA 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	26	172	$7,232,061.60	$42,046.87	$1,573.56	23,076	4,596
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	2	8	$141,059.91	$17,632.49	$796.95	880	177
OCH	1	3	$76,926.21	$25,642.07	$1,068.42	480	72
2024 Total	**26**	**183**	**$7,450,047.72**	**$40,710.64**	**$1,537.68**	**24,436**	**4,845**
Fiscal Year 2025							
FFS	24	165	$10,077,749.75	$61,077.27	$2,381.32	22,122	4,232
Aetna	2	2	$4,713,772.86	$2,356,886.43	$2,356,886.43	2	2
Humana	2	27	$507,267.94	$18,787.70	$853.99	2,780	594
OCH	4	26	$2,995,168.57	$115,198.79	$4,278.81	2,791	700
2025 Total	**30**	**220**	**$18,293,959.12**	**$83,154.36**	**$3,266.78**	**27,699**	**5,600**
% Change	**15.38%**	**20.22%**	**145.55%**	**104.26%**	**112.45%**	**13.35%**	**15.58%**
Change	**4**	**37**	**$10,843,911.40**	**$42,443.72**	**$1,729.10**	**3,263**	**755**

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.

Fiscal Year Comparison: Medical Claims (All Plans)

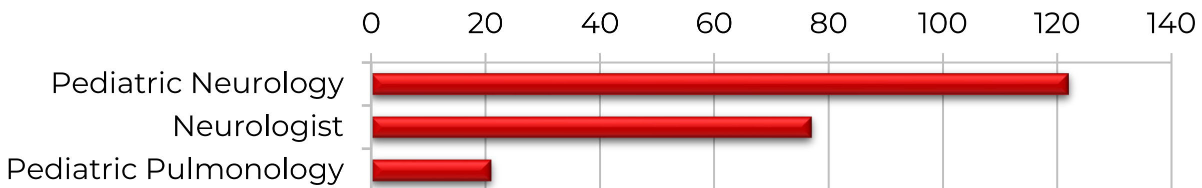
Plan Type	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	2	6	$822,739.20	$137,123.20	3
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**2**	**6**	**$822,739.20**	**$137,123.20**	**3**
Fiscal Year 2025					
FFS	2	4	$568,152.00	$142,038.00	2
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	1	1	$0.00	$0.00	1
2025 Total	**3**	**5**	**$568,152.00**	**$142,038.00**	**1.67**
% Change	**50.00%**	**-16.67%**	**-30.94%**	**3.58%**	**-44.44%**
Change	**1**	**-1**	**-$254,587.20**	**$4,914.80**	**-1.33**

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 SMA Medications: Pharmacy Claims (All Plans)

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

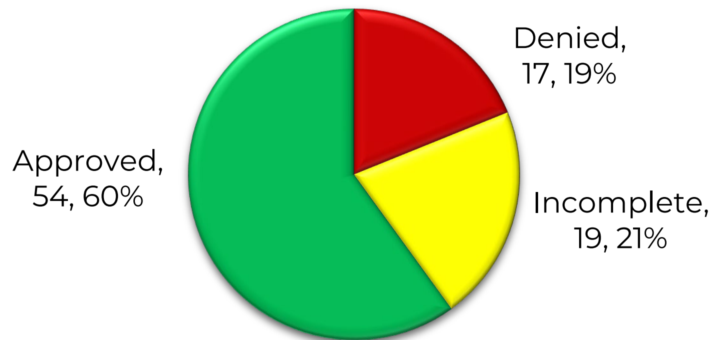
Top Prescriber Specialties of SMA Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of SMA Medications

There were 90 prior authorization requests submitted for SMA 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	43	61%	17	24%	10	14%	**70**
Aetna	2	50%	1	25%	1	25%	**4**
Humana	1	33%	0	0%	2	67%	**3**
OCH	8	62%	1	8%	4	31%	**13**
Total	**54**	**60%**	**19**	**21%**	**17**	**19%**	**90**

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

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

Anticipated Patent Expiration(s):

- Spinraza® (nusinersen) injection: September 2035
- Evrysdi® (risdiplam) for oral solution: October 2038
- Evrysdi® (risdiplam) tablet: April 2041

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

- **November 2025:** The FDA approved Itvisma® (onasemnogene abeparvovec-brve), an adeno-associated virus (AAV) vector-based gene therapy, for the treatment of SMA in patients 2 years of age and older with confirmed mutation in the *survival motor neuron 1* (*SMN1*) gene. Itvisma® contains the same active ingredient as Zolgensma® (onasemnogene abeparvovec-xioi), which is FDA approved for use in patients younger than 2 years of age. Itvisma® is administered as a one-time intrathecal injection at a fixed dose, while Zolgensma® is administered one-time intravenously at a weight-based dose.
- **March 2026:** The FDA approved a high dose regimen of Spinraza® (nusinersen) for the treatment of SMA in adult and pediatric patients. The new high dose regimen has a rapid loading dose schedule, consisting of 2 intrathecal doses of 50mg administered 14 days apart as compared to the previously approved low dose regimen loading dose schedule, which consisted of 3 doses of 12mg 14 days apart followed by

a fourth dose of 12mg 30 days after the third. The new high dose maintenance regimen consists of 28mg intrathecally every 4 months, compared to 12mg every 4 months for the previously approved low dose regimen. The approval was supported by the positive results of the Phase 2/3 randomized, controlled, dose-escalating DEVOTE trial, which showed benefits in the safety, tolerability, pharmacokinetics, and efficacy of this higher dosing regimen in treatment-naïve patients and in patients previously treated with the low dose Spinraza® regimen. Both the low dose and high dose regimens are included in the Spinraza® FDA package labeling as treatment options.

Pipeline:

- **Apitegromab:** In November 2025, Scholar Rock announced that the FDA issued a complete response letter (CRL) for the Biologics License Application (BLA) for apitegromab, an investigational treatment for SMA. The CRL was related to observations identified during a routine general site inspection of a third-party fill-finish facility. Scholar Rock plans to resubmit the BLA with an anticipated FDA decision in 2026. If approved, apitegromab will be the first muscle-targeted treatment approved for SMA. The BLA submission is supported by the positive results of the Phase 3 SAPPHIRE trial, including statistically significant and clinically meaningful motor function improvement in patients with SMA receiving apitegromab as compared to placebo; both groups received chronic dosing of either nusinersen or risdiplam.

Itvisma® (Onasemnogene Abeparvovec-brve) Product Summary[7,8]

Therapeutic Class: AAV vector-based gene therapy

Indication(s): Treatment of SMA in adult and pediatric patients 2 years of age and older with confirmed mutation in *survival motor neuron 1 (SMN1)* gene

How Supplied: Single-dose vial containing 1.2×10^{14} vector genomes (vg) of onasemnogene abeparvovec in 3mL of suspension

Dosing and Administration:

- Patients previously treated with Zolgensma® should not be treated with Itvisma®.
- Baseline testing for the presence of anti-AAV9 antibodies should be performed.
- The recommended dose is 1.2×10^{14} vg in 3mL of suspension administered as an intrathecal bolus injection over approximately 1 to 2 minutes.
- Administration should be postponed in patients with infections until the infection has resolved and the patient is clinically stable.

- Beginning 1 day prior to Itvisma® administration, systemic corticosteroids (equivalent to oral prednisolone at 1mg/kg of body weight per day) should be administrated for a total of 30 days.
    - At the end of the 30-day period, liver function should be evaluated by clinical examination and laboratory testing.
        - For patients with unremarkable findings, the corticosteroid dose should be tapered gradually over 28 days.
        - Alternatively, if liver function abnormalities persist, corticosteroids should be continued until findings become unremarkable and then tapered gradually over 28 days or longer.
- Liver function should be evaluated weekly for the month after Itvisma® administration and during the corticosteroid taper period; liver function should be monitored every other week for another month after the corticosteroid taper period ends.
- Platelet counts should be monitored weekly for the first month and as clinically indicated until platelet counts return to baseline.

Efficacy: The safety and efficacy of Itvisma® were evaluated in a randomized, double-blind, sham-controlled trial.

- Key Inclusion Criteria:
    - Confirmed diagnosis of SMA
    - Onset of clinical signs and symptoms at ≥6 months of age
    - Treatment-naïve for all survival motor neuron (SMN)-targeting therapies
    - Able to sit but never able to walk independently
- Key Exclusion Criteria:
    - Elevated baseline serum anti-AAV9 antibody titer >1:50
    - Requiring invasive or noninvasive ventilation or requiring tracheostomy
- Intervention(s): Patients were stratified by age and pre-treatment Hammersmith Functional Motor Scale – Expanded (HFMSE) and then randomized 3:2 to receive Itvisma® 1.2 x 10^{14} vg by single lumbar intrathecal injection or sham procedure
- Primary Endpoint(s): Change in baseline in HFMSE total score at the end of follow-up, defined as the average of the week 48 and week 52 assessments
- Results:
    - The mean change from baseline in HFMSE total score at the end of follow-up was 2.39 [standard error of the mean (SEM): 0.439] for the Itvisma® group (N=75) and 0.51 (SEM: 0.532) for the sham group (N=51), with a treatment difference of 1.88 [95% confidence interval (CI): 0.51, 3.25; P=0.0074].

Cost: The Wholesale Acquisition Cost (WAC) of Itvisma® is $2.59 million per 1-time treatment.

Recommendations

The College of Pharmacy recommends the prior authorization of Itvisma® (onasemnogene abeparvovec-brve) with the following criteria (shown in red):

Itvisma® (Onasemnogene Abeparvovec-brve) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Member must be 2 years of age or older; and
3. Molecular genetic testing confirming biallelic mutations in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
4. Member must be able to sit without support and is unable to walk without assistance (i.e., unable to walk without assistive devices); and
5. Must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests and platelet counts at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Itvisma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Itvisma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam) or Spinraza® (nusinersen) following Itvisma® infusion (current authorizations for risdiplam or nusinersen will be discontinued upon Itvisma® approval); and
11. Member must not have previously received Zolgensma® (onasemnogene abeparvovec-xioi); and
12. Only 1 Itvisma® infusion will be approved per member per lifetime.

The College of Pharmacy also recommends updating the Evrysdi® (risdiplam) and Zolgensma® (onasemnogene abeparvovec-xioi) approval criteria based on the FDA approval of Itvisma® (changes shown in red):

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and

2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1 (SMN1)* gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. For the tablet formulation, the member must be 2 years of age or older and weigh ≥20kg (recent weight measured within the last 3 months must be submitted); and
6. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
7. Pharmacy must confirm Evrysdi® oral solution will be constituted by a pharmacist prior to dispensing and must confirm Evrysdi® oral solution will be shipped via cold chain supply to adhere to the storage and handling requirements in the package labeling; and
8. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® formulations prior to administration of the first dose; and
9. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
10. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and
11. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
12. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
13. Member must not have previously received treatment with Itvisma® (onasemnogene abeparvovec-brve) or Zolgensma® (onasemnogene abeparvovec-xioi); and
14. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and

15. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and
16. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
17. A quantity limit of 240mL per 36 days will apply.
18. For the oral solution, a quantity limit of 240mL per 36 days will apply and for the tablets, a quantity limit of 30 tablets per 30 days will apply.

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric members younger than 2 years of age; and
2. Member must have reached full-term gestational age prior to Zolgensma® infusion; and
3. Molecular genetic testing to confirm biallelic mutations in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
4. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
5. Zolgensma® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests and platelet counts at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Zolgensma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Zolgensma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam), Itvisma® (onasemnogene abeparvovec-brve), or Spinraza® (nusinersen) following Zolgensma® infusion (current authorizations for risdiplam or nusinersen will be discontinued upon Zolgensma® approval); and
11. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
12. Only 1 Zolgensma® infusion will be approved per member per lifetime.

Lastly, the College of Pharmacy recommends updating the Spinraza® (nusinersen) approval criteria to be consistent with the other SMA medications' approval criteria and based on the FDA approval of Itvisma® (changes shown in red):

Spinraza® (Nusinersen) Approval Criteria:

1. An FDA approved ~~D~~diagnosis of spinal muscular atrophy (SMA)~~:~~; and
   ~~a. Type 1; or~~
   ~~b. Type 2; or~~
   ~~c. Type 3 with symptoms; and~~
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Itvisma® (onasemnogene abeparvovec-brve) or Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam); and
7. Prescriber must verify platelet count, coagulation laboratory testing, and quantitative spot urine protein testing have been assessed at baseline, levels are acceptable to the prescriber, and levels will be monitored prior to each dose; and
8. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
   a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
9. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
   a. Hammersmith Infant Neurological Exam (HINE); or
   b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
   c. Upper Limb Module (ULM) Test; or
   d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
10. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance

of function from pretreatment baseline status using the same exam as performed at baseline assessment:
   a. HINE; or
   b. CHOP-INTEND; or
   c. ULM Test; or
   d. HFMSE; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
   a. Only (1) 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

Utilization Details of SMA Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
RISDIPLAM PRODUCTS					
EVRYSDI SOL 0.75MG/ML	178	22	$4,126,060.37	8.09	$23,180.11
EVRYSDI TAB 5MG	25	9	$839,574.32	2.78	$33,582.97
SUBTOTAL	**203**	**31**	**$4,965,634.69**	**6.55**	**$24,461.25**
NUSINERSEN PRODUCTS					
SPINRAZA INJ 12MG/5ML	12	6	$1,578,722.90	2	$131,560.24
SUBTOTAL	**12**	**6**	**$1,578,722.90**	**2**	**$131,560.24**
ONASEMNOGENE ABEPARVOVEC-XIOI PRODUCTS					
ZOLGENSMA INJ 2x5.5ML/1x8.3ML KIT	5	5	$11,749,601.53	1	$2,349,920.31
SUBTOTAL	**5**	**5**	**$11,749,601.53**	**1**	**$2,349,920.31**
TOTAL	**220**	**30***	**$18,293,959.12**	**7.33**	**$83,154.36**

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

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NUSINERSEN INJ (J2326)	5	3	$568,152.00	1.67	$142,038.00
TOTAL	**5**	**3**	**$568,152.00**	**1.67**	**$142,038.00**

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 Interstitial Lung Disease (ILD) Medications and 30-Day Notice to Prior Authorize Jascayd® (Nerandomilast)

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

Esbriet® (Pirfenidone) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Esbriet®, monthly for the first 6 months of treatment, and every 3 months thereafter and as clinically indicated; and
4. 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
5. A quantity limit of 270 capsules or tablets per 30 days will apply for the 267mg strength capsules and tablets, and a quantity limit of 90 tablets per 30 days will apply for the 543mg and 801mg strength tablets.

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of idiopathic pulmonary fibrosis (IPF); or
    b. Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; or
    c. To slow the rate of decline in pulmonary function in members with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Ofev® treatment, at regular intervals during the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
4. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 3 months after therapy completion; and
5. 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
6. A quantity limit of 60 capsules per 30 days will apply.

Utilization of ILD Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

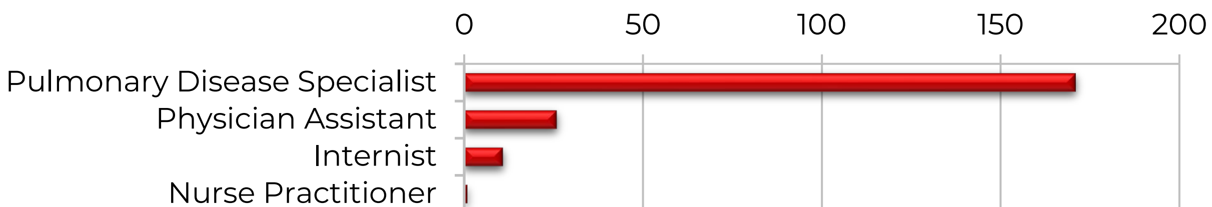
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	28	138	$1,686,445.72	$12,220.62	$411.83	8,757	4,095
Aetna	4	9	$81,114.46	$9,012.72	$433.77	374	187
Humana	4	11	$143,087.45	$13,007.95	$433.60	660	330
OCH	4	8	$104,063.60	$13,007.95	$433.60	480	240
2024 Total	**33**	**166**	**$2,014,711.23**	**$12,136.81**	**$415.23**	**10,271**	**4,852**
Fiscal Year 2025							
FFS	14	79	$1,019,733.73	$12,908.02	$437.65	4,660	2,330
Aetna	7	26	$331,448.48	$12,748.02	$441.93	1,500	750
Humana	7	46	$605,643.72	$13,166.17	$443.70	2,730	1,365
OCH	10	58	$771,096.62	$13,294.77	$443.16	3,480	1,740
2025 Total	**36**	**209**	**$2,727,922.55**	**$13,052.26**	**$441.05**	**12,370**	**6,185**
% Change	**9.10%**	**25.90%**	**35.40%**	**7.50%**	**6.20%**	**20.40%**	**27.50%**
Change	**3**	**43**	**$713,211.32**	**$915.45**	**$25.82**	**2,099**	**1,333**

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 ILD Medications: Pharmacy Claims (All Plans)

- All members utilizing ILD medications during fiscal year 2025 were adults; however, detailed demographic information cannot be provided due to the limited number of members using ILD medications during fiscal year 2025.

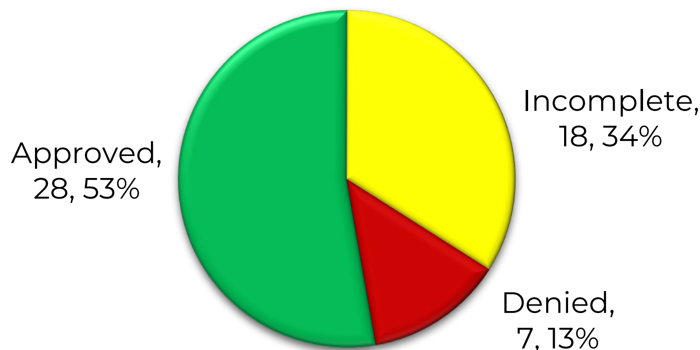
Top Prescriber Specialties of ILD Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of ILD Medications

There were 53 prior authorization requests submitted for ILD 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	21	40%	16	30%	2	4%	39
Aetna	2	4%	1	2%	0	0%	3
Humana	2	4%	0	0%	3	5%	5
OCH	3	5%	1	2%	2	4%	6
Total	28	53%	18	34%	7	13%	53

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

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

Anticipated Patent Expiration(s):

- Ofev® (nintedanib): December 2029
- Esbriet® (pirfenidone): March 2037
- Jascayd® (nerandomilast): October 2038

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

- **October 2025:** The FDA approved Jascayd® (nerandomilast) for the treatment of the signs and symptoms of idiopathic pulmonary fibrosis (IPF) in adult patients.
- **February 2026:** The FDA approved Jascayd® (nerandomilast) for the treatment of progressive pulmonary fibrosis (PPF) in adult patients.

Pipeline:

- **Deupirfenidone:** Deupirfenidone is an investigational deuterated form of pirfenidone, the current active ingredient in the FDA approved product Esbriet®, currently being studied for IPF. In the Phase 2 trial,

ELEVATE IPF, deupirfenidone showed a reduction in gastrointestinal adverse drug reactions compared to pirfenidone while maintaining the preservation of lung function. SURPASS-IPF is an ongoing 52-week, Phase 3, randomized, double-blind, head-to-head trial comparing deupirfenidone 825mg to pirfenidone 801mg and has an estimated completion date of June 2029. Deupirfenidone received Orphan Drug designation by the FDA in February 2026.

- **Tyvaso® (Treprostinil Inhalation Solution):** Tyvaso® was previously FDA approved for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with ILD (PH-ILD). It is currently being studied for potential label expansion in IPF and PPF. TETON 1 is an ongoing Phase 3 trial. The primary endpoint of TETON 1 is the change in forced vital capacity (FVC) from baseline to week 52, with data is expected to be released during the first half of 2026. TETON 2 is similar in design. In the fall of 2025, United Therapeutics announced that TETON 2 met the primary endpoint with an absolute change in FVC of 95.6mL. TETON-PPF is an ongoing 52-week, Phase 3, randomized, double-blind, placebo-controlled trial evaluating FVC in adults with PPF and has an estimated completion date of November 2027. Treprostinil inhalation solution received Orphan Drug designation for the treatment of IPF by the FDA in December 2020.

Jascayd® (Nerandomilast) Product Summary[8,9,10,11]

Therapeutic Class: Phosphodiesterase-4B enzyme (PDE4) inhibitor

Indication(s): Treatment of IPF and PPF in adult patients

How Supplied: 9mg or 18mg oral tablets

Dosing and Administration:

- The recommended dose is 18mg twice daily with or without food.
- Jascayd® tablets should be swallowed whole and should not be crushed or chewed.
- If needed, the tablet may be placed into 3 to 4 ounces of room temperature water until fragmented to create a mixture. Jascayd® will not fully dissolve.
- The dosage should be reduced to 9mg twice daily with concomitant use of strong CYP3A inhibitors or for those unable to tolerate 18mg twice daily.
- The dosage should not be reduced to 9mg twice daily with concomitant use of pirfenidone. The clinical study FIBRONEER-IPF showed a 50% decrease in steady state of Jascayd® in combination with pirfenidone. Target dosing with this combination is 18mg twice daily.

Efficacy: The efficacy of Jascayd® for IPF was evaluated in 2 randomized, double-blind, placebo-controlled trials, FIBRONEER-IPF and Trial 2, in adults with IPF with or without background antifibrotic therapy. The efficacy of Jascayd® for PPF was evaluated in a randomized, double-blind, placebo-controlled trial, FIBRONEER-ILD, with or without background treatment with nintedanib.

- Key Inclusion Criteria:
  - FIBRONEER-IPF and Trial 2:
    - 40 years of age or older
    - Confirmed IPF diagnosis
    - FVC at least 45% of predicted
    - Carbon monoxide diffusing capacity [(DLCO), corrected for hemoglobin] at least 25% of predicted
  - FIBRONEER-ILD:
    - 18 years of age or older
    - Fibrosis with more than 10% fibrotic features
    - Clinical signs of progression with:
      - FVC decline ≥10%; or
      - FVC decline ≥5% and <10% with worsening of respiratory symptoms or imaging; or
      - Worsening of respiratory symptoms and worsening imaging all in the 24 months prior to screening
    - FVC at least 45% of predicted
    - DLCO (corrected for hemoglobin) at least 25% of predicted
    - On stable dosing of nintedanib for at least 12 weeks, had discontinued treatment for at least 8 weeks, or treatment naïve
- Intervention(s):
  - FIBRONEER-IPF and FIBRONEER-ILD: Patients were randomized 1:1:1 to receive Jascayd® 9mg twice daily, Jascayd® 18mg twice daily, or placebo twice daily until the last patient completed 52 weeks of treatment.
  - Trial 2: Patients were randomized 2:1 to receive Jascayd® 18mg twice daily or placebo twice daily for 12 weeks.
- Primary Endpoint(s):
  - FIBRONEER-IPF and FIBRONEER-ILD: Absolute change from baseline in FVC at week 52
  - Trial 2: Change from baseline in FVC at week 12
- Results:
  - Jascayd® 18mg twice daily: Mean change from baseline in FVC was:
    - FIBRONEER-IPF: -106mL vs. -170mL in the placebo group [treatment difference: 64mL; 95% confidence interval (CI): 25, 102]

        - FIBRONEER-ILD: -86mL vs. -152mL in the placebo group (treatment difference: 65mL; 95% CI: 30, 101)
- Jascayd® 9mg twice daily: Mean change from baseline in FVC was:
    - FIBRONEER-IPF: -122mL vs. -170mL in the placebo group (treatment difference: 48mL; 95% CI: 10, 86)
    - FIBRONEER-ILD: -69mL vs. -152mL in the placebo group (treatment difference: 83 mL; 95% CI: 48, 118)
- Trial 2 (Jascayd® 18mg twice daily): Change from baseline in FVC was -91mL compared to placebo (95% CI: 44, 138)

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Jascayd® (nerandomilast) 18mg tablets	**$270.33**	**$16,219.80**	**$194,637.60**
Ofev® (nintedanib) 150mg capsules	$229.78	$13,786.80	$165,441.60
Esbriet® (pirfenidone) 801mg tablets	$116.10	$10,449.00	$125,388.00
pirfenidone 801mg tablets (generic)	$4.03	$362.70	$4,352.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = each capsule or tablet
*Cost per month based on the maximum FDA approved dose for each product: 18mg twice daily for Jascayd®, 150mg twice daily for Ofev®, and 801mg three times daily for Esbriet® and generic pirfenidone.

Recommendations

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

Jascayd® (Nerandomilast) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Idiopathic pulmonary fibrosis (IPF); or
    b. Progressive pulmonary fibrosis (PPF); and
2. Member must be 18 years of age or older; and
3. Medication must be prescribed by a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
4. Requests must indicate if Jascayd® will be used as monotherapy or in combination with nintedanib or pirfenidone; and
    a. If combination therapy is being requested, a patient-specific, clinically significant reason why the member requires combination therapy must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Ofev® (nintedanib) and generic pirfenidone must be provided; and
6. A quantity limit of 60 tablets per 30 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Ofev® (nintedanib) based on net costs (changes shown in red):

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of idiopathic pulmonary fibrosis (IPF); or
    b. Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; or
    c. To slow the rate of decline in pulmonary function in members with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Ofev® treatment, at regular intervals during the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
4. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 3 months after therapy completion; and
5. 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
6. A patient-specific, clinically significant reason why the member cannot use generic pirfenidone must be provided; and
7. A quantity limit of 60 capsules per 30 days will apply.

Utilization Details of ILD Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NINTEDANIB PRODUCTS						
OFEV 150MG CAP	106	22	$1,400,413.52	$13,211.45	4.82	51.34%
OFEV 100MG CAP	103	18	$1,327,509.03	$12,888.44	5.72	48.66%
TOTAL	**209**	**36***	**$2,727,922.55**	**$13,052.26**	**5.23**	**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

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Appendix R

30-Day Notice to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue–agdc)

Oklahoma Health Care Authority
April 2026

Introduction[1,2,3,4,5,6]

Congenital athymia (CA) is an ultra-rare disorder characterized by the absence of a functional thymus, resulting in profound T-cell immunodeficiency in pediatric patients. The prevalence is unknown due to its rarity. Affected individuals have increased susceptibility to severe and recurrent infections, as well as an increased risk of autologous graft-versus-host disease (GVHD) due to dysregulated T-cell development.

Advances in newborn screening have improved early detection of this condition. T-cell receptor excision circle (TREC)-based screening, now universally implemented across the United States, identifies T-cell lymphopenia. Low or undetectable TRECs may serve as an early indicator of conditions such as CA and severe combined immunodeficiency (SCID), though confirmatory diagnostic evaluation is required. CA is most commonly associated with complete DiGeorge syndrome, typically resulting from a 22q11.2 deletion; however, this does not represent an exhaustive list of genetic etiologies.

Prior to 2021, there were no U.S. Food and Drug Administration (FDA)-approved therapies for CA, and management was limited to supportive care, with most patients dying by 2 to 3 years of age. There are no standardized treatment guidelines for CA; however, clinical management is guided by international expert consensus guidelines for defects in thymic development. These recommendations focus on immunologic evaluation, infection prevention, and supportive care, including antimicrobial prophylaxis and immunoglobulin replacement when indicated. Given the high mortality and lack of effective treatment options, there remains a significant unmet need for therapies that restore immune function in this population.

In October 2021, the FDA approved Rethymic® (allogeneic processed thymus tissue-agdc), the first therapy indicated for immune reconstitution in pediatric patients with CA. Rethymic® is currently available at a single specialized center, Duke University Hospital in Durham, North Carolina.

Rethymic® (Allogeneic Processed Thymus Tissue–agdc) Product Summary[3]

Therapeutic Class: Allogeneic thymus tissue-based treatment

Indication(s): Immune reconstitution in pediatric patients with CA
- **Limitation(s) of Use:** Not indicated for the treatment of patients with SCID

How Supplied: Yellow to brown slices of processed thymus tissues with varying thickness and shape

Dosing and Administration:
- Rethymic® is administered by a surgical procedure.
- The recommended dose range is 5,000 to 22,000mm^2 of Rethymic® per m^2 of recipient's body surface area (BSA).
- Immunosuppressive therapy is recommended for patients receiving Rethymic® based on disease phenotype and phytohemagglutinin (PHA) levels.

Efficacy: The efficacy and safety of Rethymic® were evaluated in 105 pediatric patients across 10 open-label, prospective, single-center clinical trials, with a follow-up of up to 25.5 years. The primary efficacy analysis included 95 patients [median age at time of treatment: 9 months (range: 1 to 36 months of age)].
- Key Inclusion Criteria:
  - Pediatric patients with CA
- Key Exclusion Criteria:
  - Pediatric patients with SCID
  - Pre-existing cytomegalovirus (CMV) infection
  - Pre-existing renal impairment
- Intervention(s): Patients received a single surgical implantation of Rethymic® with dosing based on BSA (approximately 4,900 to 24,000 mm^2 per m^2), along with concomitant immunosuppressive therapy as clinically indicated based on disease phenotype and pre-treatment immune function.
- Primary Endpoint(s): Overall survival at 1 year post-treatment
- Results:
  - Kaplan-Meier estimated survival was 77% at 1 year [95% confidence interval (CI): 67.0%, 84.1%] and 76% at 2 years (95% CI: 65.8%, 83.2%).
  - Among patients alive at 1 year post-treatment, 94% remained alive long-term with a median follow-up of 10.7 years.
  - Survival was significantly improved compared to natural history, where untreated patients with CA typically die by age 2–3 years.

- Treatment resulted in the development of functional naïve T cells, indicating immune reconstitution.
- Treatment resulted in a significant reduction in infections over time, including a 38% decrease in the number of patients with an infection event 6–12 months post-treatment and a mean reduction of 2.9 infection events per patient at 2 years (P<0.001).

Cost: The Wholesale Acquisition Cost (WAC) of Rethymic® is $2.8 million for the one-time dose (not including procedural costs).

Recommendations

The College of Pharmacy recommends the prior authorization of Rethymic® (allogeneic processed thymus tissue–agdc) with the following criteria (shown in red):

Rethymic® (Allogeneic Processed Thymus Tissue-agdc) Approval Criteria:

1. An FDA approved indication for immune reconstitution in pediatric patients with congenital athymia (CA). Diagnosis must be confirmed by the following (supporting documentation must be submitted):
    a. Flow cytometry documenting <50 naïve T-cells/mm³ (CD45RA+, CD62L+) in the peripheral blood or <5% of total T-cells being naïve in phenotype; and
    b. Clinical, genetic, and/or immunologic findings, including evaluation to exclude severe combined immunodeficiency (SCID); and
2. Member must be younger than 18 years of age; and
3. Member must not have SCID; and
4. Member must not have a pre-existing cytomegalovirus (CMV) infection or pre-existing renal impairment; and
5. Rethymic® must be prescribed by a specialist with expertise in CA and in the administration of Rethymic®; and
6. Prescriber must attest that the member will not receive immunizations until immune function is established; and
7. Documentation of anti-human leukocyte antigen (HLA) antibody screening; and
    a. If the member is positive for anti-HLA antibodies, prescriber must verify the member will receive Rethymic® from a donor who does not express those HLA alleles; and
8. If the member has received a hematopoietic cell transplant (HCT) or a solid organ transplant, the following will be required:
    a. HLA matching; and
    b. Member will receive Rethymic® HLA matched to recipient alleles that were not expressed in the HCT donor to minimize the risk of graft-versus-host disease (GVHD); and

9. Verification that the member will be monitored and the member and/or caregiver will be counseled on all the following after treatment with Rethymic®, as per package labeling:
    a. Lymphoproliferative disorders; and
    b. Transmission of infectious disease; and
    c. Development of autoimmune disorders; and
    d. Development of GVHD; and
    e. Infection control measures and immune prophylaxis; and
10. Prescriber attestation that Rethymic® will be prescribed with immunosuppressive therapy based on disease phenotype and phytohemagglutinin levels; and
11. Member has no history of receiving a previous thymus tissue implantation in their lifetime; and
12. Approval will be for 1 treatment per member per lifetime.

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Appendix S

Fiscal Year 2025 Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Eydenzelt® (Aflibercept-boav)

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

Enzeevu® (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Eylea®/Eylea® HD (aflibercept) or Pavblu® (aflibercept-ayyh) 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.

Izervay® (Avacincaptad Pegol) Approval Criteria:

1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Izervay® must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescribers must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and neovascular (wet) AMD; and
5. A quantity limit of (1) 0.1mL single-dose vial per eye once monthly will apply.

Susvimo® (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Neovascular (wet) age-related macular degeneration (AMD) in adults; or
    b. Diabetic macular edema (DME); or
    c. Diabetic retinopathy (DR); and
2. Member must have previously responded to ≥2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and

4. Susvimo® must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal surgery; and
5. Prescriber must verify the member will be monitored for endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs; and
6. A patient-specific, clinically significant reason why the member cannot use ranibizumab intravitreal injection or other VEGF inhibitor injection products (appropriate to disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz® (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab), Pavblu® (aflibercept-ayyh)] must be provided; and
7. The following quantity limits will apply per eye:
    a. <u>AMD or DME:</u> (1) 0.1mL single-dose vial (SDV) per 6 months; or
    b. <u>DR:</u> (1) 0.1mL SDV per 9 months.

Syfovre® (Pegcetacoplan) Approval Criteria:
1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Syfovre® must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, intraocular inflammation, and neovascular (wet) AMD; and
5. A quantity limit of (1) 0.1mL single-dose vial per eye every 25 to 60 days will apply.

Vabysmo® (Faricimab-svoa Intravitreal Injection) Approval Criteria:
1. An FDA approved diagnosis of 1 of the following:
    a. Neovascular (wet) age-related macular degeneration (AMD); or
    b. Diabetic macular edema (DME); or
    c. Macular edema following retinal vein occlusion (RVO); and
2. Member must be 18 years of age or older; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Vabysmo® must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal injections; and
5. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and arterial thromboembolic events, and

6. 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 3 months after the final dose of Vabysmo®; and
7. Member must have previously tried and failed 1 VEGF inhibitor injection product (appropriate to the disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz® (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab), Pavblu® (aflibercept-ayyh)] or a patient-specific, clinically significant reason why a preferred VEGF inhibitor injection product is not appropriate for the member must be provided; and
8. A quantity limit of 0.05mL per 28 days will apply.

Utilization of AMD Medications: Fiscal Year 2025

Comparison of Fiscal Years: Medical Claims (All Plans)

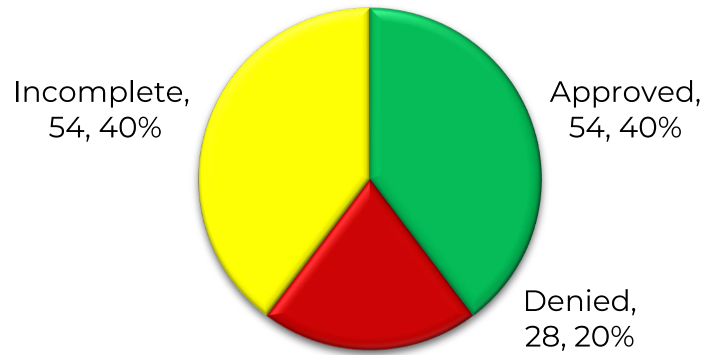
Plan Type	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	322	846	$1,680,346.72	$1,986.23	2.63
Aetna	8	8	$16,352.99	$2,044.12	1
Humana	28	34	$63,552.74	$1,869.20	1.21
OCH	17	19	$43,406.18	$2,284.54	1.12
2024 Total	**333**	**907**	**$1,803,658.63**	**$1,988.60**	**2.72**
Fiscal Year 2025					
FFS	216	587	$1,054,844.94	$1,797.01	2.72
Aetna	46	111	$188,957.77	$1,702.32	2.41
Humana	114	300	$494,105.18	$1,647.02	2.63
OCH	55	166	$307,669.95	$1,853.43	3.02
2025 Total	**395**	**1,164**	**$2,045,577.84**	**$1,757.37**	**2.95**
% Change	**18.62%**	**28.34%**	**13.41%**	**-11.63%**	**8.46%**
Change	**62**	**257**	**$241,919.21**	**-$231.23**	**0.23**

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.

Prior Authorization of AMD Medications

There were 136 prior authorization requests submitted for AMD 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	43	38%	54	47%	17	15%	**114**
Aetna	2	29%	0	0%	5	71%	**7**
Humana	9	82%	0	0%	2	18%	**11**
OCH	0	0%	0	0%	4	100%	**4**
Total	**54**	**40%**	**54**	**40%**	**28**	**20%**	**136**

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

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

Anticipated Patent Expiration(s):

- Izervay™ (avacincaptad pegol): July 2034
- Syfovre® (pegcetacoplan injection): December 2038

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

- **October 2025:** The FDA approved Eydenzelt® (aflibercept-boav) as a biosimilar to Eylea® (aflibercept). The cost is not available at this time.

Pipeline:

- **Lytenava™:** Lytenava™ is an ophthalmic formulation of bevacizumab for intravitreal injection. Currently, there are no FDA approved ophthalmic formulations of bevacizumab available; however, Avastin® (bevacizumab) is often used off-label and repackaged via a compounding pharmacy for use in the eye. In December 2025, Outlook Therapeutics announced the FDA issued a complete response letter (CRL) to Lytenava™ which noted that the additional information provided in the biologics license application (BLA) resubmission does not change their previous review conclusion and they have again recommended that confirmatory evidence of efficacy be submitted to support the application. In March 2026, a Type A meeting was held with the FDA to discuss what evidence is needed to support the application.

Details of the meeting were not provided; however, Outlook Therapeutics stated they continue to engage in discussions with the FDA to find an appropriate path forward.

- **Ximluci®:** Ximluci® (ranibizumab) is a biosimilar candidate for the vascular endothelial growth factor (VEGF) inhibitor, Lucentis® (ranibizumab). In October 2025, the FDA issued a CRL to Xbrane Biopharma regarding its application for Ximluci® which noted unresolved observations following the inspection at 1 of the production sites without further specification. This is following a CRL received in April 2024 due to similar reasoning.

Recommendations

The College of Pharmacy recommends the prior authorization of Eydenzelt® (aflibercept-boav) with the same criteria as the other aflibercept biosimilars (changes shown in red):

Eydenzelt® (Aflibercept-boav), Enzeevu® (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Eylea®/Eylea® HD (aflibercept) or Pavblu® (aflibercept-ayyh) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Utilization Details of AMD Medications: Fiscal Year 2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J0178 AFLIBERCEPT (EYLEA)	628	262	$1,185,578.69	$1,887.86	2.4
Q5128 RANIBIZUMAB-EQRN (CIMERLI)	311	131	$269,704.53	$867.22	2.37
J2777 FARICIMAB-SVOA (VABYSMO)	159	56	$413,794.34	$2,602.48	2.84
J0177 AFLIBERCEPT HD (EYLEA HD)	44	29	$143,718.10	$3,266.32	1.52
Q5124 RANIBIZUMAB-NUNA (BYOOVIZ)	14	6	$11,688.30	$834.88	2.33
J2782 AVACINCAPTAD PEGOL (IZERVAY)	4	1	$17,528.80	$4,382.20	4
J2778 RANIBIZUMAB (LUCENTIS)	4	2	$3,565.08	$891.27	2
TOTAL	**1,164**	**395**	**$2,045,577.84**	**$1,757.37**	**2.95**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 03/2026. Last accessed 03/13/2026.
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Appendix T

Fiscal Year 2025 Annual Review of Sofdra™ (Sofpironium 12.45% Topical Gel)

Oklahoma Health Care Authority
April 2026

Current Prior Authorization Criteria

Sofdra™ (Sofpironium 12.45% Topical Gel) Approval Criteria:

1. An FDA approved diagnosis of primary axillary hyperhidrosis; and
2. Member must be 9 to 20 years of age; and
3. Documentation of assessment by a licensed behavior specialist or the prescribing physician indicating the member's hyperhidrosis is causing social anxiety, depression, or similar mental health-related issues that impact the member's ability to function in day-to-day living must be provided; and
4. Member must have failed a trial, at least 3 weeks in duration, with the following:
    a. Xerac® AC (aluminum chloride hexahydrate 6.25% topical solution) or at least 1 over-the-counter Certain Dri® antiperspirant; and
    b. Drysol® (aluminum chloride 20% topical solution); and
5. Prescriber must verify that the member has received counseling on the safe and proper use of Sofdra™; and
6. A quantity limit of 40.2mL per 30 days will apply; 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.

Utilization of Sofdra™ (Sofpironium 12.45% Topical Gel): Fiscal Year 2025

There was no SoonerCare utilization of Sofdra™ (sofpironium 12.45% topical gel) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Prior Authorization of Sofdra™ (Sofpironium 12.45% Topical Gel)

There were no prior authorization requests submitted for Sofdra™ (sofpironium 12.45% topical gel) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Sofdra™ (sofpironium 12.45% topical gel): May 2040

Recommendations

The College of Pharmacy does not recommend any changes to the current Sofdra™ (sofpironium 12.45% topical gel) prior authorization criteria at this time.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2026. Last accessed 03/17/2026.

Appendix U

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

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: March 26, 2026

FDA Approves First Gene Therapy for Severe Leukocyte Adhesion Deficiency Type I

The FDA approved Kresladi™ (marnetegragene autotemcel), the first gene therapy for the treatment of severe Leukocyte Adhesion Deficiency Type I (LAD-I). Kresladi™ is indicated for the treatment of pediatric patients with severe leukocyte adhesion deficiency I (LAD-I) due to biallelic variants in *ITGB2* without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.

Severe LAD-I is a rare, inherited immune deficiency caused by mutations in the *ITGB2* gene, which prevent white blood cells from effectively fighting infections. Patients with severe LAD-I experience recurrent, life-threatening bacterial and fungal infections with substantial morbidity and mortality in the first decade of life. Allogeneic hematopoietic stem cell transplant is considered in some patients but is associated with significant morbidity and mortality, especially in patients without an HLA-matched sibling donor.

Kresladi™ consists of the patient's own hematopoietic stem cells (HSCs), which are genetically modified to introduce functional copies of the *ITGB2* gene. Following conditioning, a single dose of Kresladi™ is infused intravenously to address the underlying cause of severe LAD-I by restoring CD18 and CD11a cell surface expression in white blood cells, including neutrophils.

The safety and effectiveness of Kresladi™ were established in 1 open-label, single-arm, multicenter study based on increases in neutrophil CD18 and CD11a cell surface expression at month 12 with sustained effect through month 24 post-infusion. Increases in neutrophil CD18 and CD11a cell surface expression reflect improved function of a protein complex of the 2 biomarkers on the surface of neutrophils which is used as a surrogate endpoint that is reasonably likely to predict clinical benefit in LAD-I for accelerated approval. The clinical benefit of Kresladi™ will be confirmed in patients with severe LAD-I through post-marketing requirements. The most common side effects identified in the clinical study included anemia, low platelet and white blood cell counts, mouth sores, upper respiratory infections, viral infections, fever, febrile neutropenia, nausea, vomiting, skin infection, rash, vascular device-related infection, and increased liver enzymes.

The application was granted Orphan Drug, Rare Pediatric Disease, Regenerative Medicine Advanced Therapy and Fast Track designations. The FDA granted accelerated approval of Kresladi™, as well as a Rare Pediatric Disease Priority Review Voucher, to Rocket Pharmaceuticals, Inc. As a condition of accelerated approval, Rocket Pharmaceuticals, Inc., is required to conduct post-approval studies to verify and describe the clinical benefit of Kresladi™. Continued approval may be contingent upon verification of clinical benefit in confirmatory trials.

FDA NEWS RELEASE

For Immediate Release: March 25, 2026

FDA Approves Drug to Treat Neurologic Manifestations of Hunter Syndrome

The FDA approved Avlayah™ (tividenofusp alfa-eknm) to treat certain individuals with Hunter syndrome [Mucopolysaccharidosis type II (MPS II)].

Hunter syndrome is a rare inherited lysosomal disorder in which glycosaminoglycans build up within the cells' lysosomes. This substrate accumulation affects physical and mental development by causing abnormalities in the skeleton, heart, respiratory system, brain, and other organs.

Avlayah™, an intravenous (IV) infusion given once weekly, is approved to treat neurologic manifestations of Hunter syndrome when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5kg prior to advanced neurologic impairment.

To support approval, the sponsor submitted results from a phase 1/2 multi-cohort, single-arm, open-label trial that enrolled 47 pediatric patients who were 3 months to 13 years of age with Hunter syndrome. In the trial, Avlayah™ significantly reduced cerebrospinal fluid heparan sulfate (CSF HS), a type of glycosaminoglycan. The 44 patients with measurements at week 24 had a 91% average decrease from baseline in CSF HS; the minimum and maximum percent change in CSF HS from baseline were 72% and 98%, respectively. At baseline, no patients had CSF HS levels below the upper limit of normal (ULN); at week 24, 93% of Avlayah™-treated patients with CSF measurements had CSF HS levels below the ULN.

Avlayah™'s labeling includes a *Boxed Warning* for allergic reactions, including anaphylaxis, associated with the drug. Patients should start therapy in a health care setting with appropriate medical monitoring and support measures. The most common side effects of Avlayah™ include upper respiratory tract infection, ear infection, fever, anemia, cough, vomiting, diarrhea, rash, COVID-19, runny nose, nasal congestion, fall, headache, skin abrasion, and hives. Due to the risk of anemia, hemoglobin levels should be obtained at baseline, at 3 months after starting therapy, and then periodically as clinically indicated. Health care providers should treat anemia based on clinical judgment. Due to the risk of membranous nephropathy, kidney

function and urine protein levels should be monitored. If kidney disease is suspected, patients should have an appropriate evaluation and therapy.

Avlayah™ received Breakthrough, Fast Track, Priority Review, and Orphan Drug designations and accelerated approval for this indication. The approval was granted to Denali Therapeutics.

FDA NEWS RELEASE

For Immediate Release: March 10, 2026

FDA Launches New Adverse Event Look-Up Tool

The FDA launched a new unified platform for analyzing adverse event reports. This platform - called the FDA Adverse Event Monitoring System (AEMS) - represents a major achievement in the FDA's mission to modernize and provide radical transparency into the safety of regulated products.

With the new system, adverse event reports submitted to the FDA for drugs, biologics, vaccines, cosmetics, and animal food can be displayed in a single streamlined dashboard. In the months ahead, all remaining product centers will begin processing adverse event reports in AEMS. The FDA will also migrate historical adverse event data to AEMS, decommission certain legacy systems, and roll out enhanced application program interfaces (APIs) and data analytics tools. By the end of May 2026, AEMS will contain real-time adverse event reports for all FDA-regulated products, consistent with meeting FDA obligations not to release individually identifiable patient or consumer information.

In the past, the FDA processed approximately 6 million adverse event reports per year across a patchwork of 7 databases, which were expensive and had a poor user interface, making searches difficult. These platforms collectively cost the FDA approximately $37 million per year to operate. Given the efficiencies of AEMS, the FDA expects to save approximately $120 million over the next 5 years. The FDA also expects the new searchable system to significantly reduce FDA Freedom of Information Act (FOIA) requests for unreleased adverse event reports, given that AEMS will publish reports in real time, rather than quarterly.

Transparency around adverse event reports submitted by patients, consumers, clinicians, and manufacturers is a critical component of the FDA's postmarket surveillance capability. Although these reports have limitations, they can help identify potential safety signals, such as patterns or clusters of adverse events that might indicate previously unknown risks. However, the utility of these reports has often been undermined by the FDA's inefficient infrastructure.

Legacy systems to be replaced by AEMS now include:

- FAERS (FDA Adverse Event Reporting System) - containing reports for drugs, biologics, cosmetic products, and color additives.
- VAERS (Vaccine Adverse Event Reporting System) - containing reports for vaccines. Note: The FDA will display VAERS data in

AEMS. VAERS is co-managed by the FDA and Centers for Disease Control and Prevention.

- AERS (Adverse Event Reporting System) - 2 databases containing reports for animal drugs and animal foods.

Legacy systems to be replaced by AEMS in May include:

- MAUDE (Manufacturer and User Facility Device Experience) - containing reports for medical devices.
- HFCS (Human Foods Complaint System) - containing reports for human foods and dietary supplements.
- CTPAE (Center for Tobacco Products Adverse Event Reporting System) - containing reports for Electronic Nicotine Delivery Systems (ENDS) and other tobacco products.

FDA NEWS RELEASE

For Immediate Release: March 10, 2026

FDA Approves First Treatment for Patients with Cerebral Folate Transport Deficiency

The FDA approved expanded use of Wellcovorin (leucovorin calcium) tablets for the treatment of cerebral folate deficiency (CFD) in adult and pediatric patients who have a confirmed variant in the folate receptor 1 (*FOLR1*) gene.

This action reflects the FDA's commitment to accelerating cures and expanding treatment options including for patients with serious and unmet needs. Leucovorin is the first treatment for the rare genetic condition of CFD.

The approval was based on a systematic review of the published literature including published case reports with patient-level information, as well as mechanistic data. CFD is a neurological condition that affects folate transport into the brain. People with *FOLR1*-related CFD (CFD-*FOLR1*) often have severe developmental delays, movement disorders, seizures, and other serious neurological complications.

The FDA collaborated with GSK, the New Drug Application holder of Wellcovorin, on a process to update the labeling to include the essential scientific information needed for the safe and effective use of the drug for adults and pediatric patients with CFD-*FOLR1*.

Possible side effects associated with leucovorin include pruritus, rash, urticaria, dyspnea, rigors, and impaired thermoregulation. Anaphylaxis is a serious side effect requiring immediate medical attention.

The approval addresses a critical need for individuals with CFD-*FOLR1* and builds on the FDA's commitment to advancing the health of all Americans, including those affected by rare genetic conditions.

<u>FDA NEWS RELEASE</u>

For Immediate Release: March 9, 2026

FDA Takes Further Steps to Streamline Biosimilar Development and Make Medicines More Affordable

The FDA announced another major step in its initiative to streamline the development of biosimilar medicines, which are like “generic” versions of biologic drugs. In the new draft guidance issued, the FDA recommended streamlining unnecessary clinical pharmacokinetic (PK) testing when scientifically justified. This change could save biosimilar developers up to 50% of their PK study costs, or approximately $20 million, and help lower drug costs.

Biologic medicines can be powerful treatments for many diseases, including autoimmune diseases and cancer, but are often expensive. Despite accounting for just 5% of prescriptions, biologics account for 51% of drug spending, and commonly cost hundreds of thousands of dollars per year. Biosimilars, like generic drugs, can give patients more affordable treatment options and increase access to medications that are otherwise unaffordable.

The announcement builds on a prior FDA effort in October, where Commissioner Makary announced another draft guidance reducing certain unnecessary comparative efficacy studies, which can require 1-3 years and cost $24 million.

The new draft guidance, “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)” is intended to inform prospective applicants and facilitate the development of proposed biosimilars and proposed interchangeable biosimilars. It revises and replaces the draft guidance for industry entitled “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)” issued September 17, 2021, and includes revisions to certain Q&As that appeared in a previous version of the final guidance entitled “Questions and Answers on Biosimilar Development and the BPCI Act.”

Specifically, this draft guidance provides updated recommendations to prospective biosimilar applicants seeking to use data from a comparator product approved outside the United States. as evidence that a proposed product is biosimilar to the United States-licensed product. The recommendations describe scenarios in which a biosimilar applicant may use clinical data from outside the United States without additional data from a three-way PK study (using the proposed biosimilar, the United States-licensed reference product, and the non-United States-licensed comparator product). The revisions also remove the earlier recommendation for at least 1 clinical PK study that directly compares the proposed biosimilar with the United States-licensed reference product to support a demonstration of biosimilarity; instead, a PK study can use a comparator product approved outside the United States if scientifically justified.

The FDA is withdrawing final guidance titled “Scientific Considerations in Demonstrating Biosimilarity to a Reference Product,” because it no longer represents the FDA’s current thinking. Since the issuance of this guidance in April 2015 (when the FDA had approved only 1 biosimilar application), the FDA has gained significant experience with review of proposed biosimilars and its scientific thinking has evolved.

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated licensure (approval) pathway to help provide patients with greater access to safe and effective biological products. To date, the FDA has approved 82 biosimilars that provide Americans with additional affordable treatment options for conditions such as cancer, rheumatoid arthritis, diabetes, Crohn’s disease, and osteoporosis.

FDA NEWS RELEASE

For Immediate Release: March 5, 2026

FDA Grants Third Approval Under the National Priority Voucher Program

The FDA approved teclistamab-cqvy in combination with daratumumab/hyaluronidase-fihj (Tec-Dara) to treat adult patients with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy. This decision, which was issued 55 days after filing, marks the third approval under the new Commissioner’s National Priority Voucher (CNPV) pilot program.

The FDA proactively awarded a voucher for the drug combination on December 15, 2025, after FDA leaders learned about a Phase 3 clinical trial in which Tec-Dara showed significant improvements over the standard of care in both progression-free survival and overall survival. Notably, in that study, Tec-Dara reduced the risk of disease progression or death by 83% relative to the standard of care control arm.

The CNPV program seeks to expedite approval of applications that address critical national health priorities, such as bringing innovative therapies to the American people, addressing large unmet medical needs, promoting domestic manufacturing, and increasing affordability. A company selected for the program is issued a voucher entitling the company to benefits including enhanced communications and rolling review to allow for a shortened review time.

Additionally, the Phase 3 study supporting the Tec-Dara indication provided confirmatory evidence for the existing indication of Tecvayli® (teclistamab-cqyv) used as monotherapy, which will be converted from accelerated approval to traditional approval. The *Prescribing Information* for Tecvayli® comes with a *Boxed Warning* for life threatening or fatal cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity (ICANS). CRS is a severe inflammatory response, which causes high fever, low blood pressure, and in some cases death. Because of these risks, Tec-Dara is available only through a restricted program

under a Risk Evaluation and Mitigation Strategy (REMS), called the Tecvayli®-Talvey® REMS.

In addition to CRS, the most common side effects of Tecvayli® in combination with daratumumab/hyaluronidase-fihj include hypogammaglobulinemia, upper respiratory tract infection, cough, diarrhea, musculoskeletal pain, COVID-19, pneumonia, injection site reaction, fatigue, pyrexia, headache, nausea, gastroenteritis, and decreased weight. The FDA granted the approval to Janssen Biotech, Inc.

FDA NEWS RELEASE

For Immediate Release: March 05, 2026

FDA to Address Unused Opioids in American Homes

The FDA issued a Request for Information (RFI) seeking public comment on potential new standards for in-home opioid disposal products. This effort is part of the FDA's broader work to combat the opioid crisis.

Companies selling opioid analgesics are currently required to make available prepaid mail-back envelopes to outpatient pharmacies and other dispensers. Now, the FDA is considering whether to require that opioid sponsors, through dispensers, make available in-home disposal systems.

At present, FDA recommends dropping off unused opioids at a drug take-back location or mailing them back using a pre-paid envelope provided by a pharmacy. Alternatively, the FDA recommends flushing unused opioids down the toilet (something the FDA only recommends for certain high-risk medications). A 2017 study in the Science of Total Environment concluded that flushing unused opioids presents a "negligible eco-toxicological risk."

Today's RFI seeks input from industry, health care providers, and advocates on appropriate criteria for in-home disposal kits. This aligns with the SUPPORT for Patients and Communities Reauthorization Act of 2025, which mandates the FDA to issue guidance to facilitate in-home safe disposal, as well as President Trump's Great American Recovery initiative.

Responses to the RFI are due by 11:59 p.m. Eastern Time on April 6, 2026. All interested parties are invited to submit comments to the docket.

FDA NEWS RELEASE

For Immediate Release: March 3, 2026

FDA Warns 30 Telehealth Companies Against Illegal Marketing of Compounded GLP-1s

The FDA announced the issuance of 30 warning letters to telehealth companies for making false or misleading claims regarding compounded GLP-1 products offered on their websites.

This is the second group of warning letters sent to telehealth firms since the FDA launched in September a crackdown on misleading direct-to-consumer pharmaceutical advertisements. Over the past 6 months, the FDA has sent thousands of letters warning pharmaceutical and telehealth firms to

remove misleading ads, more than had been sent over the entire preceding decade.

Primary violations identified in the letters included making claims implying sameness with FDA-approved products and obscuring product sourcing by advertising drug products branded with the telehealth firm's name or trademark without qualification, implying they are the compounder.

Compounded drugs are not FDA-approved. This means the FDA does not review their safety, effectiveness, or quality before they are marketed. Compounded drugs are also not the same as generic drugs, which are FDA-approved.

Current Drug Shortages Index (as of March 31, 2026):

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

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

Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***

Sodium Bicarbonate Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***