OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
April 10, 2024
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 10, 2024

DATE: April 3, 2024

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/SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – Appendix B

Action Item – Vote to Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox) – Appendix C

Action Item – Vote to Prior Authorize Ngenla™ (Somatrogon-ghla) and Update the Approval Criteria for the Growth Hormone Products and Voxzogo® (Vosoritide) – Appendix D

Action Item – Vote to Prior Authorize Ryzneuta® (Efbemalenogastim Alfa) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) – Appendix E

Action Item – Vote to Prior Authorize Tyruko® (Natalizumab-sztn) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications – Appendix F

Action Item – Vote to Prior Authorize Aphexda™ (Motixafortide) and Update the Approval Criteria for the Stem Cell Mobilizers – Appendix G

Action Item – Vote to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp) and Update the Approval Criteria for the Lymphoma Medications – Appendix H

Action Item – Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications – Appendix I

Action Item – Annual Review of Phenylketonuria (PKU) Medications – Appendix J

Action Item – Annual Review of Ileal Bile Acid Transporter (IBAT) Inhibitors – Appendix K

Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Augtyro™ (Repotrectinib) – Appendix L

Annual Review of Anti-Diabetic Medications and 30-Day Notice to Prior Authorize Inpefa® (Sotagliflozin), Glipizide 2.5mg Tablet, Lantidra™ (Donislecel-jujn), Metformin 625mg Tablet, Zituvio™ (Sitagliptin), and Zituvimet™ (Sitagliptin/Metformin) – Appendix M

Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Izervay™ (Avacincaptad Pegol) – Appendix N

Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin), Voquenza® (Vonoprazan), Voquenza® Dual Pak® (Vonoprazan/ Amoxicillin), Voquenza® Triple Pak® (Vonoprazan/Amoxicillin/ Clarithromycin) – Appendix O

Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Rezzayo™ (Rezafungin) – Appendix P

Annual Review of Filspari™ (Sparsentan) – Appendix Q

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – April 10, 2024 @ 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. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Bret Haymore –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Vineetha Thomas –	participating in person
Dr. Beth Walton –	participating in person
Dr. Cindy West –	participating in person

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https://oklahoma.zoom.us/webinar/register/WN_R_AmCBepQpGQggKXT40uxg
After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 919 6475 4191
Passcode: 95646190

Public Comment for Meeting:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. March 13, 2024 DUR Board Meeting Minutes
   B. March 13, 2024 DUR Board Recommendations Memorandum

Items to be presented by Dr. Moss, Dr. Travers, Dr. Muchmore, Chairman:

4. **Update on Medication Coverage Authorization Unit/SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update – See Appendix B**
   A. Pharmacy Help Desk Activity for March 2024
   B. Medication Coverage Activity for March 2024
   C. SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

Items to be presented by Dr. Ratterman, Dr. Muchmore, Chairman:

5. **Action Item – Vote to Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox) – See Appendix C**
   A. Market News and Updates
   B. Roctavian™ (Valoctocogene Roxaparvovec-rvox) Product Summary
   C. OHCA Recommendations

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

6. **Action Item – Vote to Prior Authorize Ngenla™ (Somatrogon-ghla) and Update the Approval Criteria for the Growth Hormone Products and Voxzogo® (Vosoritide) – See Appendix D**
   A. Market News and Updates
   B. Ngenla™ (Somatrogon-ghla) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Ryzneuta® (Efbemalenogastim Alfa) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) – See Appendix E**
   A. Market News and Updates
   B. Ryzneuta® (Efbemalenogastim Alfa) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Tyruko® (Natalizumab-sztn) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications – See Appendix F**
   A. Market News and Updates
   B. Tyruko® (Natalizumab-sztn) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Aphexda™ (Motixafortide) and Update the Approval Criteria for the Stem Cell Mobilizers – See Appendix G**
   A. Market News and Updates
   B. Aphexda™ (Motixafortide) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Vote to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp) and Update the Approval Criteria for the Lymphoma Medications – See Appendix H**
    A. Market News and Update
    B. Product Summaries
    C. College of Pharmacy Recommendations

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

11. **Action Item – Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications – See Appendix I**
    A. Current Prior Authorization Criteria
    B. Utilization of ADHD and Narcolepsy Medications
    C. Prior Authorization of ADHD and Narcolepsy Medications

D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of ADHD and Narcolepsy Medications

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

12. Action Item – Annual Review of Phenylketonuria (PKU) Medications – See Appendix J

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

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

13. Action Item – Annual Review of Ileal Bile Acid Transporter (IBAT) Inhibitors – See Appendix K

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

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

14. Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Augtyro™ (Repotrectinib) – See Appendix L

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

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

15. Annual Review of Anti-Diabetic Medications and 30-Day Notice to Prior Authorize Inpefa® (Sotagliflozin), Glipizide 2.5mg Tablet, Lantidra™ (Donislecel-jujn), Metformin 625mg Tablet, Zituvio™ (Sitagliptin), and Zituvimet™ (Sitagliptin/Metformin) – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of Anti-Diabetic Medications
C. Prior Authorization of Anti-Diabetic Medications
D. Market News and Updates
E. Product Summaries

F. College of Pharmacy Recommendations
G. Utilization Details of Anti-Diabetic Medications

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

16. Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Izervay™ (Avacincaptad Pegol) – See Appendix N

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

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

17. Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize PrevPak® (Lansoprazole/Amoxicillin/Clarithromycin), Voquenza® (Vonoprazan), Voquenza® Dual Pak® (Vonoprazan/Amoxicillin), Voquenza® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin) – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of Anti-Ulcer Medications
C. Prior Authorization of Anti-Ulcer Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Anti-Ulcer Medications

Items to be presented by Dr. Morgan, Dr. Muchmore, Chairman:

18. Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Rezzayo™ (Rezafungin) – See Appendix P

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

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

19. Annual Review of Filspari™ (Sparsentan) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Filspari™ (Sparsentan)
C. Prior Authorization of Filspari™ (Sparsentan)
D. Market News and Updates

E. College of Pharmacy Recommendations
F. Utilization Details of Filspari™ (Sparsentan)

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

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

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

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

No DUR Board meeting scheduled for May 2024.

A. Amyotropic Lateral Sclerosis (ALS) Medications
B. Annual Review of the SoonerCare Pharmacy Benefit
C. Atypical Antipsychotic Medications
D. Various Special Formulations

*Future product and class reviews subject to change.

22. 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.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING MARCH 13, 2024

DUR BOARD MEMBERS:	PRESENT	ABSENT
Kenneth Foster, MHS, PA-C	X	
Megan A. Hanner, D.O.	X	
Bret Haymore, M.D.	X	
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.		X
Edna Patatanian, Pharm.D., FASHP; Interim Vice Chairwoman	X	
Vineetha Thomas, Pharm.D., BCOP	X	
Beth Walton, Pharm.D.	X	
Cindy West, D.O., FAAP		X

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Mattie Morgan, Pharm.D.; Pharmacy Resident	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: Tad Autry Pharm.D., BCPS, BCOP		X
Brooke Daugherty, Pharm. D., BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.	X	
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.		X
Visiting Pharmacy Student(s): Sharon Thomson, Mason Hooper	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Josh Holloway, J.D.; Deputy General Counsel		X
Traylor Rains; State Medicaid Director		X

Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X
Rhiannon Wheeler-Sisk, J.D.; Deputy General Counsel IV	X	

OTHERS PRESENT:	
Jennifer Golwyn, Ascendis Pharma	Rema Thyagarajan, Genentech
Paul Miner, Ascendis Pharma	Lindsey Baker, Genentech
Irene Chung, Aetna	Paul Isikwe, Biogen
Bob Atkins, Biogen	Brent Parker, Merck
Deidra Williams, Humana	Amanda Nowakowski, ViiV
Gustavo Rodriguez, Pfizer	Kristen Winters, Centene
David Prather, Novo Nordisk	Ervin Wilson, Novo Nordisk
Bryan Steffan, Boehringer	Lori Howarth, Bayer
John King, AbbVie	Rhonda Clark Indivior
Melissa Abbott, Eisai	Paul Ford, Johnson and Johnson
Frank Alvarado, Johnson and Johnson	Gina Heinen, Novo Nordisk
Joanna Janota, Verrica	Brian Wesley, OU Health
Jay Milton, Bayer	Todd Dickerson, Jazz Pharmaceuticals
Michael Faithe, Jazz Pharmaceuticals	Saurabh Patel, AbbVie
Brielle Dozier, Artia Solutions	Mark Friederich, D2 Solutions
Aaron Austin, Takeda	Melanie Kitto, BioCryst
Amy Breen, Teva Pharmaceuticals	Stacey Hale, OU Health
Dave Miley, Teva Pharmaceuticals	Jacqueline Thatcher, OU Health

PRESENT FOR PUBLIC COMMENT:	
Paul Isikwe, Biogen	Rema Thyagarajan, Genentech
Paul Miner, Ascendis Pharma	Gustavo Rodriguez, Pfizer

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 9 PAUL ISIKWE
2B: AGENDA ITEM NO. 12 REMA THYAGARAJAN
2C: AGENDA ITEM NO. 13 PAUL MINER
2D: AGENDA ITEM NO. 13 GUSTAVO RODRIGUEZ

ACTION: NONE REQUIRED

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

3A: FEBRUARY 14, 2024 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore
Mr. Foster moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SPRING 2024 PIPELINE UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR FEBRUARY 2024
4B: MEDICATION COVERAGE ACTIVITY FOR FEBRUARY 2024
4C: SPRING 2024 PIPELINE UPDATE

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE RIZAFILM® (RIZATRIPTAN FILM) AND ZAVZPRET™ (ZAVEGEPANT NASAL SPRAY) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-MIGRAINE MEDICATIONS**

5A: MARKET NEWS AND UPDATES
5B: PRODUCT SUMMARIES
5C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss
Mr. Foster moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE ALINIA® (NITAZOXANIDE TABLET) AND XDEMVY™ (LOTILANER OPHTHALMIC SOLUTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-PARASITIC MEDICATIONS**

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

Materials included in agenda packet; presented by Dr. Wilson
Dr. Walton moved to approve; seconded by Dr. Muñoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE YCANTH™ (CANTHARIDIN) AND ZELSUVMI™ (BERDAZIMER)**

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

Materials included in agenda packet; presented by Dr. Morgan
Mr. Foster moved to approve; seconded by Dr. Thomas

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE VANFLYTA® (QUIZARTINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE LEUKEMIA MEDICATIONS**

8A: MARKET NEWS AND UPDATES
8B: VANFLYTA® (QUIZARTINIB) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Sinko
Dr. Haymore moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF SKYCLARYS™ (OMAVELOXOLONE)**

9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF SKYCLARYS™ (OMAVELOXOLONE)
9C: PRIOR AUTHORIZATION OF SKYCLARYS™ (OMAVELOXOLONE)
9D: MARKET NEWS AND UPDATES
9E: COLLEGE OF PHARMACY RECOMMENDATIONS

9F: UTILIZATION DETAILS OF SKYCLARYS™ (OMAVELOXOLONE)
Materials included in agenda packet; presented by Dr. O'Halloran
Mr. Foster moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF VESICULAR MONOAMINE TRANSPORTER 2 (VMAT2) INHIBITOR MEDICATIONS
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF VMAT2 INHIBITOR MEDICATIONS
10C: PRIOR AUTHORIZATION OF VMAT2 INHIBITOR MEDICATIONS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF VMAT2 INHIBITOR MEDICATIONS
Materials included in agenda packet; presented by Dr. Morgan
Dr. Haymore moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF LYMPHOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE COLUMVI™ (GLOFITAMAB-GXBM) AND EPKINLY™ (EPCORITAMAB-BYSP)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF LYMPHOMA MEDICATIONS
11C: PRIOR AUTHORIZATION OF LYMPHOMA MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF LYMPHOMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

AGENDA ITEM NO. 12: ANNUAL REVIEW OF HEMOPHILIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ROCTAVIAN™ (VALOCTOCOGENE ROXAPARVOVEC-RVOX)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF HEMOPHILIA MEDICATIONS
12C: PRIOR AUTHORIZATION OF HEMOPHILIA MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: ROCTAVIAN™ (VALOCTOCOGENE ROXAPAROVEVEC-RVOX) PRODUCT SUMMARY
12F: OKLAHOMA HEALTH CARE AUTHORITY (OHCA) RECOMMENDATIONS
12G: UTILIZATION DETAILS OF HEMOPHILIA MEDICATIONS
Materials included in agenda packet; presented by Dr. Ratterman
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

AGENDA ITEM NO. 13: ANNUAL REVIEW OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE) AND 30-DAY NOTICE TO PRIOR AUTHORIZE NGENLA™ (SOMATROGON-GHLA)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
13C: PRIOR AUTHORIZATION OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
13D: MARKET NEWS AND UPDATES
13E: NGENLA® (SOMATROGON-GHLA) PRODUCT SUMMARY

13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND 30-DAY NOTICE TO PRIOR AUTHORIZE RYZNEUTA® (EFBEMALENOGRASTIM ALFA-VUXW)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF G-CSFS
14C: PRIOR AUTHORIZATION OF G-CSFS
14D: MARKET NEWS AND UPDATES
14E: RYZNEUTA® (EFBEMALENOGRASTIM ALFA-VUXW) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF G-CSFS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF MULTIPLE SCLEROSIS (MS) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE TYRUKO® (NATALIZUMAB-SZTN)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF MS MEDICATIONS
15C: PRIOR AUTHORIZATION OF MS MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF MS MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF STEM CELL MOBILIZERS AND 30-DAY NOTICE TO PRIOR AUTHORIZE APHEXDA™ (MOTIXAFORTIDE)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF STEM CELL MOBILIZERS
16C: PRIOR AUTHORIZATION OF STEM CELL MOBILIZERS
16D: PRIOR AUTHORIZATIONMARKET NEWS AND UPDATES
16E: APHEXDA™ (MOTIXAFORTIDE) PRODUCT SUMMARY
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF STEM CELL MOBILIZERS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN APRIL

<u>AGENDA ITEM NO. 17:</u> U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 18:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
18A: AGE-RELATED MACULAR DEGENERATION (AMD) MEDICATIONS
18B: ANTI-DIABETIC MEDICATIONS
18C: ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS

18D: PHENYLKETONURIA MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: ADJOURNMENT
The meeting was adjourned at 5:45pm.

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

Memorandum

Date: March 15, 2024

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 13, 2024

Recommendation 1: Spring 2024 Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize RizaFilm® (Rizatriptan Film) and Zavzpret® (Zavegepant Nasal Spray) 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 approvals, net costs, and product availability (changes shown in red in the following Tier chart and approval criteria):

1. Adding RizaFilm® (rizatriptan film) and Zavzpret™ (zavegepant nasal spray) to the Special PA Tier with the following additional criteria; and
2. Removing the brand preferred status on dihydroergotamine injection (D.H.E. 45®) and dihydroergotamine nasal spray (Migranal®) and making dihydroergotamine nasal spray (Migranal®) the preferred dihydroergotamine product; and
3. Moving Zomig® (zolmitriptan) nasal spray from Tier-1 to the Special PA Tier and removing the brand preferred status; and
4. Moving naratriptan tablet (Amerge®) and zolmitriptan tablet and ODT (Zomig®, Zomig-ZMT®) from Tier-2 to Tier-1; and

5. Moving frovatriptan tablet (Frova®) from Tier-3 to Tier-2; and
6. Moving sumatriptan/naproxen tablet (Treximet®) from Tier-1 to Tier-3.

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	**frovatriptan tablet (Frova®)**	almotriptan tablet (Axert®)	dihydroergotamine injection (D.H.E. 45®) ~~– Brand Preferred~~
naratriptan tablet (Amerge®)	~~**naratriptan tablet (Amerge®)**~~	~~**frovatriptan tablet (Frova®)**~~	dihydroergotamine nasal spray (Migranal®) – ~~**Brand Preferred**~~
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)	~~**zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)**~~	**sumatriptan/ naproxen tablet (Treximet®)**	dihydroergotamine nasal spray (Trudhesa®)
sumatriptan tablet (Imitrex®)			ergotamine sublingual tablet (Ergomar®)
~~**sumatriptan/ naproxen tablet (Treximet®)**~~			lasmiditan tablet (Reyvow®)
~~**zolmitriptan nasal spray (Zomig® nasal spray) – Brand Preferred**~~			rimegepant ODT (Nurtec® ODT)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			**rizatriptan film (RizaFilm®)**
			sumatriptan injection (Imitrex®)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal powder (Onzetra® Xsail®)
			sumatriptan nasal spray (Imitrex®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zolmitriptan nasal spray (~~**generic**~~ Zomig® nasal spray)

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			zavegepant nasal spray (Zavzpret™)

*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).
ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of ~~brand D.H.E. 45® (dihydroergotamine injection) or brand~~ Migranal® (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications. ~~Brand formulation is preferred for D.H.E. 45® and Migranal®; use of the generic formulations will require a patient-specific, clinically significant reason why the member cannot use the brand formulation and lower-tiered triptan medications.~~
2. Use of D.H.E. 45® (dihydroergotamine injection) or Trudhesa® (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use ~~the brand formulation of D.H.E. 45®;~~ Migranal® (dihydroergotamine nasal spray)~~,~~ and lower-tiered triptan medications.
3. 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.
4. Use of Reyvow® (lasmiditan), ~~or~~ 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
    a. Reyvow®, ~~and~~ Ubrelvy®, and Zavzpret™ will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor.
5. 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 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®, ~~and~~ Ubrelvy®, and Zavzpret™ and; however, Nurtec® ODT will follow the same criteria as Reyvow®, ~~and~~ 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.

6. Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.
7. Use of Zembrace® SymTouch® (sumatriptan injection) or Tosymra® (sumatriptan nasal spray) 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 ~~generic~~ any non-oral zolmitriptan formulation ~~nasal spray~~ will require a patient-specific, clinically significant reason why the member cannot use the ~~brand formulation of Zomig® nasal spray (brand formulation is preferred) and~~ oral tablet formulation and lower-tiered triptan medications.
9. Use of RizaFilm® (rizatriptan film) will require a patient-specific, clinically significant reason why the member cannot use the ODT formulation and lower-tiered triptan medications.

Additionally, the College of Pharmacy recommends updating the Nurtec® ODT (rimegepant), Qulipta® (atogepant), and Vyepti® (eptinezumab-jjmr) approval criteria based on the new FDA approved indication for Qulipta® and to be in line with current guideline recommendations (changes shown in red):

Nurtec® ODT (Rimegepant)*, Qulipta® (Atogepant)*, and Vyepti® (Eptinezumab-jjmr) Approval Criteria:

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
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; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT ~~and Qulipta® are~~ is only FDA approved for the preventive treatment of episodic migraines.); and
        i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and

4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. ~~Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:~~
   a. ~~Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); or~~
   b. ~~Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and~~
6. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
   a. Hormone replacement therapy or hormone-based contraceptives; and
   b. Chronic insomnia; and
   c. Obstructive sleep apnea; and
7. The member has failed medical migraine preventive therapy with at least 3 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. This includes, but is not limited to:
   a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
   b. Select anticonvulsant therapy; or
   c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
8. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
   a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and
   d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
   e. Ergotamine-containing medications (≥10 days/month for >3 months); and
   d. Triptans (≥10 days/month for >3 months); and
9. Member is not taking any medications that are likely to be the cause of the headaches; and
10. ~~Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g.,~~

~~Nurtec® ODT, Qulipta®, Vyepti®) recommended as treatment (not necessarily prescribed by a neurologist); and~~

11. 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
12. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
13. For Vyepti®, prescriber must verify the medication will be prepared and administered according the Vyepti® package labeling; and
14. A patient-specific, clinically significant reason why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), or Emgality® (galcanezumab-gnlm) must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement); and
15. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
16. 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
17. Quantity limits will apply based on FDA-approved dosing:
    a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
    b. For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and
    c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Finally, the College of Pharmacy recommends updating the Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), and Emgality® (galcanezumab-gnlm) approval criteria to be in line with current guideline recommendations (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
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; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and

i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and

4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. ~~Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:~~
   a. ~~Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); or~~
   b. ~~Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and~~
6. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
   a. Hormone replacement therapy or hormone-based contraceptives; and
   b. Chronic insomnia; and
   c. Obstructive sleep apnea; and
7. The member has failed medical migraine preventive therapy with at least 2¥ agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. [¥The manufacturers of Ajovy® and Emgality® have currently provided a supplemental rebate to be the preferred calcitonin gene-related peptide (CGRP) inhibitor(s) and require a trial with 2 other migraine preventative therapies; however, Ajovy® and Emgality® will follow the original criteria and require trials with 3 other migraine preventative therapies if the manufacturers choose not to participate in supplemental rebates.] This includes, but is not limited to:
   a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
   b. Select anticonvulsant therapy; or
   c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
8. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
   a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and

d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
e. Ergotamine-containing medications (≥10 days/month for >3 months); and
f. Triptans (≥10 days/month for >3 months); and

9. Member is not taking any medications that are likely to be the cause of the headaches; and
10. ~~Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g., Aimovig®, Ajovy®, Emgality®) recommended as treatment (not necessarily prescribed by a neurologist); and~~
11. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative CGRP inhibitor; and
12. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
13. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
14. 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
15. 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 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.

Emgality® (Galcanezumab-gnlm) Approval Criteria [Episodic Cluster Headache Diagnosis]:

1. An FDA approved indication for the treatment of episodic cluster headache in adults; and
2. Member must be 18 years of age or older; and
3. Member has a diagnosis of episodic cluster headache as defined by the International Headache Society (IHS) International Classification of Headache Disorders (ICHD) guideline and meets the following criteria:

a. Member has a history of episodic cluster headache with at least 2 cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥~~1~~ 3 months; and

4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
   a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and
   d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
   e. Ergotamine-containing medications (≥10 days/month for >3 months); and
   f. Triptans (≥10 days/month for >3 months); and
6. Member has failed prophylactic therapy with at least 1 other medication (e.g., verapamil, select anticonvulsants, corticosteroids); and
7. ~~Member must have been evaluated within the last 6 months by a neurologist for cluster headaches and the requested medication (e.g., Emgality®) recommended as treatment (not necessarily prescribed by a neurologist); and~~
8. Member will not use Emgality® concurrently with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
9. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
10. Initial approvals will be for the duration of 3 months. Continuation approvals will be granted until the end of the cluster period if the prescriber documents that the member is responding well to treatment as indicated by a reduction in cluster headache attack frequency; and
11. A quantity limit of (3) 100mg/mL syringes per 30 days will apply.

Recommendation 3: Vote to Prior Authorize Alinia® (Nitazoxanide Tablet) and Xdemvy™ (Lotilaner Ophthalmic Solution) and Update the Approval Criteria for the Anti-Parasitic Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Alinia® (nitazoxanide tablet) and Xdemvy™ (lotilaner ophthalmic solution) with the following criteria (shown in red):

Alinia® (Nitazoxanide Tablet) Approval Criteria:

1. An FDA approved indication for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum; and*
2. Member must be 12 years of age or older; and
3. For *Giardia*, member must have a recent trial of metronidazole or tinidazole or a patient-specific, clinically significant reason why the member cannot use metronidazole and tinidazole must be provided; and
4. A quantity limit of 6 tablets per 3 days will apply.

Xdemvy™ (Lotilaner Ophthalmic Solution) Approval Criteria:

1. An FDA approved diagnosis of *Demodex* blepharitis; and
2. Member must be 18 years or older; and
3. Must be prescribed by an ophthalmologist or optometrist; and
4. Member must meet all of the following in at least 1 eye:
    a. >10 lashes with collarettes present on the upper lid; and
    b. Presence of at least mild erythema of the upper eyelid margin; and
5. Member must agree to remove artificial eyelashes (if present) and forego their use during treatment with Xdemvy™; and
6. A quantity limit of 10mL per 42 days will apply. Approvals will be limited to 1 treatment course per year.

Additionally, the College of Pharmacy recommends updating the Daraprim® (pyrimethamine) approval criteria based the current FDA approved indications and to be in line with guideline-recommended use in patients with human immunodeficiency virus (HIV) (changes shown in red):

Daraprim® (Pyrimethamine) Approval Criteria:

1. An ~~FDA approved~~ indication ~~for the treatment~~ of 1 of the following:
    a. Treatment of toxoplasmosis; or
    ~~b. Susceptible strains of acute malaria; and~~
    c. Prophylaxis of *Toxoplasma gondii* encephalitis in members with human immunodeficiency virus (HIV); and
        i. Member is *Toxoplasma* IgG seropositive; and
        ii. CD4 count is <100 cells/mm^3 (or <200 cells/mm^3 for secondary prophylaxis); and

iii. A patient-specific, clinically significant reason why trimethoprim/sulfamethoxazole cannot be used must be provided; and

2. Member must take Daraprim® concomitantly with a sulfonamide (for treatment of toxoplasmosis) or with a guideline-recommended regimen (for *Toxoplasma* prophylaxis); and
3. Approval length will be based on recommended dosing regimen specific to the member's diagnosis.

Recommendation 4: Vote to Prior Authorize Ycanth™ (Cantharidin 0.7% Solution) and Zelsuvmi™ (Berdazimer 10.3% Gel)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Ycanth™ (cantharidin 0.7% solution) and Zelsuvmi™ (berdazimer 10.3% gel) with the following criteria (shown in red):

Ycanth™ (Cantharidin 0.7% Solution) Approval Criteria:

1. An FDA approved indication for the treatment of molluscum contagiosum lesions; and
2. Member must be 2 years of age or older; and
3. Member must meet 1 of the following:
   a. Is immunocompromised; or
   b. Is experiencing itching or pain; or
   c. Has concomitant bacterial infection; or
   d. Has concomitant atopic dermatitis; or
   e. There is concern for contagion (e.g., siblings, daycare) and the spread of lesions cannot be reasonably prevented using good hygiene or covered using a bandage; and
4. Prescriber must attest that it has been at least 6 months since the onset of the current infection unless the member is experiencing severe symptoms; and
5. Member must have a trial of at least 1 of the following procedures or medications for the removal of molluscum contagiosum lesions in the last 6 months:
   a. Cryotherapy; or
   b. Curettage; or
   c. Laser therapy; or
   d. Cimetidine; or
   e. Potassium hydroxide; or
   f. Salicylic acid; and
6. Member must not have lesions exclusively on genitals or around eyes; and
7. Ycanth™ must be administered by a health care professional (HCP) trained in the administration of Ycanth™. Approvals will not be granted

for self-administration. Requests must indicate who will administer Ycanth™ and in what setting; and
8. Prescriber must attest that the member or caregiver has been counseled to wash off lesions treated with Ycanth™ with soap and water 24 hours after application and to avoid skin contact with water, including bathing, prior to the 24-hour mark; and
9. Prescriber must attest that the member or caregiver has been counseled on all precautions prior to and during treatment with Ycanth™ that are listed in the package labeling, including avoiding contact with the eyes and mouth and avoiding close contact with open flames, even after the medication has dried; and
10. Approvals will be for a maximum of 12 weeks of therapy; and
11. A quantity limit of 2 applicators every 3 weeks for a maximum of 4 applications will apply; and
12. Reauthorization is not permitted. A new prior authorization request must be submitted, and the member must meet all initial approval criteria for each molluscum contagiosum infection.

Zelsuvmi™ (Berdazimer 10.3% Gel) Approval Criteria:

1. An FDA approved indication for the treatment of molluscum contagiosum lesions; and
2. Member must be 1 year of age or older; and
3. Member must meet 1 of the following:
    a. Is immunocompromised; or
    b. Is experiencing itching or pain; or
    c. Has concomitant bacterial infection; or
    d. Has concomitant atopic dermatitis; or
    e. There is concern for contagion (e.g., siblings, daycare) and the spread of lesions cannot be reasonably prevented using good hygiene or covered using a bandage;
4. Prescriber must attest that it has been at least 6 months since the onset of the current infection unless the member is experiencing severe symptoms; and
5. Member must have a trial of at least 1 of the following procedures or medications for the removal of molluscum contagiosum lesions in the last 6 months:
    a. Cryotherapy; or
    b. Curettage; or
    c. Laser therapy; or
    d. Cimetidine; or
    e. Potassium hydroxide; or
    f. Salicylic acid; and
6. Member must not have lesions exclusively on genitals or around eyes; and

7. Prescriber must attest that the member or caregiver has been counseled on and demonstrates understanding of the proper storage and preparation of Zelsuvmi™; and
8. Prescriber must attest that the member or caregiver has been counseled on and has demonstrated understanding of the proper administration of Zelsuvmi™, including the medication's drying time and avoiding contact with the eyes, mouth, and genital areas; and
9. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Ycanth™ (cantharidin) must be provided; and
10. Approvals will be for a maximum of 12 weeks of therapy; and
11. A quantity limit of 1 carton (14-gram tube of Zelsuvmi™ and 17 gram tube of hydrogel) every 30 days for a maximum of 3 cartons will apply; and
12. Reauthorization is not permitted. A new prior authorization request must be submitted, and the member must meet all initial approval criteria for each molluscum contagiosum infection.

Recommendation 5: Vote to Prior Authorize Vanflyta® (Quizartinib) and Update the Approval Criteria for the Leukemia Medications

MOTION CARRIED by unanimous approval.

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

Vanflyta® (Quizartinib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
2. Disease is positive for FLT3 internal tandem duplication (FLT3-ITD) as detected by an FDA-approved test; and
3. Will be used in 1 of the following settings:
   a. In combination with standard anthracycline and cytarabine-based induction; or
   b. In combination with standard cytarabine-based consolidation; or
   c. As maintenance therapy following standard anthracycline and cytarabine-based induction and cytarabine-based consolidation.

Additionally, the College of Pharmacy recommends updating the prior authorization criteria for Gazyva® (obinutuzumab) and Tibsovo® (ivosidenib) based on recent FDA approval, to be consistent with the FDA approved dosing for Calquence® (acalabrutinib) and Columvi™ (glofitamab-gxbm), and based on National Comprehensive Cancer Network (NCCN) recommendations (changes shown in red):

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

1. As a single agent in relapsed/refractory disease; or
2. In combination with acalabrutinib, bendamustine, chlorambucil, ibrutinib, or venetoclax for first-line therapy; and
3. When obinutuzumab is used in combination with venetoclax, maximum approval duration of obinutuzumab will be 6 treatment cycles.

Gazyva® (Obinutuzumab) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed or refractory DLBCL not otherwise specified, including large B-cell lymphoma (LBCL) arising from follicular lymphoma; and
2. Used as lymphoid depletion pretreatment prior to glofitamab; and
3. Member must meet criteria for glofitamab; and
4. Dosing will be 1,000mg as a single dose 7 days prior to start of glofitamab.

Gazyva® (Obinutuzumab) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Grade 1 or 2 members with Stage I (≥7cm), contiguous Stage II (≥7cm), noncontiguous Stage II, Stage III, or Stage IV members (first, second, or subsequent therapy); and
    a. In combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), cyclophosphamide, vincristine, and prednisone (CVP), or bendamustine; and
    b. When used for maintenance therapy, a total of 12 doses will be approved; or
2. Third line or subsequent therapy for FL in members with no response, relapsed, or progressive disease; and
    a. Used in combination with zanubrutinib.

Tibsovo® (Ivosidenib) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of relapsed or refractory MDS; and
2. Presence of isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test.

Next, the College of Pharmacy recommends updating the prior authorization criteria for Asparlas® (calaspargase pegol-mknl) and Oncaspar® (pegaspargase) for a diagnosis of ALL to be more consistent with the FDA-approved labeling for these medications (changes shown in red):

Asparlas® (Calaspargase Pegol-mknl) and Oncaspar® (Pegaspargase) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of ALL; and

2. Used as a component of multi-agent chemotherapy; and
~~3. Used as first line therapy; or~~
~~4. May be used to treat members with a hypersensitivity to native forms of L-asparaginase; or~~
~~5. Used as systemic central nervous system (CNS)-directed therapy; or~~
~~6. Used in relapsed/refractory disease; and~~
   ~~a. Philadelphia chromosome negative (Ph-); or~~
   ~~b. Philadelphia chromosome positive (Ph+); and~~
      ~~i. Refractory to tyrosine kinase inhibitor (TKI) therapy or used in conjunction with a TKI (if not previously used); and~~
7. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
8. For Asparlas®, member must be 1 month to 21 years of age.

The College of Pharmacy also recommends updating the prior authorization criteria for Erwinase® (crisantaspase), Erwinaze® (asparaginase *Erwinia chrysanthemi*), and Rylaze® [asparaginase *Erwinia chrysanthemi* (recombinant)-rywn] based on current product availability in the United States (changes shown in red):

~~Erwinase® (Crisantaspase), Erwinaze® (Asparaginase *Erwinia Chrysanthemi*), and~~ Rylaze® [Asparaginase *Erwinia Chrysanthemi* (Recombinant)-rywn] Approval Criteria [Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma Diagnosis]:

1. Diagnosis of ALL or lymphoblastic lymphoma; and
2. Used as a component of multi-agent chemotherapy; and
3. Member has a documented hypersensitivity to *Escherichia coli*-derived ~~asparaginase~~ asparagine-deprivation product.

The College of Pharmacy also recommends updating the approval criteria for Imbruvica® (ibrutinib) based on NCCN recommendations (changes shown in red)

Imbruvica® (Ibrutinib) Approval Criteria [~~Histologic Transformation of Marginal Zone Lymphoma (MZL) to Diffuse Large B-Cell Lymphoma (DLBCL)~~ B-Cell Lymphomas Diagnosis]:

1. As ~~third~~ second-line or ~~greater~~ subsequent therapy for members ~~who have transformed to non-germinal center DLBCL~~ with a 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].

Imbruvica® (Ibrutinib) Approval Criteria [Hairy Cell Leukemia Diagnosis]:

1. Diagnosis of hairy cell leukemia; and
2. As third-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As second-line or subsequent therapy; ~~and~~ or
2. ~~As a single agent or in combination with rituximab or lenalidomide/rituximab~~
3. Used in combination with rituximab prior to induction therapy; or
4. Used as a component of aggressive induction therapy; or
5. Used as maintenance therapy following aggressive induction therapy or hematopoietic stem cell transplant (HSCT).

Imbruvica® (Ibrutinib) Approval Criteria [Primary Central Nervous System (CNS) Lymphoma Diagnosis]:

1. Diagnosis of primary CNS lymphoma; and
2. Member is not a candidate for or is intolerant to high-dose methotrexate according to the prescriber; or
3. As second-line or subsequent therapy for refractory or progressive disease.

Lastly, the College of Pharmacy recommends adding additional approval criteria for all oncology medication categories to clarify the typical approval duration and the requirement for oncology specialist review (new criteria shown in red):

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.

Recommendation 6: Calendar Year 2023 Annual Review of Skyclarys® (Omaveloxolone)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the current Skyclarys® (omaveloxolone) approval criteria to be consistent with clinical practice (changes shown in red):

Skyclarys® (Omaveloxolone) Approval Criteria:

1. An FDA approved diagnosis of Friedrich's ataxia (FRDA); and
   a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants ~~a mutation~~ in the *FXN* gene (results of genetic testing must be submitted); and
2. Member must be 16 years of age or older; and
3. Skyclarys® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Member must have a left ventricular ejection fraction of ≥40%; and
5. Member must not be taking concomitant strong or moderate CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) or the prescriber must verify the dose of Skyclarys® will be adjusted during concomitant use according to package labeling; and
6. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and
7. Member must not have severe hepatic impairment (Child-Pugh class C); and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Skyclarys® treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
9. Prescriber must verify that B-type natriuretic peptide (BNP) will be assessed prior to initiation of Skyclarys® and cardiac function will be monitored as clinically indicated; and
10. Prescriber must verify lipid parameters will be monitored prior to initiation of Skyclarys® treatment and periodically thereafter or as clinically indicated; and
11. Female members must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective non-hormonal contraception during therapy and for 28 days after discontinuation of therapy; and
12. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by slower disease progression and/or other documentation of a positive clinical response to therapy; and

13. A quantity limit of 90 capsules per 30 days will apply.

Recommendation 7: Calendar Year 2023 Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Ingrezza® (valbenazine) approval criteria based on the new FDA approved indication (changes shown in red):

Ingrezza® (Valbenazine) Approval Criteria [Huntington's Disease Diagnosis]:

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
5. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting valbenazine therapy and throughout treatment; and
6. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
7. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
8. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
9. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
10. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
11. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
12. Member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
13. Female members must not be pregnant or breastfeeding; and
14. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
15. A quantity limit of 1 capsule per day will apply; and
16. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea

have decreased, and the member is not showing worsening signs of depression.

Ingrezza® (Valbenazine) Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
   a. Involuntary athetoid or choreiform movements; and
   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist, or a mid-level practitioner with a supervising physician that is a neurologist or psychiatrist; and
4. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
6. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
7. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
8. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
9. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
10. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
14. A quantity limit of 1 capsule per day will apply; and
15. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

The College of Pharmacy also recommends the following changes to the approval criteria for Xenazine® (tetrabenazine) to be consistent with the other VMAT2 inhibitor medications (changes shown in red):

Xenazine® (Tetrabenazine) Approval Criteria:

1. Diagnosis of 1 of the following:
   a. Chorea associated with Huntington's disease; or
   b. Tardive dyskinesia; or
   c. Tourette syndrome; and
2. Xenazine® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
3. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Xenazine® therapy and throughout treatment; and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., deutetrabenazine, valbenazine) concurrently with Xenazine®; and
8. Member must not be taking medications that are known to prolong the QTc interval concomitantly with Xenazine® [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval]; and
9. Members who require doses of tetrabenazine greater than 50mg per day must be tested and genotyped to determine if they are poor metabolizers (PMs), intermediate metabolizers (IMs), or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The following dose limits will apply based on the member's metabolizer status:
   a. Extensive and Intermediate CYP2D6 Metabolizers: 100mg divided daily; or
   b. Poor CYP2D6 Metabolizers: 50mg divided daily; and
10. The daily dose of Xenazine® must not exceed 50mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion); and
11. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea, tardive dyskinesia, or Tourette syndrome have decreased, and the member is not showing worsening signs of depression.

Recommendation 8: Calendar Year 2023 Annual Review of Lymphoma Medications and 30-Day Notice to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2024.

Recommendation 9: Calendar Year 2023 Annual Review of Hemophilia Medications and 30-Day Notice to Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2024.

Recommendation 10: Calendar Year 2023 Annual Review of Growth Hormone Products and Voxzogo® (Vosoritide) and 30-Day Notice to Prior Authorize Ngenla® (Somatrogon-ghla)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2024.

Recommendation 11: Calendar Year 2023 Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Ryzneuta® (Efbemalenograstim Alfa-vuxw)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2024.

Recommendation 12: Calendar Year 2023 Annual Review of Multiple Sclerosis (MS) Medications and 30-Day Notice to Prior Authorize Tyruko® (Natalizumab-sztn)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2024.

Recommendation 13: Calendar Year 2023 Annual Review of Stem Cell Mobilizers and 30-Day Notice to Prior Authorize Aphexda® (Motixafortide)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2024.

Recommendation 14: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

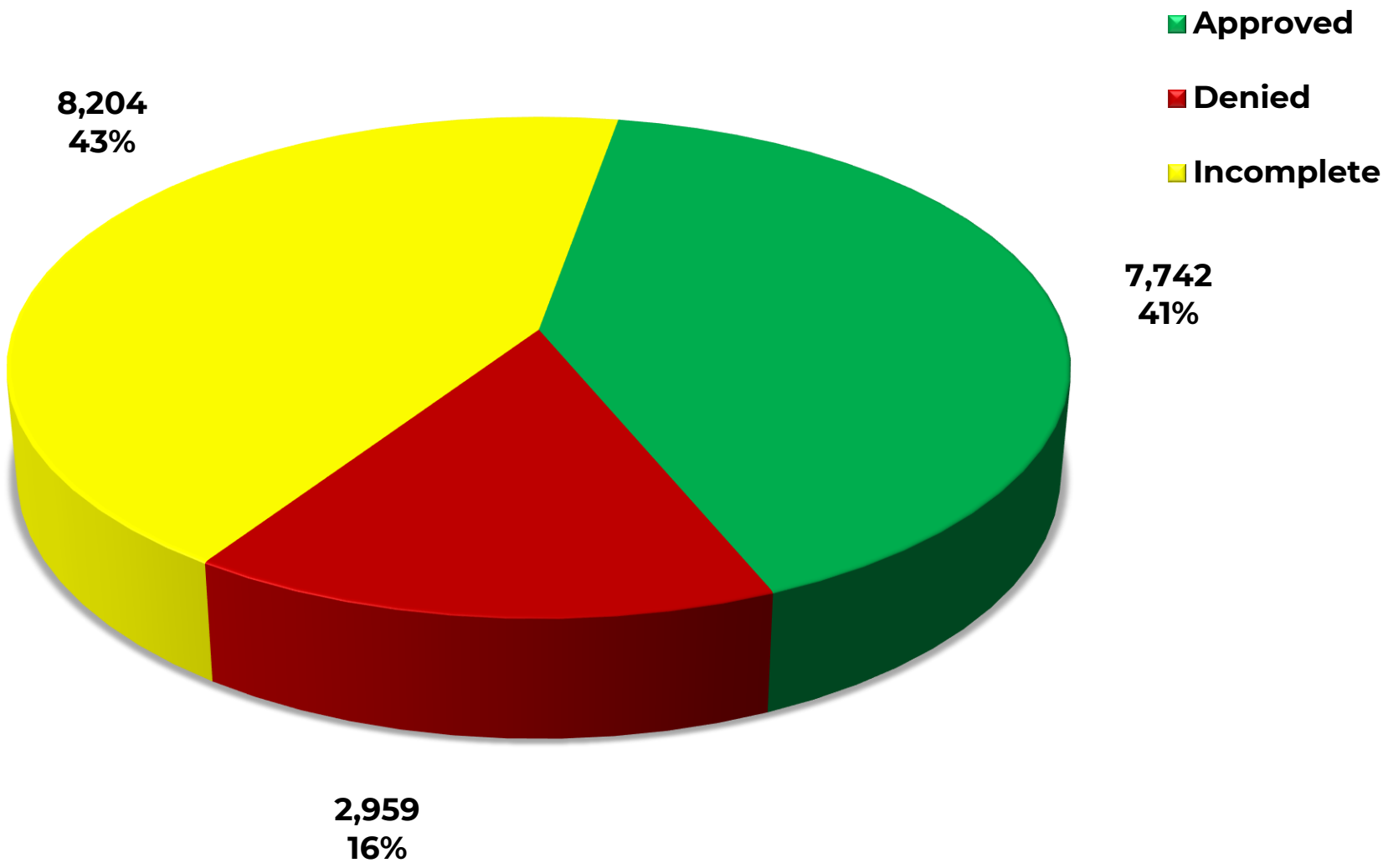
NO ACTION REQUIRED.

Recommendation 15: Future Business

NO ACTION REQUIRED.

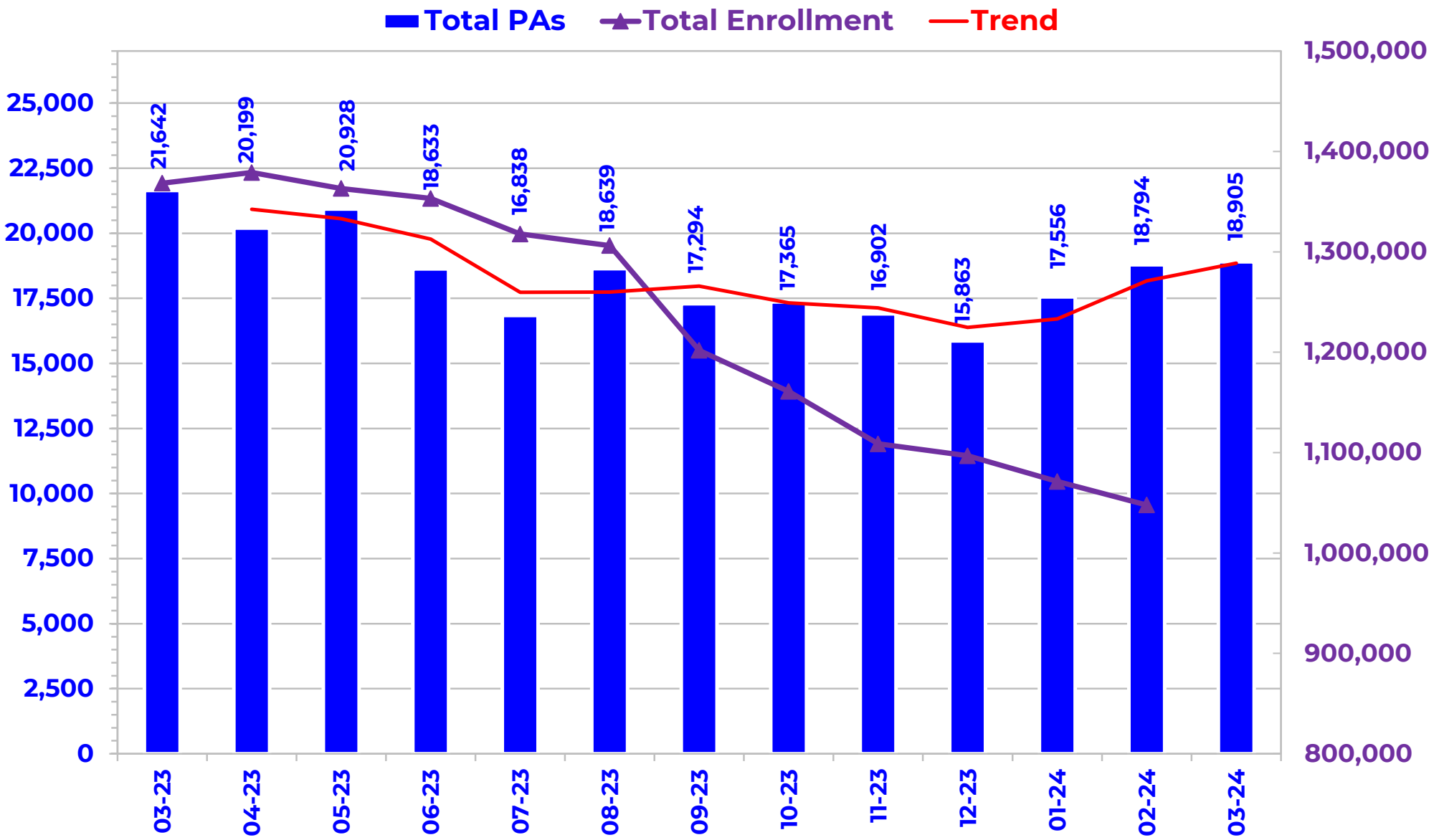
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MARCH 2024



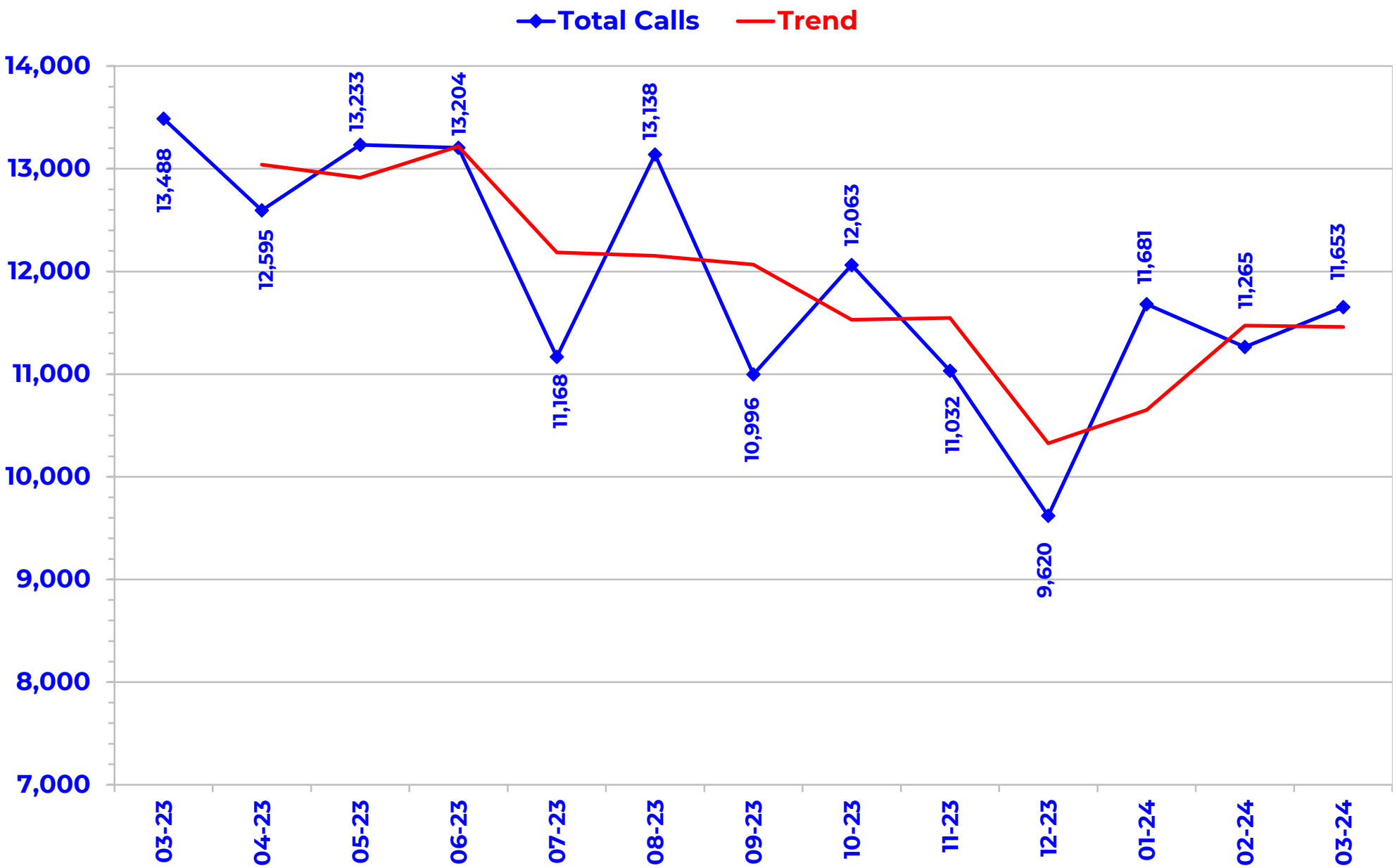
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: MARCH 2023 – MARCH 2024



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: MARCH 2023 – MARCH 2024



Prior Authorization Activity

3/1/2024 Through 3/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	279	57	26	196	355
Analgesic - NonNarcotic	15	0	3	12	0
Analgesic, Narcotic	467	216	28	223	132
Anti-inflammatory	10	5	2	3	361
Antiasthma	165	61	39	65	248
Antibiotic	46	15	5	26	209
Anticonvulsant	288	114	28	146	339
Antidepressant	500	130	84	286	273
Antidiabetic	2,744	762	716	1,266	354
Antigout	15	4	2	9	314
Antihemophilic Factor	16	9	1	6	320
Antihistamine	61	15	21	25	323
Antimigraine	766	155	292	319	248
Antineoplastic	298	212	15	71	180
Antiobesity	48	1	41	6	359
Antiparasitic	37	12	3	22	16
Antiparkinsons	17	3	4	10	268
Antiulcers	91	18	13	60	116
Antiviral	14	3	0	11	72
Anxiolytic	50	4	3	43	313
Atypical Antipsychotics	707	247	76	384	349
Benign Prostatic Hypertrophy	10	0	4	6	0
Biologics	603	304	74	225	319
Bladder Control	130	17	51	62	327
Blood Thinners	53	5	5	43	360
Botox	91	54	32	5	341
Buprenorphine Medications	113	24	15	74	163
Calcium Channel Blockers	26	5	4	17	359
Cardiovascular	195	86	14	95	329
Chronic Obstructive Pulmonary Disease	475	90	102	283	352
Constipation/Diarrhea Medications	399	80	118	201	249
Contraceptive	71	17	5	49	320
Corticosteroid	28	4	6	18	193
Dermatological	802	246	215	341	231
Diabetic Supplies	571	223	91	257	214
Endocrine & Metabolic Drugs	149	45	20	84	258
Erythropoietin Stimulating Agents	26	18	1	7	106
Estrogen Derivative	32	4	2	26	356
Fibric Acid Derivatives	14	1	2	11	361
Fibromyalgia	18	3	4	11	360

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Fish Oils	28	7	4	17	360
Gastrointestinal Agents	208	47	43	118	222
Genitourinary Agents	24	1	7	16	360
Glaucoma	30	7	4	19	202
Gonadotropin-releasing Hormone Agonist	13	9	0	4	338
Growth Hormones	131	101	13	17	144
Hematopoietic Agents	39	19	2	18	233
Hepatitis C	32	13	4	15	9
HFA Rescue Inhalers	66	1	2	63	358
Insomnia	155	14	31	110	242
Insulin	487	171	39	277	351
Miscellaneous Antibiotics	44	9	6	29	86
Multiple Sclerosis	113	65	11	37	261
Muscle Relaxant	77	11	10	56	138
Nasal Allergy	71	6	25	40	238
Neurological Agents	220	71	44	105	206
Neuromuscular Agents	35	15	7	13	335
NSAIDs	34	6	2	26	360
Ocular Allergy	12	1	3	8	20
Ophthalmic	25	5	5	15	301
Ophthalmic Anti-infectives	24	8	2	14	69
Ophthalmic Corticosteroid	16	1	2	13	20
Osteoporosis	37	21	7	9	350
Other*	490	164	72	254	283
Otic Antibiotic	17	1	3	13	8
Pediculicide	16	1	0	15	24
Respiratory Agents	40	26	2	12	327
Statins	95	24	32	39	180
Stimulant	2,880	1,666	122	1,092	348
Testosterone	220	40	61	119	344
Thyroid	32	11	3	18	339
Topical Antibiotic	12	0	3	9	0
Topical Antifungal	81	8	20	53	106
Topical Corticosteroids	48	0	18	30	0
Vitamin	160	20	105	35	180
Pharmacotherapy	73	64	2	7	276
Emergency PAs	0	0	0	0	
Total	**16,525**	**5,903**	**2,883**	**7,739**	

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	40	25	1	14	155
Compound	9	8	0	1	24
Diabetic Supplies	8	8	0	0	116
Dosage Change	405	380	1	24	17
High Dose	1	1	0	0	358
Ingredient Duplication	9	8	0	1	57
Lost/Broken Rx	104	95	2	7	21
MAT Override	266	237	2	27	86
NDC vs Age	326	226	33	67	274
NDC vs Sex	41	37	0	4	318
Nursing Home Issue	82	75	0	7	16
Opioid MME Limit	117	43	3	71	124
Opioid Quantity	22	19	0	3	150
Other	60	41	10	9	21
Quantity vs Days Supply	751	540	21	190	244
STBS/STBSM	13	9	0	4	66
Step Therapy Exception	20	12	1	7	257
Stolen	21	17	0	4	35
Third Brand Request	84	57	2	25	15
Wrong D.S. on Previous Rx	1	1	0	0	19
Overrides Total	**2,380**	**1,839**	**76**	**465**	
Total Regular PAs + Overrides	**18,905**	**7,742**	**2,959**	**8,204**	

Denial Reasons	
Unable to verify required trials.	6,852
Does not meet established criteria.	2,979
Lack required information to process request.	1,444
Other PA Activity	
Duplicate Requests	2,038
Letters	52,705
No Process	3
Changes to existing PAs	1,243
Helpdesk Initiated Prior Authorizations	1,063
PAs Missing Information	945

* Includes any therapeutic category with less than 10 prior authorizations for the month.

SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

Oklahoma Health Care Authority
April 2024

SoonerPsych Prescriber Mailing Summary

The SoonerPsych program is an educational quarterly mailing to prescribers of atypical antipsychotic (AAP) medications. Each mailing includes a gauge showing prescribers 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 are comprised of 4 modules: adherence, diagnosis, metabolic monitoring, and poly-pharmacy as defined below.

The SoonerPsych program has been using a "report card" format since April 2014. Beginning in April 2016, educational letters were sent to a consistent cohort of prescribers with all modules included in each mailing. The mailing cohort list is 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. The mailing list was last updated in January 2022, and inclusion criteria required the prescriber to have at least 4 SoonerCare members taking AAP medications.

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 following list defines the terms used for prescriber comparison within each module of the current SoonerPsych mailing:

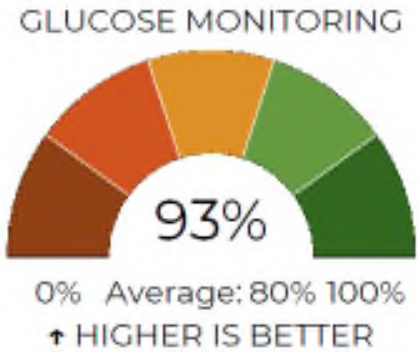
- **Medication Adherence:** Members are considered adherent when their proportion of days covered (PDC), as calculated from pharmacy claims history for AAP medications, is ≥80%. The prescriber adherence gauge shows the percentage of members receiving AAP medications who are adherent during the most recent 12-month period.
- **Target Diagnosis:** Diagnoses with a strong indication for prescribing an AAP 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 AAP medications who had ≥1 medical claim for one of the above diagnoses within the most recent 12-month period.

- **Metabolic Monitoring:** Metabolic monitoring includes both lipid and glucose monitoring. Lipid monitoring is recommended for members receiving AAP medications and with a diagnosis of hyperlipidemia. Glucose monitoring is recommended for all members receiving AAP medications. The prescriber metabolic monitoring gauges show the percentage of members receiving AAP 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 AAP medications for >90 days. The prescriber poly-pharmacy gauge shows the percentage of members receiving AAP medications whose most recent 6-month history included poly-pharmacy.

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.

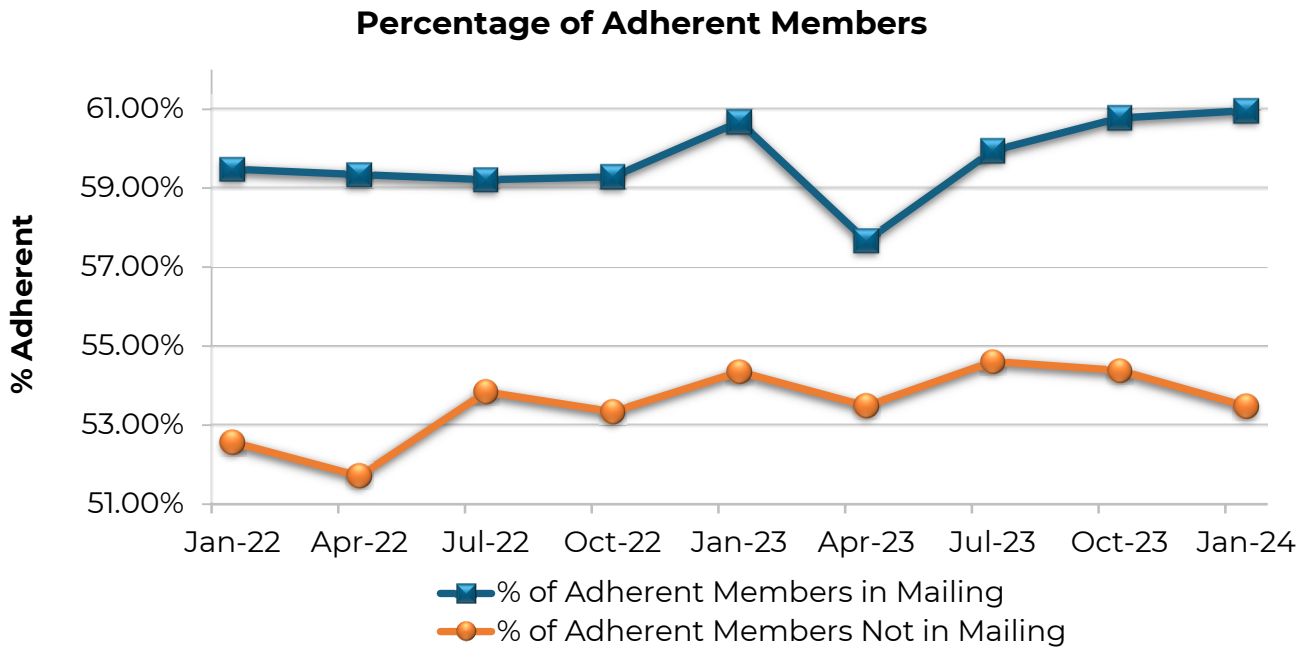


SoonerPsych Trends

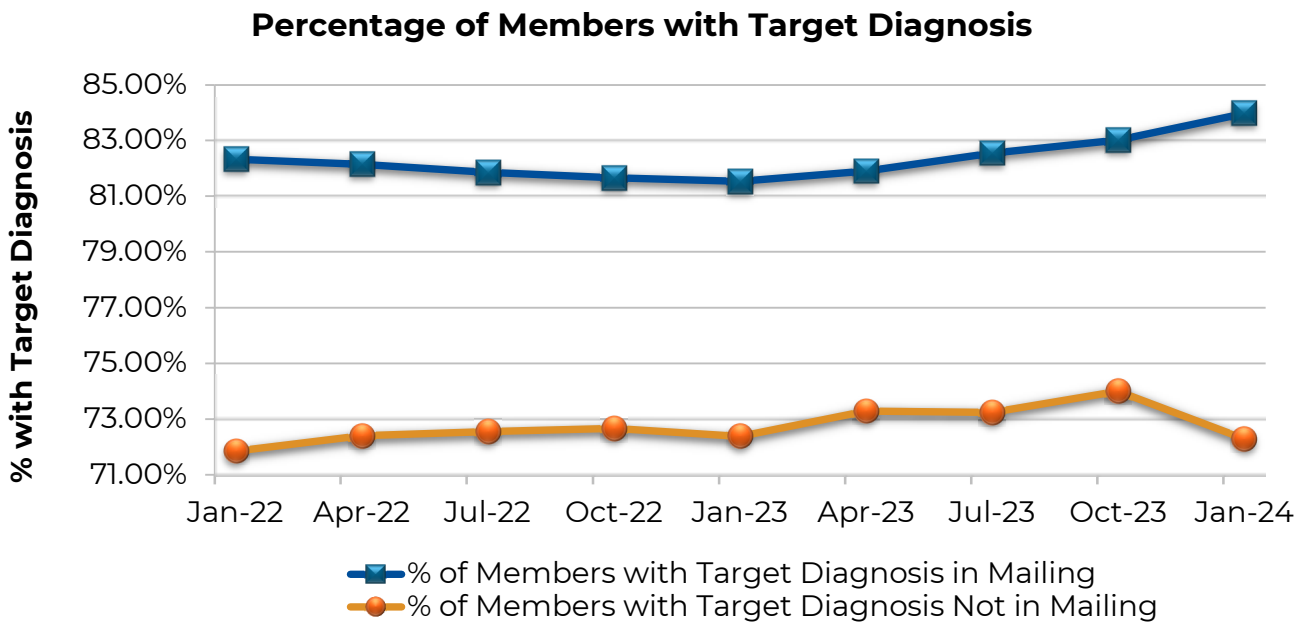
The following graphs show the SoonerPsych trends for medication adherence, diagnosis, metabolic monitoring, and poly-pharmacy from January 2022 to January 2024. Members whose prescribers were included in the SoonerPsych mailings are designated separately from those members whose prescribers were not included in the mailings. It is important to note that starting with the July 2019 mailing, the SoonerPsych data was adjusted for outliers, after input from the Drug Utilization Review (DUR) Board at the July 2019 DUR Board meeting, to show a more meaningful comparison of

prescribers included in the mailing and prescribers not included in the mailing.

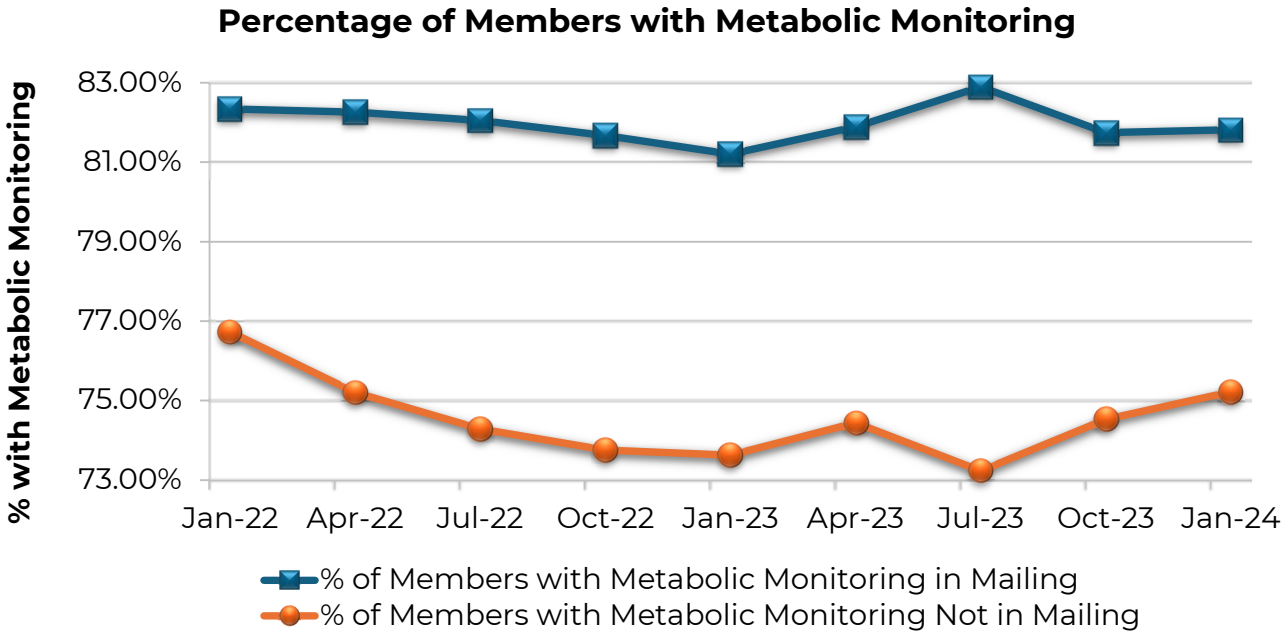
The following graph shows the SoonerPsych trends for the percentage of adherent members. Members are considered adherent if their PDC was ≥80%. Please note, the vertical axis starts at 51% of members in order to reflect small changes.



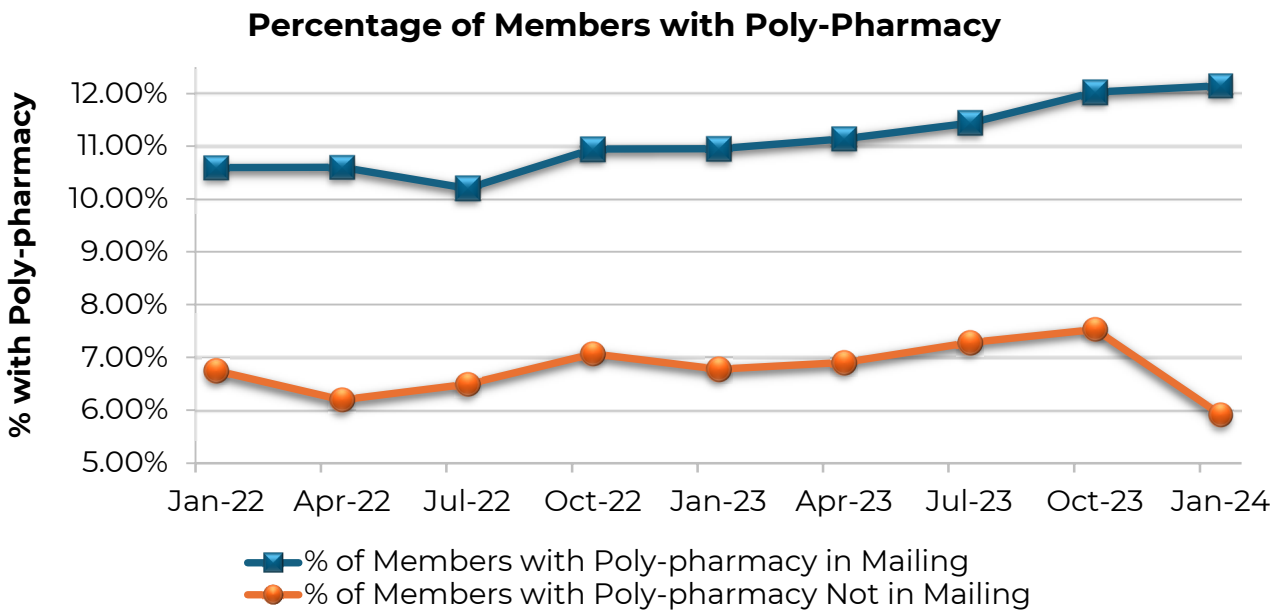
The following graph shows the SoonerPsych trends for the percentage of members having a diagnosis with a strong indication for prescribing an AAP medication. Please note, the vertical axis starts at 71% of members in order to reflect small changes.



The following graph shows the SoonerPsych trends for the percentage of members who received the recommended metabolic monitoring while on an AAP medication. Please note, the vertical axis starts at 73% 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 AAP medications.



Pediatric SoonerPsych Antipsychotic Monitoring Program 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 AAP medications specifically for children, including children in the foster care system, as part of a requirement by the Centers for Medicare and Medicaid Services (CMS). To accomplish these purposes, the College of Pharmacy developed the Pediatric SoonerPsych program in October 2019. Pediatric SoonerPsych is updated twice per year and includes prescribers caring for pediatric members receiving AAP medications. Specific prescriber focus alternates on a semi-annual basis between all children and those children in the foster care system. Pediatric SoonerPsych evaluates prescribing patterns and medical claims across 4 topics as previously described: medication adherence, target diagnosis, metabolic monitoring, and poly-pharmacy.

Pediatric SoonerPsych inclusion criteria is limited to prescribers whose prescribing of AAP medications for pediatric SoonerCare members varies significantly when compared to other SoonerCare prescribers in 1 or more of the 4 topics listed above.

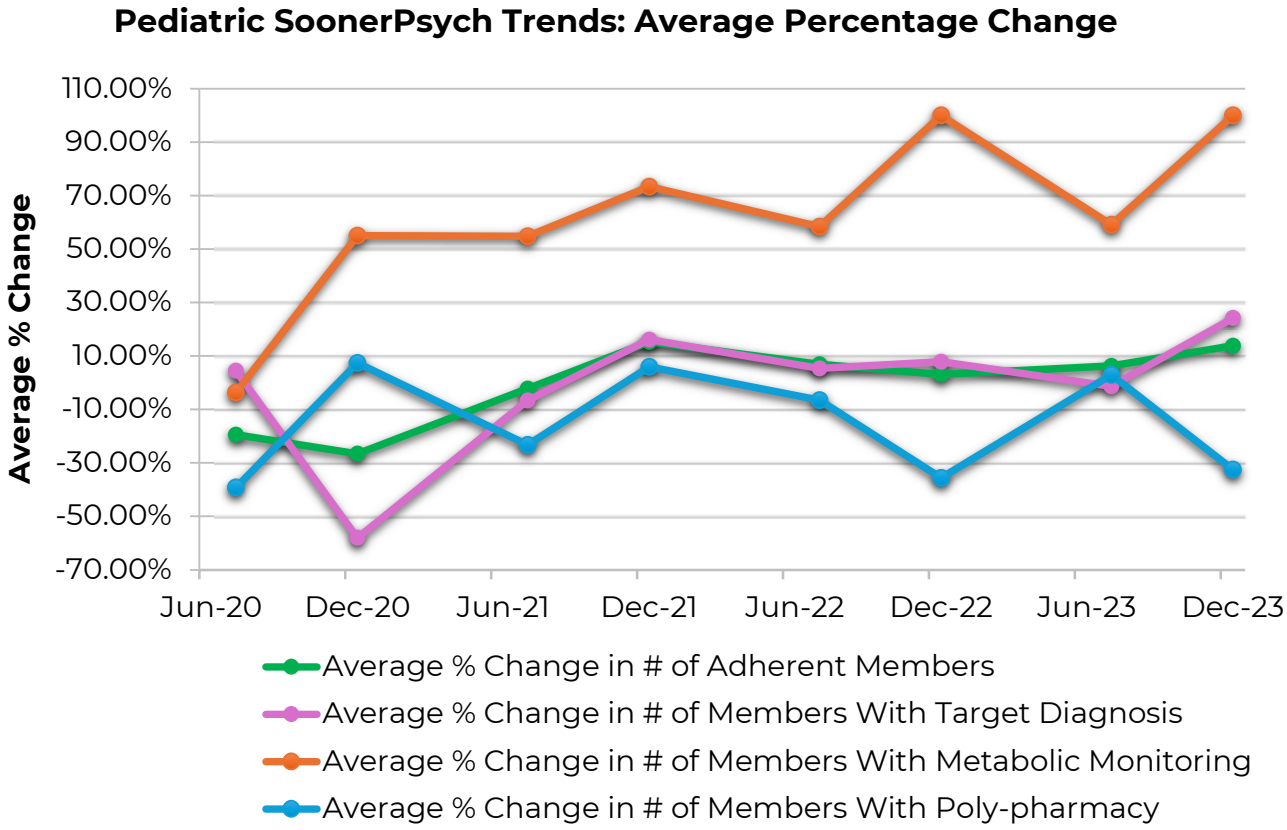
Prescribers receive an educational mailing and member list if they are the last prescriber of record for an AAP medication and are in the most concerning cohort of prescribers. Following receipt of the Pediatric SoonerPsych mailings, prescribers are offered a virtual or in-person visit by an academic 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 Child and Adolescent Psychiatry and Mental Health Access Program (OKCAPMAP). Additional services through OHCA Care Management and Behavioral Health Care Management have also been encouraged. Prescribers meeting criteria for pediatric members receive mailings and educational offerings each December. Prescribers meeting criteria for pediatric members in the foster care system receive mailings and educational offerings each June.

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 antipsychotic medications only 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 -70%, and a higher percentage change is a better outcome for adherence, diagnosis, and metabolic monitoring, indicating more members were adherent, had target diagnoses, and received metabolic monitoring. A lower percentage change is a better outcome for poly-pharmacy indicating fewer members with poly-pharmacy. To date, nearly 80 prescribers have received the Pediatric SoonerPsych mailings, AD, and additional program resources. Each of the prescribers met inclusion criteria for 1 to 9 cohorts, with an average of 2.3 cohort inclusions per prescriber.



Conclusions

Recent SoonerPsych trends comparing January 2022 through January 2024 indicate overall improvements in the percentage of adherent members and the percentage of members with a target diagnosis. Those improvements were similar to the improvements demonstrated by prescribers not in the mailings. The percentage of members with metabolic monitoring remained largely static, while prescribers not in the mailings demonstrated a sizeable worsening in metabolic monitoring rates. The percentage of members with poly-pharmacy increased for members whose prescribers received the SoonerPsych mailings compared to those not included in the mailings. Poly-pharmacy previously did not show positive trends in 2019 for those prescribers included in the mailing; however, after adjusting the data for outliers starting in July 2019, the percentage of members with poly-pharmacy was similar for members whose prescribers received the mailings compared to those not included in the mailings. 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. 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 AAP medications.

Since the Pediatric SoonerPsych program initiation, 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 metabolic monitoring, and more recently, target diagnosis. Overall results indicate the Pediatric SoonerPsych focused mailing and educational offerings are likely leading to improvements in antipsychotic medication management resulting in a lower risk of overprescribing and increased rates of recommended metabolic monitoring. The College of Pharmacy will continue to work with OHCA to identify prescribers who may benefit from Pediatric SoonerPsych activities with the goal of promoting evidence-based use of antipsychotic 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 C

Vote Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox)

Oklahoma Health Care Authority
April 2024

Market News and Updates[1]

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

- **June 2023:** The FDA approved Roctavian™ (valoctocogene roxaparvovec-rvox), an adeno-associated virus (AAV) vector-based gene therapy for the treatment of adults with severe hemophilia A.

Roctavian™ (Valoctocogene Roxaparvovec-rvox) Product Summary[2]

Therapeutic Class: AAV vector-based gene therapy

Indication(s): Adults with severe hemophilia A [congenital factor VIII deficiency with factor VIII activity <1 international units per deciliter (IU/dL)] without pre-existing antibodies to AAV serotype 5 detected by an FDA-approved test

How Supplied: Single-dose vial (SDV) containing 2×10^{13} vector genomes (vg) per mL with not less than 8mL of extractable volume per vial

Dosing and Administration: The recommended dose is 6×10^{13} vg/kg of body weight administered as a single intravenous (IV) infusion.

Cost: The Wholesale Acquisition Cost (WAC) of valoctocogene roxaparvovec is $90,625 per SDV. For a member weighing 70kg, a total of 27 SDVs would be required, resulting in an estimated cost of $2,446,875 for the one-time treatment.

Recommendations

The Oklahoma Health Care Authority recommends the prior authorization of Roctavian™ (valoctocogene roxaparvovec-rvox) with the following criteria (shown in red):

Roctavian™ (Valoctocogene Roxaparvovec-rvox) Approval Criteria:

1. An FDA approved diagnosis of severe congenital (or X-linked) hemophilia A; and
2. Member must be a male 18 years of age or older; and
3. Member must not have a history of or a recent positive screening of an inhibitor defined as ≥0.6 Bethesda units; and

4. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
5. Member must not have acute infections; and
6. Member must not have chronic active infections such as hepatitis B or C; and
7. Member must not have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts ≤200u/L; and
8. Member must not be taking efavirenz; and
9. Member must not have antibodies to AAV5; and
10. Member must not have any of the following:
    a. Significant liver fibrosis:
        i. Defined as ≥3 as rated on a scale of 0-4 on the METAVIR scoring system or equivalent grade on an alternative scale; and
        ii. Measured by ultrasound and elastography or laboratory assessments; or
    b. Liver cirrhosis; or
    c. Significant liver dysfunction with any of the following abnormal lab results:
        i. Alanine aminotransferase (ALT) >1.25x upper limit of normal (ULN); or
        ii. Aspartate aminotransferase (AST) >1.25x ULN; or
        iii. Gamma-glutamyl transferase (GGT) >1.25x ULN; or
        iv. Total bilirubin >1.25x ULN; or
        v. Alkaline phosphatase >1.25x ULN; or
        vi. International normalized ratio (INR) ≥1.4; and
11. 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
12. Prescriber must counsel member to not donate semen, and if member is of reproductive potential then their female partners must agree to prevent or postpone pregnancy for 6 months after treatment with valoctocogene roxaparvovec-rvox; and
13. Valoctocogene roxaparvovec-rvox must be administered in an appropriate clinical setting and member must be monitored for at least 3 hours post infusion; and
14. Prescriber must follow liver enzymes weekly for 26 weeks, every 1 to 2 weeks for weeks 26 through 52, every 3 months in the second year, and every 6 months thereafter; and
15. Prescriber agrees to start corticosteroids (or other immunosuppressives if corticosteroids are contraindicated) as outlined in the package labeling; and

16. Prescriber agrees to monitor factor VIII levels weekly for 26 weeks, every 1 to 2 weeks for weeks 26 through 52, every 3 months in the second year, and every 6 months thereafter; and
17. Approvals will be for 1 treatment per member per lifetime.

[1] U.S. Food and Drug Administration (FDA). FDA Approves the First Gene Therapy for Adults with Severe Hemophilia A. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-adults-severe-hemophilia. Issued 06/29/2023. Last accessed 03/27/2024.
[2] Roctavian™ (Valoctocogene Roxaparvovec-rvox) Prescribing Information. BioMarin Pharmaceuticals. Available online at: https://www.fda.gov/media/169937/download?attachment. Last revised 06/2023. Last accessed 03/27/2024.

Appendix D

Vote to Prior Authorize Ngenla® (Somatrogon-ghla) and Update the Approval Criteria for the Growth Hormone Products and Voxzogo® (Vosoritide)

Oklahoma Health Care Authority
April 2024

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

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

- **April 2023:** The FDA approved Sogroya® (somapacitan-beco) for a new indication for the treatment of pediatric patients 2.5 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone. Sogroya® was previously FDA approved in August 2020 for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD). Sogroya® is a long-acting human growth hormone analog that is administered once weekly.
- **June 2023:** The FDA approved Ngenla® (somatrogon-ghla) for the treatment of pediatric patients 3 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone. Ngenla® is a long-acting human growth hormone analog that is administered once weekly.
- **October 2023:** The FDA approved an age expansion for Voxzogo® (vosoritide) for use in pediatric patients younger than 5 years of age with achondroplasia and open epiphyses. Voxzogo® was previously only FDA approved in patients 5 years of age and older. With this new approval, Voxzogo® is now indicated to increase linear growth in pediatric patients of all ages 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 trial(s).

Guideline Update(s):

- Expert consensus guidelines for the use of human growth hormone therapy in patients with Prader-Willi syndrome (PWS) recommend early initiation of growth hormone, as early as 3 months of age, following genetic confirmation of the diagnosis.

Ngenla® (Somatrogon-ghla) Product Summary[5]

Therapeutic Class: Human growth hormone analog

Indication(s): Treatment of pediatric patients 3 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone

How Supplied: Single-patient-use, prefilled pens available in 2 formulations:
- 24mg/1.2mL (20mg/mL) Pen: Delivers a dose in 0.2mg increments
- 60mg/1.2mL (50mg/mL) Pen: Delivers a dose in 0.5mg increments

Dosing and Administration: The recommended initial dose for all patients is 0.66mg/kg once weekly via subcutaneous (sub-Q) injection into the abdomen, thighs, buttock, or upper arms.
- The dose should then be individualized and titrated based on growth response.
- Ngenla® is contraindicated in children with closed epiphyses.

Cost Comparison:

Product	Cost Per Dose	Cost Per 28 Days⁺	Cost Per Year⁺
Ngenla® (somatrogon-ghla) 60mg/1.2mL pen	**$2,199.50**	**$8,798.00**	**$114,374.00**
Skytrofa® (lonapegsomatropin-tcgd) 9.1mg cartridge	$2,181.72	$8,726.88	$113,449.44
Sogroya® (somapacitan-beco) 15mg/1.5mL cartridge	$1,786.43	$7,145.72	$92,894.36
Genotropin® (somatropin) 1.4mg MiniQuick	$212.52	$5,950.56	$77,357.28

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 28 days and cost per year based on recommended initial dosing for each product for a pediatric member weighing 40kg.

Recommendations

The College of Pharmacy recommends the placement of Ngenla® (somatrogon-ghla) into Tier-2 of the Growth Hormone Products Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Growth Hormone Products	
Tier-1*	**Tier-2**
Genotropin® (somatropin) (Pfizer) - Cartridge, MiniQuick	**Humatrope®** (somatropin) (Eli Lilly) - Vial, Cartridge Kit
	⁺Ngenla® (somatrogon-ghla) (Pfizer) - Pen
	Norditropin® (somatropin) (Novo Nordisk) - FlexPro® Pen

Growth Hormone Products	
Tier-1*	**Tier-2**
	Nutropin® and Nutropin AQ® (somatropin) (Genentech) - Vial, Pen Cartridge, NuSpin®
	Omnitrope® (somatropin) (Sandoz) - Vial, Cartridge
	Saizen® (somatropin) (EMD Serono) - Vial, click.easy®
	ᵗSerostim® (somatropin) (EMD Serono) - Vial
	ᵗSkytrofa® (lonapegsomatropin-tcgd) (Ascendis) - Cartridge
	ᵗSogroya® (somapacitan-beco) (Novo Nordisk) - Pen
	Zomacton® and Zoma-Jet® (somatropin) (Ferring) - Vial, Injection Device
	ᵗZorbtive® (somatropin) (EMD Serono) - Vial

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).
*Supplementally rebated product(s)
ᵗAdditional approval criteria applies.

Ngenla® (Somatrogon-ghla) Approval Criteria:

1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; and
2. Member must be 3 years of age or older; 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 Ngenla®; and
5. Initial approvals will be for the 0.66mg/kg dose recommended in 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; and
    e. Prescriber must verify member still has open epiphyses; and
7. Ngenla® will not be approved following epiphyseal closure. Ngenla® is contraindicated in children with closed epiphyses.

The College of Pharmacy also recommends updating the approval criteria for Sogroya® (somapacitan-beco) and Voxzogo® (vosoritide) based on recent FDA approvals (changes shown in red):

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
2. Member must be ~~18~~ 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 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 between -2 and +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. A maximum approved dose of 8mg per week will apply for members with adult GHD.

Voxzogo® (Vosoritide) 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 5 years of age or older; and~~
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height and growth velocity (GV) must be provided; and
5. Voxzogo® 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 in accordance with the package labeling; and
7. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Voxzogo®, including the need for adequate food and fluid intake prior to each dose; and
8. A quantity limit of 30 vials per 30 days will apply; and
9. 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
10. Voxzogo® will not be approved following epiphyseal closure.

Lastly, the College of Pharmacy recommends updating the growth hormone approval criteria for a diagnosis of PWS based to be consistent with clinical practice and guideline recommendations (changes shown in red):

Short Stature Associated with Prader-Willi Syndrome (PWS) Approval Criteria:

1. Initial Approval:
    a. ~~Member must be 2 years of age or older; and~~
    b. Member must have a chromosome analysis confirming the diagnosis of PWS; and
    c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    d. ~~Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and~~
    e. ~~Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and~~

f. ~~Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and~~
g. 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, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: 0.5-1mg/m^2/day or 0.24mg/kg/week. Treatment should 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: After attainment of adult height, adults with PWS may be considered for adult dosing if evidence is submitted documenting adult growth hormone deficiency [e.g., low insulin-like growth factor 1 (IGF-1) level and GH stimulation testing].
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. GV should not be <2.5cm/year; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

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[1] Novo Nordisk. FDA Approves Once-Weekly Sogroya® for the Treatment of Children Living with Growth Hormone Deficiency. Available online at: https://www.novonordisk-us.com/media/news-archive/news-details.html?id=166098. Issued 04/28/2023. Last accessed 03/27/2024.

[2] Pfizer, Inc. and OPKO Health, Inc. FDA Approves Pfizer's Ngenla®, a Long-Acting Once-Weekly Treatment for Pediatric Growth Hormone Deficiency. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/fda-approves-pfizers-ngenlatm-long-acting-once-weekly. Issued 06/28/2023. Last accessed 03/27/2024.

[3] BioMarin Pharmaceutical, Inc. U.S. Food and Drug Administration Approves BioMarin's Voxzogo® (Vosoritide) for Children Under 5 Years with Achondroplasia. Available online at: https://investors.biomarin.com/news/news-details/2023/U.S.-Food-and-Drug-Administration-Approves-BioMarins-VOXZOGO-vosoritide-for-Children-Under-5-Years-with-Achondroplasia-10-20-2023/default.aspx. Issued 10/20/2023. Last accessed 03/27/2024.

[4] Deal CL, Tony M, Hoybye C, et al. Growth Hormone Research Society Workshop Summary: Consensus Guidelines for Recombinant Human Growth Hormone Therapy in Prader-Willi Syndrome. *J Clin Endocrinol Metab* 2013; 98(6):E1072-87. doi: 10.1210/jc.2012-3888.

[5] Ngenla® (Somatrogon-ghla) Prescribing Information. Pfizer, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761184Orig1s000Corrected_lbl.pdf. Last revised 06/2023. Last accessed 03/27/2024.

Appendix E

Vote to Prior Authorize Ryzneuta® (Efbemalenograstim Alfa-vuxw) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs)

Oklahoma Health Care Authority
April 2024

Market News and Updates[1,2]

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

- **November 2023:** The FDA approved Ryzneuta® (efbemalenograstim alfa-vuxw) to treat chemotherapy-induced neutropenia (CIN), the first long-acting, non-pegylated G-CSF approved by the FDA.
- **December 2023:** The FDA approved an on-body injector formulation of Udenyca® (pegfilgrastim-cbqv), a biosimilar to Neulasta® (pegfilgrastim).

Ryzneuta® (Efbemalenograstim Alfa-vuxw) Product Summary[3]

Therapeutic Class: Leukocyte growth factor

Indication(s): To decrease the incidence of infections, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

- **Limitation(s) of Use:** Ryzneuta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

How Supplied: 20mg/mL solution in a single-dose prefilled syringe

Dosing and Administration:

- 20mg administered subcutaneously once per chemotherapy cycle
- Administer approximately 24 hours after cytotoxic chemotherapy
- Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy

Cost: The Wholesale Acquisition Cost (WAC) of Ryzneuta® is not available at this time to allow for a cost analysis.

Recommendations

The College of Pharmacy recommends adding Ryzneuta® (efbemalenograstim alfa-vuxw) to the current prior authorization criteria for

Rolvedon® (eflapegrastim-xnst) and updating the current criteria based on net costs and to be consistent with clinical practice (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), ~~Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz)~~, Neulasta® Onpro® (pegfilgrastim), or Ziextenzo® (pegfilgrastim-bmez) must be provided; and
3. Neulasta® Onpro® (pegfilgrastim) will be covered as a medical only benefit without prior authorization.

Additionally, the College of Pharmacy recommends updating the current prior authorization criteria for the G-CSF medications based on net costs and to be consistent with clinical practice (changes shown in red):

~~Fulphila® (Pegfilgrastim-jmdb),~~ 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), ~~Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz)~~, Neulasta® Onpro® (pegfilgrastim), 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) will be covered as a medical only benefit without prior authorization.

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[1] Evive Biotech. Evive Biotech and Acrotech Biopharma Announce FDA Approval of Ryzneuta® (Efbemalenograstim Alfa Injection) for Chemotherapy-Induced Neutropenia. Available online at: https://www.evivebiotech.com/en/newsd/index?id=56. Issued 11/22/2023. Last accessed 3/13/2024.
[2] Park B. FDA Approves On-Body Injector Presentation of Udenyca®. *Cancer Therapy Advisor*. Available online at: https://www.cancertherapyadvisor.com/home/cancer-topics/general-oncology/fda-approves-on-body-injector-presentation-udenyca/. Issued 12/28/2023. Last accessed 03/13/2024.
[3] Ryzneuta® (Efbemalenograstim Alfa-vuxw) Prescribing Information. BioLineRx. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761134s000lbl.pdf. Last revised 09/2023. Last accessed 03/13/2024.

Appendix F

Vote to Prior Authorize Tyruko® (Natalizumab-sztn) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications

Oklahoma Health Care Authority
April 2024

Market News and Updates[1]

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

- **August 2023:** The FDA approved Tyruko® (natalizumab-sztn), a biosimilar to Tysabri® (natalizumab). Tyruko® is approved to treat all the same indications as Tysabri®, which include Crohn's disease and relapsing forms of multiple sclerosis (RMS), making Tyruko® the first and only biosimilar medication approved for RMS. Tyruko® will be available in the same intravenous (IV) dosage form and follow the same dosing and administration. Similar to Tysabri®, Tyruko® will only be available through a Risk Evaluation and Mitigation Strategy (REMS) program due to the increased risk of progressive multifocal leukoencephalopathy (PML).

Recommendations

The College of Pharmacy recommends the prior authorization of Tyruko® (natalizumab-sztn) with criteria similar to Tysabri® (natalizumab) (changes shown in red):

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 Tyruko® 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.

[1] Novartis Pharma. Sandoz Receives FDA Approval for Tyruko® (Natalizumab-sztn), First and Only FDA-Approved Biosimilar for Relapsing Forms of Multiple Sclerosis. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2023/08/25/2731654/0/en/Sandoz-receives-FDA-approval-for-Tyruko-natalizumab-sztn-first-and-only-FDA-approved-biosimilar-for-relapsing-forms-of-multiple-sclerosis.html. Issued 08/25/2023. Last accessed 03/20/2024.

Appendix G

Vote to Prior Authorize Aphexda® (Motixafortide) and Update the Approval Criteria for the Stem Cell Mobilizers

Oklahoma Health Care Authority
April 2024

Market News and Updates[1,2,3]

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

- **July 2023:** The FDA approved plerixafor injection, a generic equivalent to Mozobil® (plerixafor).
- **September 2023:** The FDA approved Aphexda® (motixafortide) in combination with filgrastim, a granulocyte colony-stimulating factor (G-CSF), to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.
- **September 2023:** The FDA updated the indication for Mozobil® (plerixafor) to specify filgrastim as the G-CSF to be used in combination with Mozobil®.

Aphexda® (Motixafortide) Product Summary[4]

Therapeutic Class: Stem cell mobilizer

Indication(s): In combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma

How Supplied: 62mg as a lyophilized powder in a single-dose vial for reconstitution

Dosing and Administration:

- Aphexda® treatment should be initiated after filgrastim has been administered daily for 4 days.
- The recommended dosage is 1.25mg/kg actual body weight by subcutaneous injection 10 to 14 hours prior to initiation of apheresis.
- A second dose of Aphexda® can be administered 10 to 14 hours to a third apheresis if necessary.
- See full *Prescribing Information* for instructions on preparation and administration.

Cost Comparison

Product	Cost Per Vial	Cost Per Treatment*
Aphexda® (motixafortide) 62mg SDV	**$5,900.00**	**$23,600.00**
Mozobil® (plerixafor) 24mg/1.2mL SDV	$9,968.07	$39,872.28
plerixafor 24mg/1.2mL SDV (generic)	$3,987.23[α]	$15,948.92

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 treatment is based on the maximum FDA approved dosing of each product for an 80kg patient, resulting in 2 doses of Aphexda® and 4 doses of plerixafor per treatment.
[α]Cost per vial varies per NDC.
SDV = single-dose vial

Recommendations

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

Aphexda® (Motixafortide) Approval Criteria:

1. An FDA approved indication for use in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with multiple myeloma (MM); and
2. Member must have an oncology diagnosis of MM. This medication is not covered for the diagnosis of leukemia; and
3. Aphexda® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and
5. Aphexda® must be given in combination with the granulocyte-colony stimulating factor (G-CSF) filgrastim per package labeling; and
6. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic plerixafor must be provided; and
7. The following dosing restrictions will apply (current body weight in kilograms is required):
    a. Recommended dose is 1.25mg/kg actual body weight by subcutaneous injection 10 to 14 hours prior to initiation of apheresis; and
    b. A second dose of Aphexda® can be administered 10 to 14 hours prior to a third apheresis if necessary; and
8. Approvals will be for 2 cycles for the duration of 2 months.

Additionally, the College of Pharmacy recommends updating the current approval criteria for Mozobil® (plerixafor) to be consistent with the FDA approved indication and to be consistent with clinical practice (changes shown in red):

Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with ~~a granulocyte-colony stimulating factor (G-CSF)~~ filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM); and
2. Member must have an oncology diagnosis of NHL or MM. This medication is not covered for the diagnosis of leukemia; and
3. Mozobil® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and
5. Mozobil® must be used in combination with the granulocyte-colony stimulating factor (G-CSF) filgrastim per package labeling; and
6. The following dosing restrictions will apply (current body weight in kilograms is required):
    a. Recommended dose is 0.24mg/kg (maximum dose is 40mg/day) administered 11 hours prior to apheresis for up to 4 consecutive days; or
    b. For members with renal impairment (creatinine clearance ≤50mL/min), the recommended dose is 0.16mg/kg (maximum dose is 27mg/day); and
7. Approvals will be for 2 cycles for the duration of 2 months.

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[1] U.S. FDA. First Generic Drug Approvals 2023. Available online at: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/2023-first-generic-drug-approvals. Last revised 03/08/2024. Last accessed 03/13/2024.

[2] BioLineRx. BioLineRx Announces FDA Approval of Aphexda® (Motixafortide) in Combination with Filgrastim (G-CSF) to Mobilize Hematopoietic Stem Cells for Collection and Subsequent Autologous Transplantation in Patients with Multiple Myeloma. Available online at: https://ir.biolinerx.com/news-releases/news-release-details/biolinerx-announces-fda-approval-aphexdatm-motixafortide. Issued 09/11/2023. Last accessed 03/13/2024.

[3] Mozobil® (Plerixafor) Prescribing Information. Genzyme Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022311s023lbl.pdf. Last revised 09/2023. Last accessed 03/28/2024.

[4] Aphexda® (Motixafortide) Prescribing Information. BioLineRx. Available online: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217159s000lbl.pdf. Last revised 09/2023. Last accessed 03/13/2024.

Appendix H

Vote to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp) and Update the Approval Criteria for the Lymphoma Medications

Oklahoma Health Care Authority
April 2024

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

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

- **November 2019:** The FDA approved dosing for Calquence® (acalabrutinib) for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) indicates that it may be used in combination with obinutuzumab in patients with previously untreated CLL or SLL.
- **April 2023:** The FDA approved Polivy® (polatuzumab vedotin-piiq) for a new indication, in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP), for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified, or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.
- **May 2023:** The FDA granted accelerated approval to Epkinly™ (epcoritamab-bysp) for the treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, including DLBCL arising from indolent lymphoma, and HGBL after 2 or more lines of systemic therapy.
- **June 2023:** The FDA granted accelerated approval to Columvi™ (glofitamab-gxbm) for the treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after 2 or more lines of systemic therapy.
- **December 2023:** The FDA granted accelerated approval to Jaypirca® (pirtobrutinib) for a new indication for the treatment of adult patients with CLL or SLL who have received at least 2 prior lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor and a BCL-2 inhibitor.

News:

- **November 2023:** Bayer, the manufacturer of Aliqopa® (copanlisib) announced the planned withdrawal of Aliqopa® based on the results of the required confirmatory study. Aliqopa® was granted accelerated

approval for the treatment of adult patients with relapsed follicular lymphoma who have received at least 2 prior systemic therapies.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for relapsed/refractory DLBCL allow the use of Polivy® with or without bendamustine and rituximab.
- The NCCN guidelines for follicular lymphoma allow the use of Brukinsa® (zanubrutinib) as a third-line or subsequent line therapy in combination with obinutuzumab.
- The NCCN guidelines for peripheral T-cell lymphomas (PTCL) recommend Copiktra® (duvelisib) as a preferred regimen for initial palliative therapy or second-line/subsequent therapy in patients with PTCL.
- The NCCN guidelines for primary cutaneous lymphomas no longer recommend the use of Beleodaq® (belinostat) for mycosis fungoides (MF)/Sézary syndrome (SS).

Columvi™ (Glofitamab-gxbm) Product Summary[12]

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

Indication(s): Treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified or LBCL arising from follicular lymphoma, after 2 or more lines of systemic therapy

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

How Supplied:

- 2.5mg/2.5mL single-dose vial (SDV)
- 10mg/10mL SDV

Dosing and Administration: Administered as an intravenous (IV) infusion in 21-day cycles (for a maximum of 12 cycles) according to the following schedule:

- Cycle 1:
  - Day 1: Pretreat with a single dose of obinutuzumab 1,000mg by IV infusion
  - Day 8: Columvi™ 2.5mg
  - Day 15: Columvi™ 10mg
- Cycles 2 through 12:
  - Day 1: Columvi™ 30mg

Cost: The Wholesale Acquisition Cost (WAC) is $2,554.74 for the 2.5mg vial and $10,218.98 for the 10mg vial. This results in a cost of $12,773.72 for cycle 1 and $30,656.94 for each subsequent cycle. This would result in an estimated cost of approximately $350,000 for the recommended 12 cycles.

Epkinly™ (Epcoritamab-bysp) Product Summary[13]

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

Indication(s): Treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, including DLBCL arising from indolent lymphoma, and HGBL after 2 or more lines of systemic therapy

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

How Supplied:

- 4mg/0.8mL SDV which must be diluted prior to use
- 48mg/0.8mL SDV

Dosing and Administration:

- Administered by subcutaneous (sub-Q) injection in 28-day cycles according to the following schedule:
  - Cycle 1: 0.16mg on day 1, 0.8mg on day 8, 48mg on day 15, and 48mg on day 22
  - Cycles 2 and 3: 48mg on days 1, 8, 15, and 22
  - Cycles 4 through 9: 48mg on days 1 and 15
  - Cycles 10 and beyond: 48mg on day 1

Cost: The WAC is $1,287.83 for the 4mg vial and $15,453.96 for the 48mg vial. This results in a cost of $33,483.58 for cycle 1, a cost of $61,815.84 for cycles 2-3, a cost of $30,907.92 for cycles 4-9, and a cost of $15,453.96 for each subsequent cycle.

Recommendations

The College of Pharmacy recommends the prior authorization of Columvi™ (glofitamab-gxbm) and Epkinly™ (epcoritamab-bysp) with the following criteria (shown in red):

Columvi™ (Glofitamab-gxbm) Approval Criteria [Lymphoma Diagnosis]:

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

3. Will receive a single dose of obinutuzumab for pre-treatment purposes.

Epkinly™ (Epcoritamab-bysp) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory 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.

The College of Pharmacy also recommends updating the approval criteria for Calquence® (acalabrutinib) and Jaypirca® (pirtobrutinib) for CLL/SLL based on recent FDA approval and to be consistent with the FDA approved dosing for Calquence® (changes shown in red):

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

1. ~~Must be~~ Used as a single agent; or
2. In combination with obinutuzumab.

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

1. Diagnosis of CLL/SLL; and
2. Has received ≥2 lines of systemic therapy, including a Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor.

Next, the College of Pharmacy recommends updating the approval criteria for Polivy® (polatuzumab vedotin-piiq) based on recent FDA approval and NCCN recommendations (changes shown in red):

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

1. Previously untreated DLBCL not otherwise specified or high-grade B-cell lymphoma; and
   a. Has an International Prognostic Index score of ≥2; and
   b. Used in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP); or
2. Relapsed/refractory DLBCL not otherwise specified or high-grade B-cell lymphoma; and
   ~~a. Has received at least 2 prior therapies; and~~
   ~~b. Used in combination with bendamustine and rituximab; and~~
   c. Member is not a candidate or has no intention to proceed to hematopoietic stem cell transplant.

Additionally, the College of Pharmacy recommends updating the approval criteria for Beleodaq® (belinostat), Brukinsa® (zanubrutinib) and Copiktra® (duvelisib) based on NCCN recommendations (changes shown in red):

~~**Beleodaq® (Belinostat) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:**~~

~~1. Primary treatment in stage IV non Sézary or visceral disease (solid organ) with or without radiation therapy for local control; or~~
~~2. Primary treatment for large cell transformation with generalized cutaneous or extracutaneous lesions with or without skin-directed therapy; or~~
~~3. As a single agent (with or without skin-directed therapy) in relapsed/refractory disease.~~

Brukinsa® (Zanubrutinib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Third line or subsequent therapy for no response, relapsed, or progressive disease; and
3. Used in combination with obinutuzumab.

Copiktra® (Duvelisib) Approval Criteria [Peripheral T-Cell Lymphomas (PTCL) Diagnosis]:

1. Diagnosis of PTCL; and
2. As a single agent.

Lastly, the College of Pharmacy recommends updating the approval criteria for Aliqopa® (copanlisib) based on the planned withdrawal of its accelerated approval (changes shown in red):

Aliqopa® (Copanlisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of relapsed/refractory FL; and
2. Member must have failed at least 2 prior systemic therapies; and
3. Members who are new to treatment with Aliqopa® will not generally be approved.

[1] Calquence® (Acalabrutinib) Prescribing Information. AstraZeneca. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216387Orig2s000Correctedlbl.pdf. Last revised 08/2022. Last accessed 03/27/2024.
[2] U.S. FDA. FDA Approves Polatuzumab Vedotin-piiq for Previously Untreated Diffuse Large B-Cell Lymphoma, Not Otherwise Specified, and High-Grade B-Cell Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-polatuzumab-vedotin-piiq-previously-untreated-diffuse-large-b-cell-lymphoma-not. Issued 04/19/2023. Last accessed 03/27/2024.
[3] U.S. FDA. FDA Grants Accelerated Approval to Epcoritamab-bysp for Relapsed or Refractory Diffuse Large B-Cell Lymphoma and High-Grade B-Cell Lymphoma. Available online at: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-epcoritamab-bysp-relapsed-or-refractory-diffuse-large-b-cell. Issued 05/19/2023. Last accessed 03/27/2024.
[4] U.S. FDA. FDA Grants Accelerated Approval to Glofitamab-gxbm for Selected Relapsed or Refractory Large B-Cell Lymphomas. Available online at: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-glofitamab-gxbm-selected-relapsed-or-refractory-large-b-cell. Issued 06/15/2023. Last accessed 03/27/2024.
[5] U.S. FDA. FDA Grants Accelerated Approval to Pirtobrutinib for Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pirtobrutinib-chronic-lymphocytic-leukemia-and-small-lymphocytic. Issued 12/01/2023. Last accessed 03/27/2024.
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[7] National Comprehensive Cancer Network (NCCN). B-Cell Lymphomas Clinical Practice Guidelines in Oncology. Available online at: http://www.nccn.org. Last revised 01/18/2024. Last accessed 03/27/2024.
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[9] NCCN. T-Cell Lymphomas Clinical Practice Guidelines in Oncology. Available online at: http://www.nccn.org. Last revised 12/21/2023. Last accessed 03/27/2024.
[10] Pro B, Brammer JE, Casulo C, et al. Duvelisib in Patients with Relapsed/Refractory Peripheral T-Cell Lymphoma from the Phase 2 Primo Trial: Dose Optimization Efficacy Update and Expansion Phase Initial Results. *Blood* 2020; 136(1):38-39. doi: 10.1182/blood-2020-140412.
[11] NCCN. Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology. Available online at: http://www.nccn.org. Last revised 12/21/2023. Last accessed 03/27/2024.
[12] Columvi™ (Glofitamab-gxbm) Prescribing Information. Genentech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761309s000lbl.pdf. Last revised 06/2023. Last accessed 03/27/2024.
[13] Epkinly™ (Epcoritamab-bysp) Prescribing Information. Genmab US, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761324s000lbl.pdf. Last revised 05/2023. Last accessed 03/27/2024.

Appendix I

Calendar Year 2023 Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine ER susp (Adzenys ER™) amphetamine ER ODT (Adenyls XR-ODT®) amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™) amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®) dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™) dextroamphetamine (Zenzedi®) methamphetamine (Desoxyn®) methylphenidate ER 72mg methylphenidate ER ODT (Cotempla XR-ODT®)
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap and chew tab (Vyvanse®)+	amphetamine ER susp and tab (Dyanavel® XR) dextroamphetamine ER (Dexedrine Spansules®)		
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) methylphenidate ER (Daytrana®) – **Brand Preferred** methylphenidate ER (Metadate CD®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) – **Brand Preferred** methylphenidate ER susp (Quillivant XR®) methylphenidate ER (Ritalin LA®)	methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)			methylphenidate ER (Relexxii®) methylphenidate chew tab (Methylin®) methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)Δ
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)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). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
+Unique criteria applies for the diagnosis of binge eating disorder (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 Dyanavel® XR oral suspension and 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.
4. Kapvay® [Clonidine Extended-Release (ER) Tablet] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. 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

c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

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.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, 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® [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and
   c. Previously failed trial(s) (within the last 180 days) with atomoxetine or any 2 Tier-1 or Tier-2 ADHD medications, 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 2 Tier-1 or Tier-2 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)-contracted psychiatrist.
3. For Daytrana® patches, Methylin® oral solution, and Vyvanse® chewable tablet, 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
   a. Daytrana® patches are brand preferred. Approval of generic methylphenidate transdermal patches will require a patient-specific, clinically significant reason why brand name Daytrana® cannot be used.
4. Vyvanse® (Lisdexamfetamine) 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 or chewable tablets 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®.

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 Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and

5. 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®; or
    d. Provigil®; or
    e. Clarithromycin; and
6. 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
7. 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 Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or
3. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or
4. Use of Lumryz™ (sodium oxybate), 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®, and Nuvigil®, 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
5. Additionally, use of Lumryz™ (sodium oxybate) or 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
6. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
7. 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: Calendar Year 2023

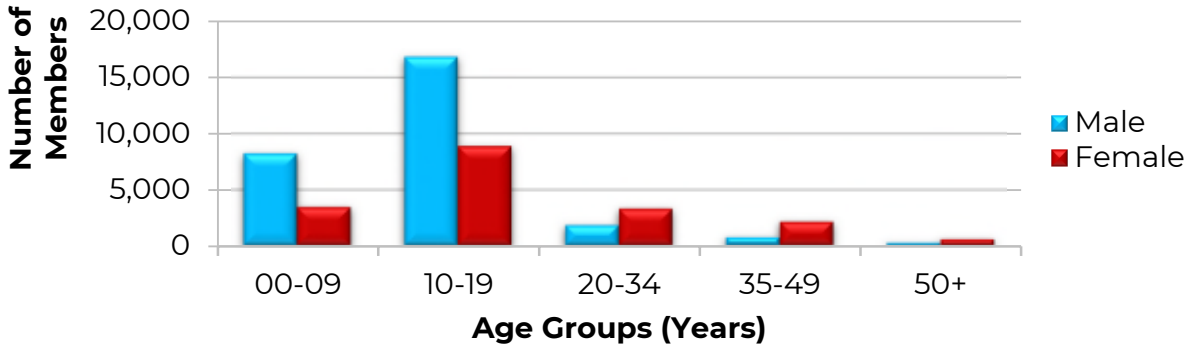
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	46,024	356,505	$50,458,756.01	$141.54	$4.77	12,494,502	10,582,336
2023	51,343	367,487	$59,027,559.66	$160.62	$5.31	13,006,245	11,108,617
% Change	**11.60%**	**3.10%**	**17.00%**	**13.50%**	**11.30%**	**4.10%**	**5.00%**
Change	**5,319**	**10,982**	**$8,568,803.65**	**$19.08**	**$0.54**	**511,743**	**526,281**

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

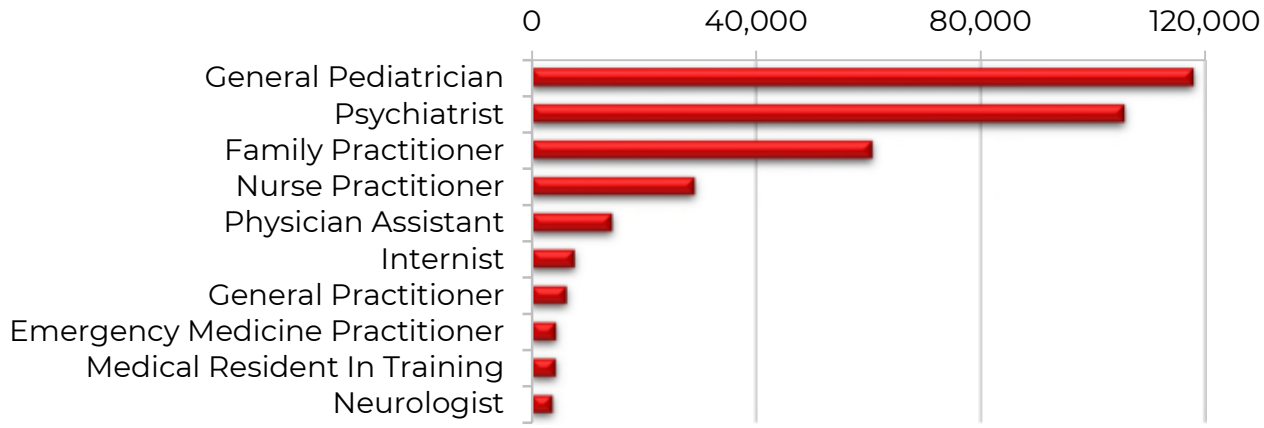
- Aggregate drug rebates collected during fiscal year 2023 (07/01/2022 to 06/30/2023) for ADHD and narcolepsy medications totaled $46,635,825.01.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2023 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing ADHD and Narcolepsy Medications



[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 ADHD and Narcolepsy Medications by Number of Claims



Prior Authorization of ADHD and Narcolepsy Medications

There were 34,664 prior authorization requests submitted for ADHD and narcolepsy medications during calendar year 2023. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions

There were 250 prior authorization requests submitted for a total of 186 unique members for ADHD and narcolepsy medications during calendar year 2023 that were referred for a psychiatric consultation. Most requests were for children 3 or 4 years of age. The following chart shows the status of the submitted petitions referred for psychiatric consultation for calendar year 2022.

Status of Psychiatric Consultations

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/.

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

Anticipated Patent Expiration(s):

- Daytrana® [methylphenidate extended-release (ER) transdermal patch]: October 2025
- Mydayis® (amphetamine/dextroamphetamine ER capsule): August 2029
- Wakix® (pitolisant tablet): March 2030
- Quillivant XR® (methylphenidate ER suspension): February 2031
- Jornay PM® (methylphenidate ER capsule): March 2032
- Adzenys ER™ (amphetamine ER suspension): June 2032

- Adzenys XR-ODT® [amphetamine extended-release (ER) orally disintegrating tablet (ODT)]: June 2032
- Qelbree® (viloxazine ER capsule): February 2033
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Dyanavel® XR (amphetamine ER suspension): September 2036
- Evekeo ODT™ (amphetamine ODT): March 2037
- Xywav® (calcium/magnesium/potassium/sodium oxybates oral solution): September 2037
- Azstarys® (serdexmethylphenidate/dexmethylphenidate capsule): December 2037
- Cotempla XR-ODT® (methylphenidate ER ODT): January 2038
- Dyanavel® XR (amphetamine ER tablet): September 2038
- Adhansia XR® (methylphenidate ER capsule): November 2038
- Xelstrym™ (dextroamphetamine transdermal system): January 2042
- Lumryz™ (sodium oxybate ER): March 2042
- Sunosi® (solriamfetol tablet): December 2042

News:

- **August 2023:** Several generic equivalent formulations of Vyvanse® (lisdexamfetamine) have been approved by the U.S. Food and Drug Administration (FDA), and generic formulations are now available for both the capsule and chewable tablet dosage forms. The generic formulations are indicated for the treatment of ADHD in patients 6 years of age and older and for the treatment of moderate-to-severe binge-eating disorder (BED) in adults.
- **October 2023:** The first generic formulations of Mydayis® (amphetamine/dextroamphetamine) have now been launched. The generic formulations are indicated for the treatment of ADHD in patients 13 years of age and older. Similar to brand name Mydayis®, there is a limitation of use stating that pediatric patients 12 years of age and younger experienced higher plasma exposure than patients 13 years of age and older at the same dose and experienced higher rates of adverse reactions, consisting mainly of insomnia and decreased appetite.

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. Making Vyvanse® (lisdexamfetamine) capsules and chewable tablets brand preferred based on net costs; and

2. Moving Dyanavel® XR (amphetamine ER suspension) to Tier-3 based on net costs; and
3. Removing the brand preferred status on Aptensio XR® (methylphenidate ER) and Nuvigil® (armodafinil) based on net costs; and
4. Updating the Idiopathic Hypersomnia Medications and Narcolepsy Medications approval criteria based on net costs.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine ER susp (Adzenys ER™) amphetamine ER ODT (Adenyls XR-ODT®) amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™) amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®) dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™) dextroamphetamine (Zenzedi®) methamphetamine (Desoxyn®) methylphenidate ER 72mg methylphenidate ER ODT (Cotempla XR-ODT®) methylphenidate ER (Relexxii®)
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap and chew tab (Vyvanse®)+ - **Brand Preferred**	amphetamine ER ~~**susp and**~~ tab (Dyanavel® XR) dextroamphetamine ER (Dexedrine Spansules®)	**amphetamine ER susp (Dyanavel® XR)**	
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) methylphenidate ER (Daytrana®) – **Brand Preferred** methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) ~~**— Brand Preferred**~~ methylphenidate ER susp (Quillivant XR®) methylphenidate ER (Ritalin LA®)	methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)			methylphenidate chew tab (Methylin®) methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)Δ
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)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). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
+Unique criteria applies for the diagnosis of binge eating disorder (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 ~~Dyanavel® XR oral suspension and~~ 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.
4. Kapvay® [Clonidine Extended-Release (ER) Tablet] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. 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
   c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

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 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.

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 Daytrana® patches, Methylin® oral solution, and Vyvanse® chewable tablet, 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
    a. Daytrana® patches and Vyvanse® chewable tablets are brand preferred. Approval of generic methylphenidate transdermal patches or lisdexamfetamine chewable tablets will require a patient-specific, clinically significant reason why brand name Daytrana® or Vyvanse® cannot be used.
4. Vyvanse® (Lisdexamfetamine) 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. Vyvanse® is brand preferred. Approval of generic lisdexamfetamine will require a patient-specific, clinically significant reason why brand name Vyvanse® cannot be used; and
f. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
g. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

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 Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and~~
   ~~a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and~~
~~4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and~~

5. 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
6. 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
7. 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 Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and~~
    a. ~~Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or~~
3. ~~Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or~~
4. Use of Lumryz™ (sodium oxybate), 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
5. Additionally, use of Lumryz™ (sodium oxybate) or 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
6. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Utilization Details of ADHD and Narcolepsy Medications: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	22,997	6,140	$7,950,395.00	$345.71	3.75	13.47%
VYVANSE CAP 20MG	19,041	5,744	$6,532,112.98	$343.06	3.31	11.07%
VYVANSE CAP 40MG	18,080	4,234	$6,191,423.69	$342.45	4.27	10.49%
VYVANSE CAP 50MG	12,456	2,699	$4,278,477.75	$343.49	4.62	7.25%
VYVANSE CAP 10MG	8,538	3,323	$2,903,734.17	$340.10	2.57	4.92%
VYVANSE CAP 60MG	6,615	1,421	$2,286,987.61	$345.73	4.66	3.87%
VYVANSE CAP 70MG	4,795	934	$1,643,831.80	$342.82	5.13	2.78%
LISDEXAMFET CAP 30MG	297	236	$48,672.97	$163.88	1.26	0.08%
LISDEXAMFET CAP 40MG	272	218	$42,361.19	$155.74	1.25	0.07%
LISDEXAMFET CAP 50MG	221	172	$37,059.80	$167.69	1.28	0.06%
VYVANSE CHW 10MG	197	130	$67,711.61	$343.71	1.52	0.11%
LISDEXAMFET CAP 60MG	157	132	$30,688.83	$195.47	1.19	0.05%
LISDEXAMFET CAP 70MG	149	116	$31,991.01	$214.70	1.28	0.05%
VYVANSE CHW 20MG	128	69	$43,373.86	$338.86	1.86	0.07%
LISDEXAMFET CAP 20MG	119	98	$21,832.88	$183.47	1.21	0.04%
VYVANSE CHW 30MG	44	28	$14,088.10	$320.18	1.57	0.02%
VYVANSE CHW 40MG	42	23	$12,971.08	$308.84	1.83	0.02%
VYVANSE CHW 50MG	26	7	$7,654.51	$294.40	3.71	0.01%
LISDEXAMFET CAP 10MG	18	18	$4,046.34	$224.80	1	0.01%
VYVANSE CHW 60MG	9	5	$3,011.02	$334.56	1.8	0.01%
SUBTOTAL	**94,201**	**17,779***	**$32,152,426.20**	**$341.32**	**5.3**	**54.47%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	9,324	2,538	$158,270.43	$16.97	3.67	0.27%
METHYLPHENID TAB 5MG	8,221	2,532	$129,345.50	$15.73	3.25	0.22%
METHYLPHENID CAP 20MG	7,569	2,210	$351,809.08	$46.48	3.42	0.60%
METHYLPHENID CAP 30MG	6,432	1,695	$302,241.61	$46.99	3.79	0.51%
METHYLPHENID TAB 20MG	4,430	1,039	$81,093.48	$18.31	4.26	0.14%
METHYLPHENID CAP 40MG ER	3,960	964	$229,037.05	$57.84	4.11	0.39%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLPHENID CAP 10MG	3,861	1,590	$182,059.85	$47.15	2.43	0.31%
METHYLPHENID CAP 20MG ER	1,976	597	$96,921.64	$49.05	3.31	0.16%
METHYLPHENID TAB 36MG ER	1,919	644	$71,721.44	$37.37	2.98	0.12%
METHYLPHENID CAP 50MG	1,864	397	$116,802.75	$62.66	4.7	0.20%
METHYLPHENID CAP 60MG	1,568	298	$98,410.15	$62.76	5.26	0.17%
METHYLPHENID TAB 54MG ER	1,415	425	$42,389.96	$29.96	3.33	0.07%
CONCERTA TAB 36MG	1,412	419	$722,233.07	$511.50	3.37	1.22%
METHYLPHENID CAP 30MG ER	1,290	379	$78,583.32	$60.92	3.4	0.13%
METHYLPHENID TAB 18MG ER	1,182	599	$33,656.65	$28.47	1.97	0.06%
METHYLPHENID TAB 27MG ER	1,097	468	$33,783.83	$30.80	2.34	0.06%
METHYLPHENID TAB 20MG ER	1,065	370	$27,708.85	$26.02	2.88	0.05%
METHYLPHENID CAP 40MG ER	1,050	280	$58,993.42	$56.18	3.75	0.10%
CONCERTA TAB 54MG	908	250	$389,997.68	$429.51	3.63	0.66%
METHYLPHENID TAB 36MG ER	801	343	$33,238.13	$41.50	2.34	0.06%
METHYLPHENID CAP 10MG ER	787	313	$70,456.10	$89.52	2.51	0.12%
METHYLPHENID SOL 5MG/5ML	779	264	$33,352.38	$42.81	2.95	0.06%
METHYLPHENID CAP 40MG ER	685	187	$132,011.82	$192.72	3.66	0.22%
CONCERTA TAB 27MG	673	242	$253,717.84	$377.00	2.78	0.43%
METHYLPHENID TAB 27MG ER	672	270	$24,522.53	$36.49	2.49	0.04%
METHYLPHENID CAP 30MG ER	664	199	$111,870.37	$168.48	3.34	0.19%
QUILLIVANT SUS 25MG/5ML	603	124	$256,824.62	$425.91	4.86	0.44%
CONCERTA TAB 18MG	596	259	$214,282.95	$359.54	2.3	0.36%
METHYLPHENID CAP 60MG ER	524	103	$102,070.99	$194.79	5.09	0.17%
METHYLPHENID TAB 54MG ER	501	186	$16,095.74	$32.13	2.69	0.03%
METHYLPHENID TAB 10MG ER	492	202	$9,851.20	$20.02	2.44	0.02%
METHYLPHENID SOL 10MG/5ML	454	117	$20,523.70	$45.21	3.88	0.03%
METHYLPHENID CAP 50MG ER	413	111	$80,234.08	$194.27	3.72	0.14%
METHYLPHENID CAP 20MG ER	363	133	$69,948.75	$192.70	2.73	0.12%
JORNAY PM CAP 60MG ER	204	57	$76,604.99	$375.51	3.58	0.13%
METHYLPHENID CAP 15MG ER	202	62	$38,347.55	$189.84	3.26	0.06%
JORNAY PM CAP 40MG ER	197	58	$82,342.41	$417.98	3.4	0.14%
METHYLIN SOL 5MG/5ML	191	72	$8,972.16	$46.97	2.65	0.02%
METHYLPHENID TAB 18MG ER	185	113	$5,434.99	$29.38	1.64	0.01%
APTENSIO XR CAP 40MG	174	77	$45,075.71	$259.06	2.26	0.08%
APTENSIO XR CAP 30MG	171	77	$44,366.52	$259.45	2.22	0.08%
METHYLPHENID TAB 72MG ER	171	31	$73,141.45	$427.73	5.52	0.12%
METHYLPHENID DIS 10MG/9HR	160	73	$65,422.58	$408.89	2.19	0.11%
METHYLPHENID CAP 10MG ER	146	54	$22,345.97	$153.05	2.7	0.04%
METHYLPHENID DIS 15MG/9HR	139	54	$52,211.47	$375.62	2.57	0.09%
APTENSIO XR CAP 20MG	131	57	$33,614.55	$256.60	2.3	0.06%
METHYLPHENID DIS 20MG/9HR	128	51	$51,781.16	$404.54	2.51	0.09%
DAYTRANA DIS 30MG/9HR	125	31	$56,977.75	$455.82	4.03	0.10%
JORNAY PM CAP 80MG ER	105	22	$40,936.99	$389.88	4.77	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APTENSIO XR CAP 50MG	90	48	$23,405.18	$260.06	1.88	0.04%
JORNAY PM CAP 20MG ER	89	36	$36,496.15	$410.07	2.47	0.06%
DAYTRANA DIS 10MG/9HR	88	36	$37,573.56	$426.97	2.44	0.06%
JORNAY PM CAP 100MG ER	74	15	$30,293.09	$409.37	4.93	0.05%
METHYLPHENID CAP 60MG LA	73	23	$17,633.56	$241.56	3.17	0.03%
APTENSIO XR CAP 60MG	73	27	$18,793.58	$257.45	2.7	0.03%
METHYLPHENID DIS 30MG/9HR	71	19	$27,977.21	$394.05	3.74	0.05%
DAYTRANA DIS 20MG/9HR	59	29	$25,556.35	$433.16	2.03	0.04%
DAYTRANA DIS 15MG/9HR	56	27	$23,610.65	$421.62	2.07	0.04%
QUILLICHEW CHW 20MG ER	53	11	$18,976.03	$358.04	4.82	0.03%
APTENSIO XR CAP 10MG	53	27	$13,682.56	$258.16	1.96	0.02%
RITALIN LA CAP 10MG	49	25	$17,060.77	$348.18	1.96	0.03%
APTENSIO XR CAP 15MG	43	19	$11,121.38	$258.64	2.26	0.02%
METHYLIN SOL 10MG/5ML	42	9	$2,895.23	$68.93	4.67	0.00%
QUILLICHEW CHW 30MG ER	34	9	$11,881.61	$349.46	3.78	0.02%
QUILLICHEW CHW 40MG ER	23	3	$8,385.57	$364.59	7.67	0.01%
METHYLPHENID CHW 2.5MG	21	6	$1,354.82	$64.52	3.5	0.00%
METHYLPHENID CHW 5MG	19	5	$3,333.35	$175.44	3.8	0.01%
RITALIN TAB 20MG	12	4	$1,600.31	$133.36	3	0.00%
METHYLPHENID TAB 45MG ER	10	5	$5,838.80	$583.88	2	0.01%
METHYLPHENID CHW 10MG	6	3	$706.12	$117.69	2	0.00%
RITALIN TAB 10MG	6	5	$371.36	$61.89	1.2	0.00%
RITALIN TAB 5MG	5	4	$300.37	$60.07	1.25	0.00%
RITALIN LA CAP 40MG	3	2	$1,120.68	$373.56	1.5	0.00%
SUBTOTAL	**73,031**	**12,871***	**$5,671,605.50**	**$77.66**	**5.67**	**9.61%**
GUANFACINE ER PRODUCTS						
GUANFACINE TAB 2MG ER	19,259	4,495	$353,104.24	$18.33	4.28	0.60%
GUANFACINE TAB 1MG ER	16,130	5,239	$286,801.25	$17.78	3.08	0.49%
GUANFACINE TAB 3MG ER	12,411	2,405	$228,948.54	$18.45	5.16	0.39%
GUANFACINE TAB 4MG ER	9,528	1,471	$177,673.62	$18.65	6.48	0.30%
INTUNIV TAB 4MG	32	4	$9,065.98	$283.31	8	0.02%
INTUNIV TAB 2MG	14	2	$4,096.12	$292.58	7	0.01%
INTUNIV TAB 3MG	13	2	$3,784.04	$291.08	6.5	0.01%
SUBTOTAL	**57,387**	**10,346***	**$1,063,473.79**	**$18.53**	**5.55**	**1.80%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 10MG	9,792	2,811	$199,181.64	$20.34	3.48	0.34%
AMPHET/DEXTR TAB 20MG	9,514	2,107	$230,822.82	$24.26	4.52	0.39%
AMPHET/DEXTR TAB 5MG	6,287	1,938	$119,202.52	$18.96	3.24	0.20%
AMPHET/DEXTR TAB 30MG	4,634	989	$108,751.19	$23.47	4.69	0.18%
AMPHET/DEXTR CAP 20MG ER	4,185	1,364	$109,270.07	$26.11	3.07	0.19%
AMPHET/DEXTR CAP 30MG ER	3,623	912	$94,814.85	$26.17	3.97	0.16%
AMPHET/DEXTR CAP 10MG ER	3,593	1,339	$86,104.53	$23.96	2.68	0.15%
AMPHET/DEXTR TAB 15MG	3,451	867	$73,007.23	$21.16	3.98	0.12%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMPHET/DEXTR CAP 15MG ER	2,641	894	$69,833.41	$26.44	2.95	0.12%
AMPHET/DEXTR CAP 25MG ER	2,147	562	$51,351.45	$23.92	3.82	0.09%
AMPHET/DEXTR CAP 5MG ER	898	427	$22,942.49	$25.55	2.1	0.04%
AMPHET/DEXTR TAB 7.5MG	730	198	$19,101.30	$26.17	3.69	0.03%
AMPHET/DEXTR TAB 12.5MG	399	102	$12,322.48	$30.88	3.91	0.02%
ADDERALL XR CAP 30MG	285	99	$60,479.80	$212.21	2.88	0.10%
ADDERALL XR CAP 20MG	202	91	$47,766.40	$236.47	2.22	0.08%
ADDERALL XR CAP 25MG	90	34	$16,062.64	$178.47	2.65	0.03%
ADDERALL XR CAP 15MG	86	41	$18,844.53	$219.12	2.1	0.03%
ADDERALL XR CAP 10MG	66	36	$13,857.21	$209.96	1.83	0.02%
MYDAYIS CAP 25MG	33	7	$9,487.85	$287.51	4.71	0.02%
ADDERALL TAB 20MG	31	16	$14,125.05	$455.65	1.94	0.02%
ADDERALL TAB 30MG	23	11	$12,038.82	$523.43	2.09	0.02%
ADDERALL TAB 10MG	23	17	$10,462.30	$454.88	1.35	0.02%
ADDERALL TAB 15MG	20	6	$9,174.40	$458.72	3.33	0.02%
MYDAYIS CAP 50MG	17	4	$4,918.76	$289.34	4.25	0.01%
ADDERALL XR CAP 5MG	11	9	$2,199.47	$199.95	1.22	0.00%
MYDAYIS CAP 37.5MG	10	3	$2,406.94	$240.69	3.33	0.00%
MYDAYIS CAP 12.5MG	9	3	$3,036.69	$337.41	3	0.01%
ADDERALL TAB 5MG	6	6	$2,433.32	$405.55	1	0.00%
AMPHET/DEXTR CAP 37.5 ER	2	1	$117.96	$58.98	2	0.00%
AMPHET/DEXTR CAP 25MG ER	2	2	$604.30	$302.15	1	0.00%
AMPHET/DEXTR CAP 50MG ER	2	1	$608.30	$304.15	2	0.00%
AMPHET/DEXTR CAP 12.5 ER	1	1	$266.53	$266.53	1	0.00%
SUBTOTAL	**52,813**	**10,497***	**$1,425,597.25**	**$26.99**	**5.03**	**2.42%**
DEXMETHYLPHENIDATE PRODUCTS						
FOCALIN XR CAP 10MG	6,705	2,103	$2,658,352.28	$396.47	3.19	4.50%
FOCALIN XR CAP 20MG	6,289	1,534	$2,598,414.35	$413.17	4.1	4.40%
FOCALIN XR CAP 15MG	5,959	1,491	$2,441,800.89	$409.77	4	4.14%
DEXMETHYLPHE TAB 5MG	5,756	1,513	$97,154.36	$16.88	3.8	0.16%
DEXMETHYLPHE TAB 10MG	5,729	1,309	$114,129.55	$19.92	4.38	0.19%
FOCALIN XR CAP 5MG	3,560	1,355	$1,394,454.89	$391.70	2.63	2.36%
FOCALIN XR CAP 30MG	3,277	689	$1,298,608.94	$396.28	4.76	2.20%
FOCALIN XR CAP 25MG	3,102	647	$1,349,223.70	$434.95	4.79	2.29%
DEXMETHYLPHE TAB 2.5MG	1,881	588	$29,487.73	$15.68	3.2	0.05%
FOCALIN XR CAP 40MG	1,469	261	$667,494.15	$454.39	5.63	1.13%
FOCALIN XR CAP 35MG	845	159	$382,725.91	$452.93	5.31	0.65%
DEXMETHYLPHE CAP 10MG ER	121	84	$4,815.49	$39.80	1.44	0.01%
DEXMETHYLPHE CAP 20MG ER	61	47	$3,128.38	$51.28	1.3	0.01%
DEXMETHYLPHE CAP 15MG ER	55	38	$1,694.73	$30.81	1.45	0.00%
FOCALIN TAB 10MG	40	17	$2,694.77	$67.37	2.35	0.00%
DEXMETHYLPHE CAP 30MG ER	39	26	$1,758.28	$45.08	1.5	0.00%
DEXMETHYLPHE CAP ER 25MG	32	19	$1,384.92	$43.28	1.68	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEXMETHYLPHE CAP 5MG ER	28	25	$1,082.67	$38.67	1.12	0.00%
DEXMETHYLPHE CAP 40MG ER	18	9	$891.68	$49.54	2	0.00%
FOCALIN TAB 5MG	13	10	$885.58	$68.12	1.3	0.00%
DEXMETHYLPHE CAP ER 35MG	6	5	$506.68	$84.45	1.2	0.00%
FOCALIN TAB 2.5MG	3	3	$132.00	$44.00	1	0.00%
SUBTOTAL	**44,988**	**7,169***	**$13,050,821.93**	**$290.10**	**6.28**	**22.11%**
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	11,572	3,835	$406,685.20	$35.14	3.02	0.69%
ATOMOXETINE CAP 25MG	9,592	3,115	$312,503.62	$32.58	3.08	0.53%
ATOMOXETINE CAP 18MG	5,388	1,922	$192,724.78	$35.77	2.8	0.33%
ATOMOXETINE CAP 60MG	4,930	1,221	$170,216.90	$34.53	4.04	0.29%
ATOMOXETINE CAP 10MG	4,234	1,585	$140,998.63	$33.30	2.67	0.24%
ATOMOXETINE CAP 80MG	2,657	788	$105,312.49	$39.64	3.37	0.18%
ATOMOXETINE CAP 100MG	1,136	280	$46,734.85	$41.14	4.06	0.08%
STRATTERA CAP 40MG	24	2	$10,489.64	$437.07	12	0.02%
STRATTERA CAP 100MG	2	1	$944.57	$472.29	2	0.00%
SUBTOTAL	**39,535**	**9,294***	**$1,386,610.68**	**$35.07**	**4.25**	**2.35%**
VILOXAZINE PRODUCTS						
QELBREE CAP 200MG ER	2,012	607	$894,960.52	$444.81	3.31	1.52%
QELBREE CAP 100MG ER	934	364	$300,941.26	$322.21	2.57	0.51%
QELBREE CAP 150MG ER	419	132	$183,044.11	$436.86	3.17	0.31%
SUBTOTAL	**3,365**	**869***	**$1,378,945.89**	**$409.79**	**3.87**	**2.34%**
CLONIDINE ER PRODUCTS						
CLONIDINE TAB 0.1MG ER	1,012	170	$30,584.34	$30.22	5.95	0.05%
SUBTOTAL	**1,012**	**170***	**$30,584.34**	**$30.22**	**5.95**	**0.05%**
ARMODAFINIL PRODUCTS						
NUVIGIL TAB 250MG	163	31	$159,315.08	$977.39	5.26	0.27%
NUVIGIL TAB 150MG	84	27	$96,812.09	$1,152.52	3.11	0.16%
NUVIGIL TAB 200MG	37	7	$37,797.17	$1,021.55	5.29	0.06%
ARMODAFINIL TAB 250MG	27	6	$926.17	$34.30	4.5	0.00%
ARMODAFINIL TAB 150MG	15	9	$488.11	$32.54	1.67	0.00%
ARMODAFINIL TAB 200MG	4	3	$135.02	$33.76	1.33	0.00%
NUVIGIL TAB 50MG	3	2	$1,377.43	$459.14	1.5	0.00%
SUBTOTAL	**333**	**67***	**$296,851.07**	**$891.44**	**4.97**	**0.50%**
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	196	27	$5,792.49	$29.55	7.26	0.01%
MODAFINIL TAB 100MG	21	4	$366.29	$17.44	5.25	0.00%
PROVIGIL TAB 200MG	6	1	$25,023.02	$4,170.50	6	0.04%
SUBTOTAL	**223**	**32***	**$31,181.80**	**$139.83**	**6.97**	**0.05%**
AMPHETAMINE PRODUCTS						
DYANAVEL XR SUS 2.5MG/ML	46	14	$18,380.11	$399.57	3.29	0.03%
DYANAVEL XR CHW 15MG	37	9	$15,424.36	$416.87	4.11	0.03%
DYANAVEL XR CHW 10MG	31	11	$13,241.58	$427.15	2.82	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADZENYS XR TAB 18.8MG	17	2	$7,940.66	$467.10	8.5	0.01%
DYANAVEL XR CHW 5MG	14	9	$3,289.44	$234.96	1.56	0.01%
ADZENYS XR TAB 6.3MG	9	1	$4,190.58	$465.62	9	0.01%
DYANAVEL XR CHW 20MG	5	4	$2,072.16	$414.43	1.25	0.00%
AMPHETAMINE TAB 10MG	4	1	$133.00	$33.25	4	0.00%
SUBTOTAL	**163**	**42***	**$64,671.89**	**$396.76**	**3.88**	**0.11%**
DEXMETHYLPHENIDATE/SERDEXMETHYLPHENIDATE PRODUCTS						
AZSTARYS CAP 39.2-7.8MG	70	24	$24,855.21	$355.07	2.92	0.04%
AZSTARYS CAP 26.1-5.2MG	27	14	$10,568.69	$391.43	1.93	0.02%
AZSTARYS CAP 52.3-10.4MG	25	11	$9,414.53	$376.58	2.27	0.02%
SUBTOTAL	**122**	**33***	**$44,838.43**	**$367.53**	**3.7**	**0.08%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	46	12	$4,413.25	$95.94	3.83	0.01%
DEXTROAMPHET CAP 10MG ER	21	7	$886.29	$42.20	3	0.00%
DEXTROAMPHET TAB 5MG	15	4	$354.99	$23.67	3.75	0.00%
DEXTROAMPHET TAB 10MG	10	4	$289.89	$28.99	2.5	0.00%
DEXTROAMPHET SOL 5MG/5ML	4	2	$2,061.00	$515.25	2	0.00%
DEXTROAMPHET TAB 20MG	2	1	$389.76	$194.88	2	0.00%
DEXTROAMPHET TAB 15MG	1	1	$386.35	$386.35	1	0.00%
ZENZEDI TAB 20MG	1	1	$227.96	$227.96	1	0.00%
ZENZEDI TAB 15MG	1	1	$452.51	$452.51	1	0.00%
SUBTOTAL	**101**	**29***	**$9,462.00**	**$93.68**	**3.48**	**0.02%**
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	47	11	$792,643.27	$16,864.75	4.27	1.34%
SOD OXYBATE SOL 500MG/ML	16	5	$163,445.06	$10,215.32	3.2	0.28%
SUBTOTAL	**63**	**11***	**$956,088.33**	**$15,176.01**	**5.73**	**1.62%**
PITOLISANT PRODUCTS						
WAKIX TAB 17.8MG	50	11	$624,788.62	$12,495.77	4.55	1.06%
WAKIX TAB 4.45MG	8	8	$13,671.04	$1,708.88	1	0.02%
SUBTOTAL	**58**	**11***	**$638,459.66**	**$11,007.93**	**5.27**	**1.08%**
CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES PRODUCTS						
XYWAV SOL 0.5GM/ML	53	6	$796,928.73	$15,036.39	8.83	1.35%
SUBTOTAL	**53**	**6***	**$796,928.73**	**$15,036.39**	**8.83**	**1.35%**
SOLRIAMFETOL PRODUCTS						
SUNOSI TAB 150MG	39	5	$29,012.17	$743.90	7.8	0.05%
SUBTOTAL	**39**	**5***	**$29,012.17**	**$743.90**	**7.8**	**0.05%**
TOTAL	**367,487**	**51,343***	**$59,027,559.66**	**$160.62**	**7.16**	**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; SOD = sodium; SOL = solution; SUS = suspension; TAB = tablet

[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 03/2024. Last accessed 03/11/2024.
[2] U.S. FDA. FDA Approves Multiple Generics of ADHD and BED Treatment. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-multiple-generics-adhd-and-bed-treatment. Issued 08/28/2023. Last accessed 03/19/2024.
[3] Mydayis® (Mixed-Salts of a Single-Entity Amphetamine Product) – First-Time Generic. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_mydayis_2023-1012.pdf. Issued 10/10/2023. Last accessed 03/19/2024.
[4] Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, And Amphetamine Sulfate Prescribing Information. Teva Pharmaceuticals, Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=5e84ef60-3050-40d9-9f14-66b85d289e17&type=pdf. Last revised 10/2022. Last accessed 03/19/2024.

Appendix J

Calendar Year 2023 Annual Review of Phenylketonuria (PKU) Medications

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Kuvan® (Sapropterin) Approval Criteria:

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

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved indication to reduce blood phenylalanine concentrations in members with phenylketonuria who have uncontrolled blood phenylalanine concentrations >600micromol/L on existing management; and

2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Documentation the member's average blood phenylalanine concentration over the last 6 months is >600micromol/L on existing management; and
5. Concomitant use with Kuvan® (sapropterin) will not be approved; and
6. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
8. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
9. Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Members should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L; and
    a. If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; or
    b. If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, subsequent approvals will be for the duration of 1 year; and
10. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40mg once daily will not be approved for subsequent approvals; and
11. Subsequent approvals will be for the duration of 1 year; and
12. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

Utilization of PKU Medications: Calendar Year 2023

Comparison of Calendar Years

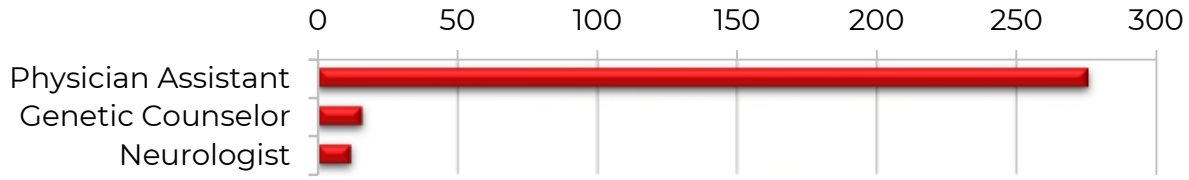
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	32	284	$3,001,676.22	$10,569.28	$354.01	58,341	8,479
2023	34	304	$3,861,350.98	$12,701.81	$431.73	64,564	8,944
% Change	**6.30%**	**7.00%**	**28.60%**	**20.20%**	**22.00%**	**10.70%**	**5.50%**
Change	**2**	**20**	**$859,674.76**	**$2,132.53**	**$77.72**	**6,223**	**465**

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

Demographics of Members Utilizing PKU Medications

- Due to the limited number of members utilizing PKU medications during calendar year 2023, detailed demographic information could not be provided.

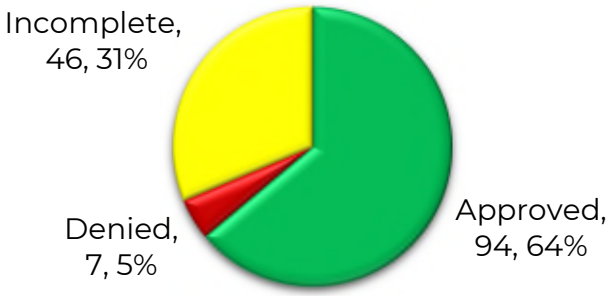
Top Prescriber Specialties of PKU Medications by Number of Claims



Prior Authorization of PKU Medications

There were 147 prior authorization requests submitted for PKU medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Kuvan® (sapropterin) tablets: May 2026
- Kuvan® (sapropterin) powder: May 2033

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

- **October 2020:** The FDA approved a label expansion to allow for a higher dose of Palynziq® (pegvaliase-pqpz) at 60mg once daily. The previous FDA maximum dose was 40mg once daily. The approval was based on the results of the PRISM Phase 3 studies that showed 19% of participants required a 60mg dose to achieve an adequate response to Palynziq®.

News:

- **October 2022:** Cycle Pharmaceuticals Limited announced the launch of Javygtor™ (sapropterin dihydrochloride), which is a generic version of Kuvan®.

Pipeline:

- **Sepiapterin:** Sepiapterin is an oral formulation of synthetic sepiapterin. Sepiapterin is a precursor to intracellular tetrahydrobiopterin, which is an enzyme cofactor used in the degradation of phenylalanine. PTC Therapeutics announced that after meeting with the FDA to discuss the New Drug Application (NDA) submission for sepiapterin, the FDA stated that sepiapterin clinical safety and efficacy data supported the NDA submission for the treatment of pediatric and adult PKU patients; however, they requested that PTC Therapeutics complete an additional 26-week nonclinical mouse study to assess sepiapterin carcinogenicity potential prior to the NDA submission.

Recommendations

The College of Pharmacy recommends the following changes to the Palynziq® (pegvaliase-pqpz) approval criteria based on the new FDA approved label expansion and to be consistent with clinical practice (changes shown in red):

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved indication to reduce blood phenylalanine concentrations in members with phenylketonuria who have uncontrolled blood phenylalanine concentrations >600micromol/L on existing management; and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. ~~Documentation the member's average blood phenylalanine concentration over the last 6 months is >600micromol/L on existing management; and~~

5. Concomitant use with Kuvan® (sapropterin) will not be approved except to allow for temporary coverage during the titration of Palynziq®; and
6. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
8. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
9. Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Members should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L. Slower dose titrations may be approved based on member's response and tolerability; and
    a. If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; ~~or~~ and
    b. If after at least 16 weeks with the 40mg dose, member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, approvals may be granted for the 60mg once daily dosing for an additional 16 weeks of treatment; or
    c. If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, subsequent approvals will be for the duration of 1 year; and
10. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L after at least 16 weeks of continuous treatment with the maximum dosage of ~~40~~ 60mg once daily will not be approved for subsequent approvals; and
11. Subsequent approvals will be for the duration of 1 year; and
12. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

Additionally, the College of Pharmacy recommends the following changes to the Kuvan® (sapropterin) approval criteria based on generic availability, net costs, and to be consistent with clinical practice (changes shown in red):

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

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

Utilization Details of PKU Medications: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SAPROPTERIN PRODUCTS						
KUVAN TAB 100MG	96	14	$1,949,027.36	$20,302.37	6.86	50.48%
KUVAN POW 100MG	58	8	$186,446.58	$3,214.60	7.25	4.38%
SAPROPTERIN POW 500MG	24	5	$168,765.84	$7,031.91	4.8	4.37%
KUVAN POW 500MG	20	4	$166,535.99	$8,326.80	5	4.31%
SAPROPTERIN POW 100MG	19	5	$41,628.54	$2,190.98	3.8	1.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SAPROPTERIN TAB 100MG	19	6	$205,138.79	$10,796.78	3.17	5.31%
JAVYGTOR PAK 100MG	5	2	$13,917.05	$2,783.41	2.5	0.36%
SUBTOTAL	**241**	**44**	**$2,731,460.15**	**$11,333.86**	**5.48**	**70.74%**
PEGVALIASE-PQPZ PRODUCTS						
PALYNZIQ INJ 20MG/ML	36	8	$823,414.76	$22,872.63	4.5	21.32%
PALYNZIQ INJ 10MG/0.5ML	18	6	$288,711.38	$16,039.52	3	7.48%
PALYNZIQ INJ 2.5MG/0.5ML	9	5	$17,764.69	$1,973.85	1.8	0.46%
SUBTOTAL	**63**	**19**	**$1,129,890.83**	**$17,934.78**	**3.32**	**29.26%**
TOTAL	**304**	**34***	**$3,861,350.98**	**$12,701.81**	**8.94**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PAK = packet; POW = powder; TAB = tablet

[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 03/2024. Last accessed 03/01/2024.
[2] Inacio, P. FDA Approves Use of Higher Palynziq® Doses in Adults with PKU. *Phenylketonuria News*. Available online at: https://phenylketonurianews.com/2020/10/14/fda-approves-use-of-higher-palynziq-doses-in-adults-with-pku/. Issued 10/14/2020. Last accessed 03/20/2024.
[3] Cycle Pharma. New U.S. Product, Javygtor™ (Sapropterin Dihydrochloride) Tablets and Powder, Launches for Phenylketonuria (PKU) Treatment. Available online at: https://cyclepharma.com/new-us-product-javygtor-sapropterin-dihydrochloride-tablets-and-powder-launches-for-phenylketonuria-pku-treatment/. Issued 10/23/2022. Last accessed 03/27/2024.
[4] PTC Therapeutics, Inc. PTC Therapeutics Provides Corporate Update and Reports Third Quarter Financial Results. Available online at: https://ir.ptcbio.com/news-releases/news-release-details/ptc-therapeutics-provides-corporate-update-and-reports-third-1. Issued 10/26/2023. Last accessed 03/13/2024.

Appendix K

Calendar Year 2023 Annual Review of Ileal Bile Acid Transporter (IBAT) Inhibitors

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Bylvay® (Odevixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying mutations in the *ATP8B1, ABCB11, or ABCB4* genes; and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ≥100micromol/L at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order

to authorize the appropriate amount of drug required according to package labeling; and

11. Initial approvals will be for 40mcg/kg/day for a duration of 3 months. After 3 months of treatment, further approval may be granted at the 40mcg/kg/day dose if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate; or
12. Dose increases to 80mcg/kg/day (for 3 months) and 120mcg/kg/day (for 3 months) may be approved if there is no improvement in pruritus after 3 months of treatment with the lower dose(s). Further approval may be granted if the prescriber documents the member is responding well to treatment at the current dose and is still not a candidate for surgical intervention; and
13. If there is no improvement in pruritus after 3 months of treatment with the maximum 120mcg/kg/day dose, further approval of Bylvay® will not be granted.

Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying mutations in the *JAG1* or *NOTCH2* genes; and
2. Member must be 1 year of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:
    a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
    b. Conjugated bilirubin >1mg/dL; or
    c. Fat soluble vitamin deficiency otherwise unexplainable; or
    d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
    e. Intractable pruritus explainable only by liver disease; and

6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and
7. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
8. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
9. Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Utilization of IBAT Inhibitors: Calendar Year 2023

Calendar Year 2023 Utilization

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2023	1	1	$86,891.41	$86,891.41	$2,896.38	60	30

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: There were no paid pharmacy claims for IBAT inhibitors during calendar year 2022 to allow for a calendar year comparison.

Demographics of Members Utilizing IBAT Inhibitors

- Due to the limited number of members utilizing IBAT inhibitors during calendar year 2023, detailed demographic information could not be provided.

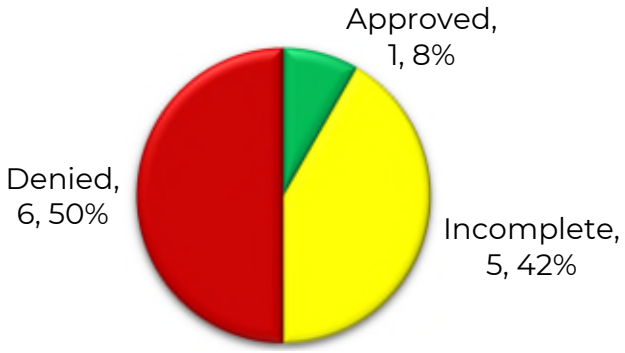
Top Prescriber Specialties of IBAT inhibitors by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for IBAT inhibitors during calendar year 2023 was physician assistant. The physician assistant was supervised by a pediatric gastroenterologist.

Prior Authorization of IBAT Inhibitors

There were 12 prior authorization requests submitted for 3 unique members for IBAT inhibitors during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Exclusivity Expiration(s):

- Livmarli® (maralixibat): February 2040
- Bylvay® (odevixibat): November 2041

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

- **March 2023:** The FDA approved Livmarli® (maralixibat) for an age expansion for the treatment cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS). Livmarli® was previously approved by the FDA in September 2021 for this indication in patients 1 year of age and older.
- **June 2023:** The FDA approved Bylvay® (odevixibat) for a new indication for the treatment of cholestatic pruritus in patients 12 months of age and older with ALGS. The recommended dosage for patients with ALGS is 120mcg/kg (up to 7,200mcg) orally once daily in the morning with a meal.
- **March 2024:** The FDA approved Livmarli® for a new indication for the treatment of cholestatic pruritus in patients 5 years of age and older with progressive familial intrahepatic cholestasis (PFIC). The recommended dosage for patients with PFIC is 570mcg/kg twice daily 30 minutes before a meal. The dose should be titrated initially, starting at 285mcg/kg once daily, then 285mcg/kg twice daily, followed by 428mcg/kg twice daily and 570mcg/kg twice daily, as tolerated.

Pipeline:

- **Volixibat:** Volixibat is an oral IBAT inhibitor that is currently being evaluated for the treatment of primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC). Phase 2b studies are currently

underway for both indications, and interim analyses are expected in the first half of 2024.

Cost Comparison: IBAT Inhibitors

Product	Cost Per Unit*	ALGS Max Cost Per Year†	PFIC Max Cost Per Year†
Bylvay® (odevixibat) 1,200mcg cap	$1,448	$3,127,680	$2,606,400
Livmarli® (maralixibat) 9.5mg/mL sol	$1,780	$1,922,400	$2,563,200

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unit = capsule or mL
†Max cost per year based on the maximum FDA approved dose for each product for each indication
ALGS = Alagille syndrome; cap = capsule; PFIC = progressive familial intrahepatic cholestasis; sol = solution

Recommendations

The College of Pharmacy recommends adding new criteria for Bylvay® (odevixibat) and Livmarli® (maralixibat) based on the new FDA approved indications with the following criteria (shown in red):

Bylvay® (Odevixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in either the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Members with a history of liver transplantation will generally not be approved for Bylvay®; and

7. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
8. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
9. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Livmarli® (Maralixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B* genes (results of genetic testing must be submitted); and
2. Member must be 5 years of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Livmarli®; and

8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

The College of Pharmacy also recommends updating the Livmarli® approval criteria for ALGS based on the new FDA approved age expansion and to be consistent with current labeling and clinical practice (changes shown in red):

Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying ~~mutations~~ a pathogenic variant in the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be ~~1 year~~ 3 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:

   a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
   b. Conjugated bilirubin >1mg/dL; or
   c. Fat soluble vitamin deficiency otherwise unexplainable; or
   d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
   e. Intractable pruritus explainable only by liver disease; and
6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
10. Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Lastly, the College of Pharmacy recommends updating the Bylvay® approval criteria for PFIC based on clinical practice (changes shown in red):

Bylvay® (Odevixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of pruritus in members with PFIC; and
   a. Diagnosis must be confirmed by genetic testing identifying ~~mutations~~ biallelic pathogenic variants in the *ATP8B1, ABCB11, or ABCB4* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a

gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and

4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ≥100micromol/L at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for 40mcg/kg/day for a duration of 3 months. After 3 months of treatment, further approval may be granted at the 40mcg/kg/day dose if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate; or
12. Dose increases to 80mcg/kg/day (for 3 months) and 120mcg/kg/day (for 3 months) may be approved if there is no improvement in pruritus after 3 months of treatment with the lower dose(s). Further approval may be granted if the prescriber documents the member is responding well to treatment at the current dose and is still not a candidate for surgical intervention; and
13. If there is no improvement in pruritus after 3 months of treatment with the maximum 120mcg/kg/day dose, further approval of Bylvay® will not be granted.

Utilization Details of IBAT Inhibitors: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ODEVIXIBAT PRODUCTS						
BYLVAY CAP 1,200MCG	1	1	$86,891.41	$86,891.41	1	100%
TOTAL	**1**	**1***	**$86,891.41**	**$86,891.41**	**1**	**100%**

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

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Appendix L

Calendar Year 2023 Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Augtyro™ (Repotrectinib) and Pemrydi RTU® (Pemetrexed)

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Utilization data for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Mektovi® (binimetinib), Opdivo® (nivolumab), Tafinlar® (dabrafenib), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) and approval criteria for indications other than lung cancer can be found in the December 2023 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 2024 DUR Board packet. Cyramza® is reviewed annually with the gastrointestinal cancer medications. Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki) and approval criteria for indications other than lung cancer can be found in the September 2023 DUR Board packet. Enhertu® is 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
2. Anaplastic lymphoma kinase (ALK) positivity; and
3. First-line or recurrent setting; and
4. 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.

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.

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.

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

1. Diagnosis of advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
3. Disease has progressed on or after platinum-based chemotherapy; and
4. As a single agent.

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 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); 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.

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 [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.

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

1. Diagnosis of unresectable stage II or III NSCLC; and
    a. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; or
2. Diagnosis of metastatic NSCLC; and
    a. No epidermal growth factor (EGFR) mutation or anaplastic lymphoma kinase (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) 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. As a single agent for disease progression on or after platinum-containing chemotherapy (e.g., 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*; and
        1. *Examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib; or*
    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*; and
        1. *Examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib*.

Keytruda® (Pembrolizumab) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

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

Keytruda® (Pembrolizumab) Approval Criteria [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 [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.

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.

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

1. Diagnosis of NSCLC; and
2. For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:
    a. Used in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Expresses programmed death ligand 1 (PD-L1) ≥1%; or
3. For first-line therapy for resectable disease (>4cm or node positive), meeting the following:
    a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or
4. For second-line therapy for metastatic disease, meeting the following:
    a. Tumor histology is 1 of the following:
        i. Adenocarcinoma; or
        ii. Squamous cell; or
        iii. Large cell; and
    b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
    d. Used as a single agent; and
    e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. Member meets 1 of the following:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease progression on initial chemotherapy; and
3. As a single agent or in combination with ipilimumab; and

4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Pemfexy® (Pemetrexed; J9304) and Pemetrexed 25mg/mL Solution (J9297 - Sandoz) Approval Criteria:

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

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. 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
3. As a single agent.

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

1. Adult and pediatric members 12 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 12 years of age or older; 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; and
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
3. Disease has progressed on or after platinum-based chemotherapy; and
4. As a single agent.

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; or
2. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease; or
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and
3. As a single agent.

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 kidney cancer; and
2. Non-clear cell type; and

3. Relapsed disease or surgically unresectable stage IV disease; and
4. As a single agent only.

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. Locally advanced, unresectable disease or metastatic disease; and
3. In combination with gemcitabine.

Tarceva® (Erlotinib) Approval Criteria [Pancreatic Cancer Diagnosis]:
1. Diagnosis of pancreatic cancer; and
2. Locally advanced unresectable or metastatic disease; and
3. First-line agent only; and
4. In combination with gemcitabine.

Tecentriq® (Atezolizumab) 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.

Tecentriq® (Atezolizumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:
1. Diagnosis of advanced unresectable or metastatic disease; and
2. Used in combination with bevacizumab; and
3. Member has not received prior systemic therapy.

Tecentriq® (Atezolizumab) Approval Criteria [Melanoma Diagnosis]:
1. Unresectable or metastatic disease; and
2. BRAF V600 mutation-positive; and
3. In combination with cobimetinib and vemurafenib.

Tecentriq® (Atezolizumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:
1. Diagnosis of Non-Squamous NSCLC:
    a. First-line therapy for metastatic disease; and
    b. Member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), *ROS1*, *BRAF*, MET exon 14 skipping, or rearranged during transfection (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:
   a. For first-line therapy for metastatic disease:
      i. As a single agent; and
      ii. Member does not have EGFR, 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:
      i. As a single agent only; or
3. Diagnosis of stage II or III3A NSCLC; and
   a. Member has undergone resection and completed platinum-based chemotherapy; and
   b. PD-L1 expression of ≥1% of TC.

Tecentriq® (Atezolizumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. First-line therapy; and
3. Extensive-stage disease; and
4. In combination with carboplatin and etoposide.

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
3. Anaplastic lymphoma kinase (ALK) positive; and
4. 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 must meet the following:
        i. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy; and
        ii. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
        iii. Expresses programmed death ligand 1 (PD-L1) ≥1%.

Yervoy® (Ipilimumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of SCLC; and
2. Member meets 1 of the following:
    a. Disease relapsed within 6 months of initial chemotherapy; or

    b. Disease is progressive on initial chemotherapy; and
3. In combination with nivolumab.

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: Calendar Year 2023

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.

Calendar Year Comparison: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	23	122	$2,031,155.02	$16,648.81	$550.45	15,510	3,690
2023	27	193	$3,183,639.66	$16,495.54	$552.91	22,702	5,758
% Change	**17.40%**	**58.20%**	**56.70%**	**-0.90%**	**0.40%**	**46.40%**	**56.00%**
Change	**4**	**71**	**$1,152,484.64**	**-$153.27**	**$2.46**	**7,192**	**2,068**

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

Calendar Year Comparison: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	161	993	$6,980,375.42	$7,029.58	6.17
2023	183	1,066	$6,832,802.45	$6,409.76	5.83
% Change	**13.66%**	**7.35%**	**-2.11%**	**-8.82%**	**-5.51%**
Change	**22**	**73**	**-$147,572.97**	**-$619.82**	**-0.34**

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

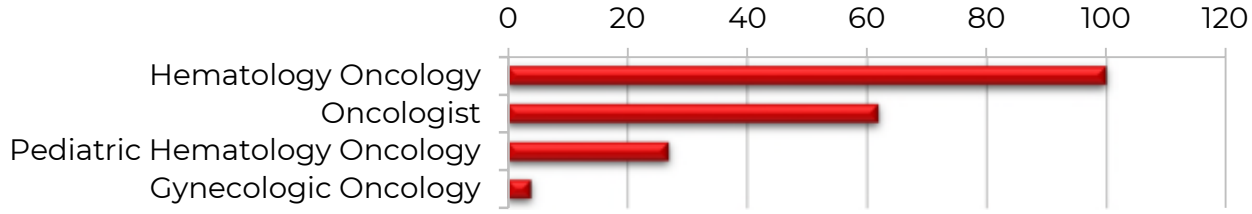
- Aggregate drug rebates collected during fiscal year 2023 (07/01/2022 to 06/30/2023) for lung cancer medications totaled $3,233,175.16.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2023 are still being collected at this time. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Lung Cancer Medications: Pharmacy Claims

- Due to the limited number of members utilizing lung cancer medications during calendar year 2023, detailed demographic information could not be provided.

Top Prescriber Specialties of Lung Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Lung Cancer Medications

There were 375 prior authorization requests submitted for lung cancer medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions

Market News and Updates[1,2,34,5,6,7,8,9,10,11,12]

Anticipated Patent Expiration(s):

- Vizimpro® (dacomitinib): August 2028
- Xalkori® (crizotinib): November 2029
- Zepzelca® (lurbinectedin): December 2029
- Tepmetko® (tepotinib): March 2030
- Gilotrif® (afatinib): January 2031
- Zykadia® (ceritinib): February 2032
- Tagrisso® (osimertinib): January 2035
- Alecensa® (alectinib): April 2035
- Exkivity® (mobocertinib): May 2035
- Tabrecta® (capmatinib): July 2035

- Alunbrig® (brigatinib): November 2035
- Pemfexy® (pemetrexed): February 2036
- Augtyro (repotrectinib): July 2036
- Krazati® (adagrasib): May 2037
- Rozlytrek® (entrectinib): July 2038
- Lorbrena® (lorlatinib): October 2038
- Retevmo® (selpercatinib): October 2038
- Gavreto® (pralsetinib): April 2039
- Cosela® (trilaciclib): July 2039
- Lumakras® (sotorasib): September 2040

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

- **June 2023:** The FDA approved Pemrydi RTU® (pemetrexed), a new formulation of pemetrexed that is available as a ready-to-use solution for intravenous (IV) infusion that does not require reconstitution or dilution prior to administration. Pemrydi RTU® will be available in 3 single-dose vial sizes: 100mg/10mL, 500mg/50mL, and 1,000mg/100mL. Pemrydi RTU® was approved through the FDA's 505(b)(2) approval process using the established safety and efficacy data for Alimta® (pemetrexed).
- **October 2023:** The FDA granted accelerated approval for an age expansion for Rozlytrek® (entrectinib) for patients 1 month of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy. Additionally, the FDA approved the medication in a new oral pellet dosage form. Rozlytrek® was previously granted accelerated approval for this indication in patients 12 years of age and older.
- **November 2023:** The FDA approved Augtyro™ (repotrectinib) for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).
- **February 2024:** The FDA approved a new indication for Tagrisso® (osimertinib), in combination with pemetrexed and platinum-based chemotherapy, for the first-line treatment of adult patients with locally advanced or metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- **March 2024:** The FDA approved a new indication for Rybrevant® (amivantamab-vmjw), in combination with carboplatin and pemetrexed, for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test.

News:

- **June 2023:** Genentech, the manufacturer of Gavreto® (pralsetinib), announced the voluntary withdrawal of the previous accelerated approval for the treatment of adults and pediatric patients 12 years of age and older with advanced or metastatic rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) who require systemic therapy. The decision to withdraw this indication was based on difficulty conducting the required confirmatory study.
- **October 2023:** Takeda, the manufacturer of Exkivity® (mobocertinib) announced the voluntary withdrawal of the previous accelerated approval for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for hepatocellular carcinoma allow the use of Imfinzi® (durvalumab) as a single agent for unresectable hepatocellular carcinoma.
- The NCCN guidelines for pancreatic adenocarcinoma recommend the use of Tarceva® (erlotinib) in combination with gemcitabine in patients with locally advanced or metastatic disease and an Eastern Cooperative Oncology Group (ECOG) score of 0 or 1 as either first-line or subsequent therapy.
- The NCCN guidelines for NSCLC recommend the use of Rybrevant® (amivantamab-vmjw) for locally advanced or metastatic NSCLC with tumors that exhibit EGFR exon 19 deletion or exon 21 L858R mutations as subsequent therapy, in combination with carboplatin and pemetrexed, after disease progression on osimertinib.

Augtyro™ (Repotrectinib) Product Summary[13]

Therapeutic Class: Kinase inhibitor

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

How Supplied: 40mg oral capsule

Dosing and Administration: 160mg [(4) 40mg capsules] orally once daily with or without food for 14 days, then increase to 160mg twice daily until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) is $120.83 per capsule, resulting in a cost of $6,766.48 for the initial 14 days of treatment. Subsequent cost

would be $28,999.20 per 30 days or $347,990.40 per year based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Augtyro™ (repotrectinib) based on recent FDA approval with the following criteria (shown in red):

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.

The College of Pharmacy also recommends the prior authorization of Pemrydi RTU® (pemetrexed) with criteria similar to Pemfexy® (pemetrexed) and recommends updating the approval criteria for the pemetrexed products based on net costs (changes shown in red):

Pemfexy® (Pemetrexed; J9304) and Pemrydi RTU® (Pemetrexed; J9324) ~~Pemetrexed 25mg/mL Solution (J9297 - Sandoz)~~ 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.

Next, the College of Pharmacy recommends updating the Rozlytrek® (entrectinib), Rybrevant® (amivantamab-vmjw), and Tagrisso® (osimertinib) approval criteria based on new FDA approvals and NCCN recommendations (changes shown in red):

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

1. Diagnosis of solid tumors; and
2. Member must be older than 1 month ~~12 years~~ of age ~~or older~~; 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. ~~Disease has progressed on or after platinum-based chemotherapy; and~~
4. ~~As a single agent.~~
5. Tumor exhibits EGFR exon 19 deletion or exon 21 L858R mutations; and
    a. As subsequent therapy in combination with carboplatin and pemetrexed after progression on osimertinib.

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; ~~or~~ and
    b. As a single agent; or
2. 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
3. ~~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.

Next, the College of Pharmacy recommends updating the approval criteria for Imfinzi® (durvalumab) and Tarceva® (erlotinib) based on NCCN guideline recommendations (changes shown in red):

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.

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.

~~**Tarceva® (Erlotinib) Approval Criteria [Pancreatic Cancer Diagnosis]:**~~

~~1. Diagnosis of pancreatic cancer; and~~
~~2. Locally advanced unresectable or metastatic disease; and~~
~~3. First-line agent only; and~~
~~4. In combination with gemcitabine.~~

Lastly, the College of Pharmacy recommends updating the approval criteria for Exkivity® (mobocertinib) based on the planned withdrawal of its accelerated approval and Gavreto® (pralsetinib) based on the withdrawal of the accelerated approval for the treatment of patients with advanced or metastatic RET-mutant MTC who require systemic therapy (changes shown in red):

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

1. Diagnosis of advanced or metastatic NSCLC; and
2. Tumor exhibits an epidermal growth factor receptor (EGFR) exon 20 insertion mutation; and
3. Disease has progressed on or after platinum-based chemotherapy; and
4. As a single agent; and
5. Members who are new to treatment with Exkivity® will generally not be approved.

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 ~~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); and
3. As a single agent.

Utilization Details of Lung Cancer Medications: Calendar Year 2023

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.

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OSIMERTINIB PRODUCTS						
TAGRISSO TAB 80MG	55	8	$887,430.41	$16,135.10	6.88	27.87%
TAGRISSO TAB 40MG	12	2	$193,705.34	$16,142.11	6	6.08%
SUBTOTAL	**67**	**10**	**$1,081,135.75**	**$16,136.35**	**6.7**	**33.96%**
ALECTINIB PRODUCTS						
ALECENSA CAP 150MG	53	5	$927,384.29	$17,497.82	10.6	29.13%
SUBTOTAL	**53**	**5**	**$927,384.29**	**$17,497.82**	**10.6**	**29.13%**
SELPERCATINIB PRODUCTS						
RETEVMO CAP 80MG	25	2	$392,163.25	$15,686.53	12.5	12.32%
RETEVMO CAP 40MG	13	1	$275,987.53	$21,229.81	13	8.67%
SUBTOTAL	**38**	**3**	**$668,150.78**	**$17,582.92**	**12.67**	**20.99%**
SOTORASIB PRODUCTS						
LUMAKRAS TAB 320MG	6	1	$120,707.64	$20,117.94	6	3.79%
LUMAKRAS TAB 120MG	3	1	$60,365.82	$20,121.94	3	1.90%
SUBTOTAL	**9**	**2**	**$181,073.46**	**$20,119.27**	**4.5**	**5.69%**
AFATINIB PRODUCTS						
GILOTRIF TAB 20MG	8	1	$88,985.66	$11,123.21	8	2.80%
SUBTOTAL	**8**	**1**	**$88,985.66**	**$11,123.21**	**8**	**2.80%**
ADAGRASIB PRODUCTS						
KRAZATI TAB 200MG	7	1	$140,632.37	$20,090.34	7	4.42%
SUBTOTAL	**7**	**1**	**$140,632.37**	**$20,090.34**	**7**	**4.42%**
ERLOTINIB PRODUCTS						
ERLOTINIB TAB 150MG	4	1	$1,289.64	$322.41	4	0.04%
ERLOTINIB TAB 100MG	3	2	$788.41	$262.80	1.5	0.02%
SUBTOTAL	**7**	**3**	**$2,078.05**	**$296.86**	**2.33**	**0.07%**
MOBOCERTINIB PRODUCTS						
EXKIVITY CAP 40MG	2	1	$53,518.82	$26,759.41	2	1.68%
SUBTOTAL	**2**	**1**	**$53,518.82**	**$26,759.41**	**2**	**1.68%**
CAPMATINIB PRODUCTS						
TABRECTA TAB 200MG	1	1	$21,584.51	$21,584.51	1	0.68%
SUBTOTAL	**1**	**1**	**$21,584.51**	**$21,584.51**	**1**	**0.68%**
ENTRECTINIB PRODUCTS						
ROZLYTREK CAP 200MG	1	1	$19,095.97	$19,095.97	1	0.60%
SUBTOTAL	**1**	**1**	**$19,095.97**	**$19,095.97**	**1**	**0.60%**
TOTAL	**193**	**27***	**$3,183,639.66**	**$16,495.54**	**7.15**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PEMETREXED J9305	394	70	$346,173.50	$878.61	5.63
ATEZOLIZUMAB J9022	314	50	$3,187,845.36	$10,152.37	6.28
DURVALUMAB J9173	286	58	$2,772,302.32	$9,693.36	4.93
LURBINECTEDIN J9223	36	11	$407,281.12	$11,313.36	3.27
PEMETREXED J9294	20	3	$7,487.20	$374.36	6.67
TREMELIMUMAB-ACTL J9347	6	3	$92,121.75	$15,353.63	2
TRILACICLIB J1448	6	1	$17,659.20	$2,943.20	6
PEMETREXED J9296	4	2	$1,932.00	$483.00	2
TOTAL	**1,066**	**183**	**$6,832,802.45**	**$6,409.76**	**5.83**

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

[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 03/2024. Last accessed 03/13/2024.
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[3] Pemrydi RTU® (Pemetrexed Injection) Prescribing Information. Amneal Pharmaceuticals, Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=0f006b06-ab85-423d-ba0c-dfc3fc25844e&type=pdf. Last revised 06/2023. Last accessed 03/22/2024.
[4] U.S. FDA. FDA Expands Pediatric Indication for Entrectinib and Approves New Pellet Formulation. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-pediatric-indication-entrectinib-and-approves-new-pellet-formulation. Issued 10/20/2023. Last accessed 03/13/2024.
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Appendix M

Calendar Year 2023 Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Glipizide 2.5mg Tablet, Inpefa® (Sotagliflozin), Lantidra™ (Donislecel-jujn), Metformin 625mg Tablet, Zituvio™ (Sitagliptin), and Zituvimet™ (Sitagliptin/Metformin)

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/ glipizide (Metaglip®)			metformin ER susp (Riomet ER™)
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	
	linagliptin/ metformin (Jentadueto®)	alogliptin/ metformin (Kazano®)	
	linagliptin/ metformin ER (Jentadueto® XR)	alogliptin/ pioglitazone (Oseni®)	
	saxagliptin (Onglyza®)		

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)		
	sitagliptin (Januvia®)		
	sitagliptin/ metformin (Janumet®)		
	sitagliptin/ metformin ER (Janumet XR®)		
DPP-4 Inhibitors/SGLT-2 Inhibitors			
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/ sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	exenatide ER autoinjector (Bydureon BCise®)	lixisenatide (Adlyxin®)
	exenatide (Byetta®)	semaglutide (Ozempic®)	tirzepatide (Mounjaro®)
	liraglutide (Victoza®)	semaglutide (Rybelsus®)	
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)+	
		insulin glargine/ lixisenatide (Soliqua® 100/33)+	
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®)	dapagliflozin/ metformin ER (Xigduo® XR)	canagliflozin (Invokana®)	bexagliflozin (Brenzavvy®)

Anti-Diabetic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
empagliflozin (Jardiance®)	empagliflozin/ metformin (Synjardy®)	canagliflozin/ metformin (Invokamet®)	canagliflozin/ metformin ER (Invokamet® XR)
	empagliflozin/ metformin ER (Synjardy® XR)		ertugliflozin (Steglatro®)
			ertugliflozin/ metformin (Segluromet®)
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)
Sulfonylureas			
glimepiride (Amaryl®)			
glipizide (Glucotrol®)			
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
⁺Unique criteria applies.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release; susp = suspension

Anti-Diabetic Medications Tier-2 Approval Criteria:

1. A trial at least 3 months in duration (unless intolerable adverse effects) of metformin titrated up to maximum tolerated dose or a patient-specific, clinically significant reason why a 3-month trial of metformin

titrated up to maximum tolerated dose is not appropriate must be provided.
2. For initiation with dual or triple therapy, additional Tier-2 medications may be approved based on current American Association of Clinical Endocrinologists (AACE) or American Diabetes Association (ADA) guidelines.
3. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Tier-3 Approval Criteria:

1. Member must have a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with 1 Tier-2 medication in the same category and have a documented clinical reason why the member cannot continue treatment with the Tier-2 medication. For intolerable adverse effects, the member must have a documented clinical reason why they cannot utilize a different Tier-2 medication in the same category, a Tier-2 medication in a different category, or provide detailed information regarding adverse effects occurring with the Tier-2 medication(s) that are not expected to occur with the requested Tier-3 medication that is in the same category. (For Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used).
2. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Special Prior Authorization (PA) Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
2. Use of Invokamet® XR [canagliflozin/metformin extended-release (ER)] will require a patient-specific, clinically significant reason why the member cannot take the immediate-release formulation(s); and
3. Use of Adlyxin® (lixisenatide) or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 (GLP-1) receptor agonists.

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

1. An FDA approved diagnosis of diabetes mellitus; and

2. A patient-specific, clinically significant reason why the member cannot use Humalog® (the brand formulation of Humalog® is preferred).

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:
1. An FDA approved diagnosis of diabetes mellitus (DM); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate must be provided; and
4. For the diagnosis of type 1 DM, the member must use Afrezza® with a long-acting insulin; and
5. Member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Basaglar® (Insulin Glargine) Approval Criteria:
1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Levemir® (insulin detemir) must be provided.

Fiasp® (Insulin Aspart) Approval Criteria:
1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use NovoLog® (insulin aspart) must be provided.

Humalog® KwikPen® U-200 (Insulin Lispro 200 Units/mL) and Lyumjev® KwikPen U-200 (Insulin Lispro-aabc 200 Units/mL) Approval Criteria:
1. An FDA approved diagnosis of diabetes mellitus; and
2. Authorization of the 200 units/mL strength requires a patient-specific, clinically significant reason why the member cannot use the 100 units/mL strength (the brand formulation of Humalog® U-100 is preferred).

Humulin® R U-500 Vials (Insulin Human 500 Units/mL) Approval Criteria:
1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use the Humulin® R U-500 KwikPen® (insulin human 500 units/mL), which is available without prior authorization, must be provided.

Kerendia® (Finerenone) Approval Criteria:
1. An FDA approved indication to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and

2. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and
3. A patient specific, clinically significant reason why the member cannot use a sodium-glucose cotransporter-2 (SGLT-2) inhibitor must be provided; and
4. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
5. Member must not have adrenal insufficiency; and
6. Member must not have severe hepatic impairment (Child Pugh C); and
7. Prescriber must measure serum potassium and eGFR prior to initiation of Kerendia®; and
8. Prescriber must verify serum potassium is not >5.0mEq/L prior to treatment initiation with Kerendia®; and
9. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
10. Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and
11. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
    a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
    b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2.

Rezvoglar™ (Insulin Glargine-aglr) and Semglee® (Insulin Glargine-yfgn) Approval Criteria:

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

Ryzodeg® (Insulin Degludec/Insulin Aspart) Approval Criteria:

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

Soliqua® 100/33 (Insulin Glargine/Lixisenatide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) with an alternative glucagon-like peptide 1 (GLP-1) receptor agonist must be provided; and
3. Current Tier-3 criteria will apply.

Symlin® (Pramlintide) Approval Criteria:

1. An FDA approved diagnosis of type 1 or type 2 diabetes; and
2. Member must be using a basal-bolus insulin regimen; and
3. Member must have failed to achieve adequate glycemic control on basal-bolus insulin regimen or are gaining excessive weight on basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a health care professional; and
5. Members meeting any of the following criteria should not be considered for Symlin® (pramlintide) therapy:
    a. Poor compliance with insulin regimen; or
    b. Poor compliance with self-blood glucose monitoring; or
    c. Hemoglobin A1C (HbA1c) >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past 6 months; or
    e. Presence of hypoglycemia unawareness; or
    f. Diagnosis of gastroparesis; or
    g. Required use of medications that stimulate gastrointestinal motility; or
    h. Pediatric members 15 years of age or younger.

Toujeo® (Insulin Glargine) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) must be provided, and the member must be using a minimum of 100 units of Lantus® (insulin glargine) per day.

Tresiba® (Insulin Degludec) Approval Criteria:

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

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
    a. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies; and

        i. Documentation must be submitted with results of autoantibody testing; and
    b. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by an abnormal oral glucose tolerance test (OGTT) meeting 1 of the following:
        i. Fasting plasma glucose ≥110mg/dL and <126mg/dL; or
        ii. 2-hour plasma glucose ≥140 mg/dL and <200mg/dL; or
        iii. 30-, 60-, or 90-minute value on OGTT ≥200mg/dL; and
2. Member must be 8 years of age or older; and
3. Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and
4. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. All of the following will be required for initiation of treatment:
    a. Verification that female members of reproductive potential are not pregnant and are currently using reliable contraception; and
    b. Verification that the member has no active infection(s); and
    c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
    d. Liver function tests and verification that levels are acceptable to the prescriber; and
    e. Verification that all age-appropriate vaccinations have been administered prior to treatment; and
    f. Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and
6. Tzield® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tzield® will be administered; and
    a. Tzield® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tzield® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver must be trained on the proper storage of Tzield®; and
7. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. A quantity limit of 28mL per 14 days will apply; and
9. Approvals will be for (1) 14-day cycle per member per lifetime.

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

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

Utilization of Anti-Diabetic Medications and Kerendia® (Finerenone): Calendar Year 2023

Comparison of Calendar Years:
Non-Insulin Anti-Diabetic Medications and Kerendia® (Finerenone)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	30,809	154,146	$59,451,352.90	$385.68	$7.32	12,085,950	8,126,976
2023	38,694	202,223	$102,446,028.55	$506.60	$9.86	14,142,666	10,391,917
% Change	**25.60%**	**31.20%**	**72.30%**	**31.40%**	**34.70%**	**17.00%**	**27.90%**
Change	**7,885**	**48,077**	**$42,994,675.65**	**$120.92**	**$2.54**	**2,056,716**	**2,264,941**

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

- Aggregate drug rebates collected during fiscal year 2023 (07/01/2022 to 06/30/2023) for anti-diabetic medications and Kerendia® totaled $74,612,048.89.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2023 are still being collected at this time. The costs included in this report do not reflect net costs.

Comparison of Calendar Years:
Insulin Medications

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	14,019	83,157	$49,135,690.62	$590.88	$13.55	1,846,308	3,625,345
2023	15,637	88,267	$52,052,561.80	$589.72	$13.28	1,969,779	3,919,554
% Change	**11.50%**	**6.10%**	**5.90%**	**-0.20%**	**-2.00%**	**6.70%**	**8.10%**
Change	**1,618**	**5,110**	**$2,916,871.18**	**-$1.16**	**-$0.27**	**123,471**	**294,209**

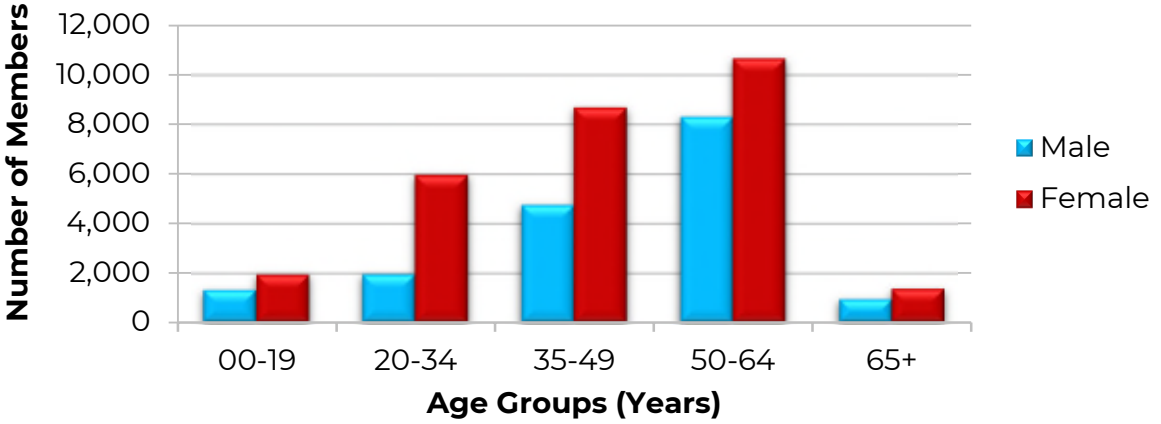
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

- Aggregate drug rebates collected during fiscal year 2023 (07/01/2022 to 06/30/2023) for insulin medications totaled $56,211,346.55.[Δ] Rebates are

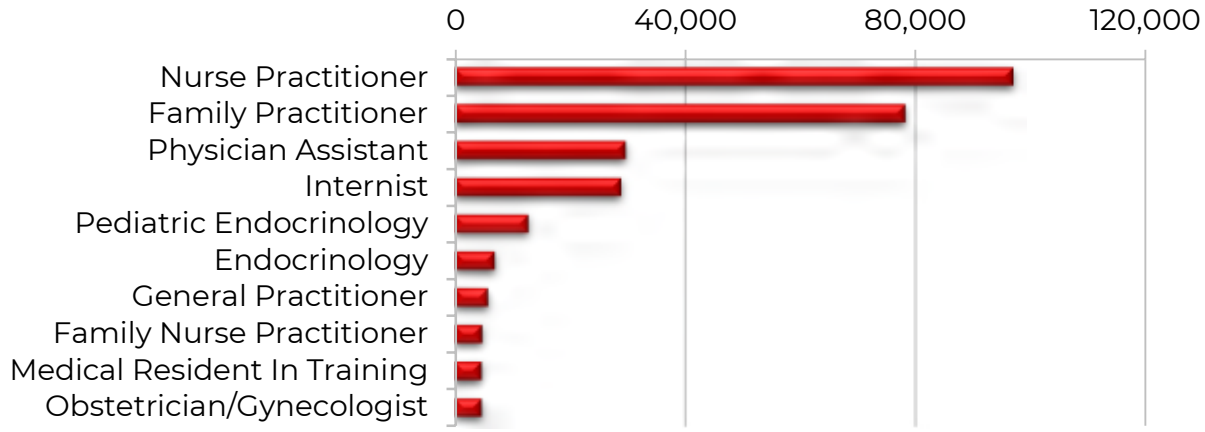
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2023 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Anti-Diabetic Medications and Kerendia® (Finerenone)



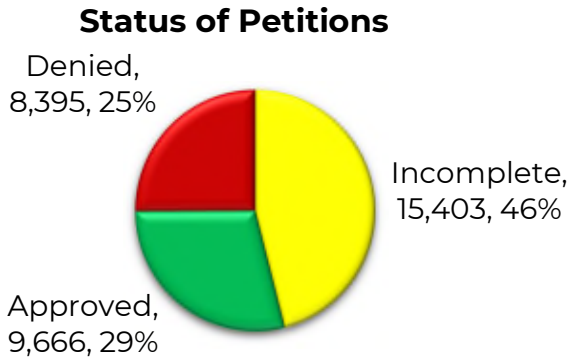
Top Prescriber Specialties of Anti-Diabetic Medications and Kerendia® (Finerenone) by Number of Claims



Prior Authorization of Anti-Diabetic Medications and Kerendia® (Finerenone)

There were 33,464 prior authorization requests submitted for anti-diabetic medications and Kerendia® during calendar year 2023. Of the 33,464 total prior authorization requests submitted, 28,815 were for non-insulin anti-diabetic medications and Kerendia® and 4,649 were for insulin products. Computer edits are in place to detect lower tiered non-insulin medications in a member's recent claims history and generate automated prior

authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2023.



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]

Anticipated Patent Expiration(s):

- Kombiglyze® XR [saxagliptin/metformin extended-release (ER) tablet]: July 2025
- Januvia® (sitagliptin tablet): May 2027
- Janumet® XR (sitagliptin/metformin ER tablet): May 2027
- Onglyza® (saxagliptin tablet): November 2028
- Janumet® (sitagliptin/metformin tablet): January 2029
- Actoplus Met® (pioglitazone/metformin tablet): February 2029
- Invokamet® XR (canagliflozin/metformin ER tablet): February 2029
- Qtern® (dapagliflozin/saxagliptin tablet): December 2029
- Farxiga® (dapagliflozin tablet): May 2030
- Invokamet® (canagliflozin/metformin tablet): July 2030
- Steglatro® (ertugliflozin tablet): July 2030
- Inpefa® (sotagliflozin tablet): October 2030
- Segluromet® (ertugliflozin/metformin tablet): October 2030
- Steglujan® (ertugliflozin/sitagliptin tablet): October 2030
- Xigduo® XR (dapagliflozin/metformin ER tablet): November 2030
- Jentadueto® (linagliptin/metformin tablet): December 2030
- Bydureon BCise® (exenatide ER auto-injector): April 2031
- Invokana® (canagliflozin tablet): May 2031
- Tradjenta® (linagliptin tablet): September 2031
- Cycloset® (bromocriptine tablet): April 2032
- Brenzavvy® (bexagliflozin tablet): May 2032
- Jentadueto XR® (linagliptin/metformin ER tablet): March 2033
- Ozempic® (semaglutide injection): June 2033
- Jentadueto® XR (linagliptin/metformin ER tablet): September 2033
- Adlyxin® (lixisenatide injection): March 2034

- Rybelsus® (semaglutide tablet): May 2034
- Glyxambi® (empagliflozin/linagliptin tablet): October 2034
- Jardiance® (empagliflozin tablet): November 2034
- Synjardy® (empagliflozin/metformin tablet): November 2034
- Synjardy® XR (empagliflozin/metformin ER tablet): December 2034
- Trijardy® XR (empagliflozin/linagliptin/metformin ER tablet): December 2034
- Zituvio™ (sitagliptin tablet): February 2035
- Riomet ER™ (metformin ER oral suspension): May 2035
- Kerendia® (finerenone tablet): July 2035
- Victoza® (liraglutide injection): July 2037
- Mounjaro® (tirzepatide injection): June 2039

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

- **May 2023:** The FDA approved Inpefa® (sotagliflozin) to reduce the risk of cardiovascular (CV) death, hospitalization for heart failure (HF), and urgent HF visit in adults with HF or type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), and other CV risk factors. Inpefa® is a sodium-glucose co-transporter (SGLT) inhibitor that inhibits SGLT type 2 (SGLT-2) and type 1 (SGLT-1).
- **June 2023:** The FDA approved Lantidra™ (donislecel-jujn) for the treatment of adults with type 1 diabetes mellitus (T1DM) who are unable to approach target glycated hemoglobin (Hgb) because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Lantidra™ is an allogeneic pancreatic islet cellular therapy made from deceased donor pancreatic cells and is believed to allow for the secretion of insulin by the infused islet beta cells, with some patients being able to now produce enough insulin from the infused cells to no longer require the use of exogenous insulin.
- **June 2023:** The FDA approved Jardiance® (empagliflozin) and Synjardy® (empagliflozin/metformin) for an age expansion in pediatric patients 10 years of age or older with T2DM. These medications were previously only approved in adults and metformin was the only approved oral therapy for pediatric patients with T2DM.
- **October 2023:** The FDA approved a New Drug Application (NDA) for Zituvio™ (sitagliptin). Zituvio™ is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM. It includes the same active ingredient as Januvia® and is available in the same strengths of 25mg, 50mg and 100mg.
- **November 2023:** Zituvimet™ (sitagliptin/metformin) was FDA approved as an adjunct to diet and exercise to improve glycemic

control in adults with T2DM. This combination is also available under the brand name Janumet® for the same indication.

News:

- **February 2022:** The FDA approved the generic formulation of dapagliflozin in a 5mg and 10mg dose. However, due to patent protection on Farxiga®, the generic formulations were not launched until January 3, 2024. An authorized generic of Xigduo® XR (dapagliflozin/metformin) has also been launched.
- **September 2022:** Novo Nordisk announced the launch of an unbranded version of Tresiba® (insulin degludec) for use in patients 1 year of age or older with diabetes. The unbranded version was originally FDA approved in July 2022.
- **March 2023:** Sanofi launched insulin glargine U-300 which is an unbranded version of Toujeo® (insulin glargine U-300). The unbranded version will have the same manufacturing and inactive ingredients as Toujeo®.
- **March 2023:** AstraZeneca has permanently discontinued brand name Onglyza® (saxagliptin) and Kombiglyze® XR (saxagliptin/metformin) due to business decisions and stated that it was not due to any safety or efficacy related concerns. Generic formulations of saxagliptin and saxagliptin/metformin were launched in August 2023 and remain available.
- **July 2023:** Metformin 625mg tablets were launched. Metformin was previously only available as 500mg, 850mg, and 1,000mg tablets in the immediate-release formulation.
- **October 2023:** Phase 3 data was presented at the International Society for Pediatric and Adolescent Diabetes (ISPAD) conference showing that Tzield® (teplizumab-mzwv) met its primary endpoint of slowing the decline of C-peptide levels in newly diagnosed patients with stage 3 T1DM who were 8 to 17 years of age. This primary endpoint shows the slowing of beta cell loss and the preservation of beta cell function in these patients. Tzield® was approved by the FDA in November 2022 to delay the onset of stage 3 T1DM.
- **October 2023:** A new strength of glipizide 2.5mg immediate-release tablets was launched and is now available from TruPharma, LLC.
- **November 2023:** Novo Nordisk announced the discontinuation of Levemir® (insulin detemir) due to manufacturing issues and available alternatives. The FlexPen® will be discontinued by April 1, 2024 and the vials will be discontinued by December 31, 2024.

Guideline Update(s):

- **American Diabetes Association (ADA) Guideline Update(s):** The ADA released the *Standards of Medical Care in Diabetes 2024*, to include

new and updated practice guidelines to care for patients with diabetes and prediabetes. Some notable updates and additions include:

- New updates on the diagnosis and classification of diabetes were included and guidance was provided on screening and the use of Tzield® for patients with T1DM. For patients with multiple confirmed islet autoantibodies, testing for dysglycemia can be used and these patients should be referred to a specialized center for further evaluation and/or consideration of approved therapies such as Tzield® to delay the onset of stage 3 T1DM.
- Additional guidance was provided on the use of glucagon-like peptide 1 (GLP-1) agonists or dual glucose-dependent insulinotropic polypeptide (GIP) receptor agonists to reach sustained weight management goals.
- Updates were provided on the use of continuous glucose monitoring (CGM) devices. This update includes offering a CGM to patients with T1DM early in the disease, including at the time of diagnosis to allow for the potential of achieving glycemic goals as early as possible.
- Recommendations were added to screen adults with diabetes for asymptomatic HF to allow for prevention or progression to symptomatic stages. SGLT-2 inhibitors or SGLT-1/2 inhibitors are also recommended for patients with diabetes and HF regardless of ejection fraction.

Pipeline:

- **Cell Pouch™ System:** Sernova is currently developing a Cell Pouch™ System that is a novel implantable and scalable medical device that can form a natural environment in the body to house therapeutic cells. The cells will release the necessary proteins or other factors that may be missing from the body to treat the patient's chronic disease as opposed to using daily drugs. The Cell Pouch™ is manufactured according to strict regulatory guidelines, and it is currently in clinical trials in patients with diabetes. Transplanted islets within the Cell Pouch™ can produce insulin naturally through a feedback system linking glucose levels to the release of insulin. This may result in reduction or elimination of the need for insulin injections. Phase 1/2 trials are currently ongoing for the study of the Cell Pouch in diabetes.
- **Orforglipron:** Orforglipron is an oral GLP-1 agonist that has been assessed in Phase 2 trials for patients with T2DM. The Phase 2 trials showed significant reductions in HbA1c and bodyweight when compared to placebo or dulaglutide. If approved, orforglipron could provide another oral GLP-1 agonist option for T2DM patients.
- **Retatrutide:** Retatrutide is a novel, once weekly, triple receptor agonist with activity at GIP, GLP-1, and glucagon receptors that is being studied

in trials for T2DM and obesity. In a Phase 2 trial, retatrutide showed clinically meaningful improvements in glycemic control and reductions in body weight. Retatrutide was also shown to have a safety profile consistent with current available GLP-1 agonists and GIP/GLP-1 agonists. Phase 3 trials are currently recruiting patients.

- **Stem Cell Educator Therapy:** Stem Cell Educator Therapy is an in vitro process that uses a patient's white blood cells and circulates them through a Stem Cell Educator device that is coated in human umbilical cord blood. The circulation "re-educates" the cells back to their pre-disease state and then those cells are circulated back to the patient. The new educated cells can now help other defective cells in the body. Unlike other stem cell treatments, the Educator Therapy does not introduce stem cells or reagents into the patient, allowing for no risk of rejection. Phase 2 trials are currently ongoing.

Inpefa® (Sotagliflozin) Product Summary[24]

Therapeutic Class: SGLT-2 inhibitor

Indication(s): Reduce the risk of CV death, hospitalization for HF, and urgent HF visit in adults with HF or T2DM, CKD, and other CV risk factors

How Supplied: 200mg and 400mg tablets

Dosing and Administration:

- The recommended starting dose is 200mg daily, and the dose is titrated to 400mg daily as tolerated
- Volume status should be corrected prior to starting Inpefa®
- In patients with decompensated HF, Inpefa® should be initiated when the patient is hemodynamically stable
- Inpefa® should be held for at least 3 days prior to major surgery or procedures associated with prolonged fasting

Cost Comparison: SGLT-2 Inhibitors

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year*
Inpefa® (sotagliflozin) 400mg	**$19.93**	**$597.90**	**$7,174.80**
Jardiance® (empagliflozin) 25mg	$19.54	$586.20	$7,034.40
Farxiga® (dapagliflozin) 10mg	$18.62	$558.60	$6,703.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month and year is based on the maximum FDA approved dosing of each product.

Lantidra™ (Donislecel-jujn) Product Summary[25]

Therapeutic Class: Allogenic pancreatic islet cellular therapy

Indication(s): Treatment of adults with T1DM who are unable to approach target hemoglobin A1c (HgbA1c) because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education

- **Limitation(s) of Use:** When considering the risks associated with the infusion procedure and long-term immunosuppression, there is no evidence to show a benefit of administration of Lantidra™ in patients whose diabetes is well-controlled with insulin therapy or in patients with hypoglycemic unawareness who are able to prevent current repeated severe hypoglycemic events using intensive diabetes management.

How Supplied: Lantidra™ is supplied as a cellular suspension. Dosage strength depends on the total number of islets packaged for infusion, which is reported on the container label and associated documents.

Dosing and Administration:

- Initial Infusion: The recommended minimum dose is 5,000 equivalent islet number (EIN) per kg of body weight
- Subsequent Infusions: 4,500 EIN/kg
  - A second infusion may be performed if the patient does not achieve independence from exogenous insulin within 1 year of infusion or within 1 year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion.
  - There is no data regarding the effectiveness or safety for patients receiving more than 3 infusions.
- Cells should be administered though the hepatic portal vein with the estimated tissue volume not exceeding 10mL per infusion.
- Lantidra™ must be used in conjunction with concomitant immunosuppression.

Cost: The Wholesale Acquisition Cost (WAC) of Lantidra™ is $300,000 per infusion bag. The maximum of 3 infusions would result in an estimated cost of $900,000.

Cost Comparison: Biguanides

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year*
metformin 625mg (generic)	**$25.00**	**$1,500.00**	**$18,000.00**
metformin 500mg (generic)	$0.01	$0.60	$7.20
metformin 1,000mg (generic)	$0.02	$1.20	$14.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month and year is based on twice daily dosing for each product

Cost Comparison: DPP-4 Inhibitors

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year*
Zituvio™ (sitagliptin) 100mg	**$18.15**	**$544.50**	**$6,534.00**
Januvia® (sitagliptin) 100mg	$18.32	$549.60	$6,595.20
Tradjenta® (linagliptin) 5mg	$16.79	$503.70	$6,044.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month and year is based on the maximum FDA approved dosing of each product.
Cost information for Zituvimet™ is not currently available.

Cost Comparison: Sulfonylureas

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year*
glipizide 2.5mg (generic)	**$1.38**	**$41.40**	**$496.80**
glipizide 5mg (generic)	$0.03	$0.45	$5.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month and year is based on 2.5mg once daily for each product

Recommendations

The College of Pharmacy recommends the prior authorization of Lantidra™ (donislecel-jujn) with the following criteria (shown in red):

Lantidra™ (Donislecel-jujn) Approval Criteria:

1. An FDA approved diagnosis of type 1 diabetes mellitus (T1DM); and
2. Member must be 18 years of age or older; and
3. Must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member must have had T1DM for ≥5 years and has been receiving intensive insulin management defined as:
    a. Self-monitoring of blood glucose levels at least 3 times per day on average; and
    b. Using insulin pump therapy or using at least 3 insulin injections per day; and
    c. Under the care of a diabetes specialist with at least 3 evaluations in the past 12 months; and
5. Member is exhibiting 1 of the following despite intensive insulin management efforts:
    a. Hypoglycemic unawareness; or
    b. Two or more episodes of severe hypoglycemia, defined as an event with symptoms consistent with hypoglycemia in which the patient

requires the assistance of another person and which is associated with a blood glucose level <54mg/dL; or
   c. Two or more hospital visits (inpatient and/or emergency department) for diabetic ketoacidosis over the last year; or
   d. Progressive secondary complications of diabetes as defined by retinopathy, nephropathy, or neuropathy despite efforts at optimal glucose control; and
6. Member must receive concomitant immunosuppression. Lantidra™ is contraindicated in adults who have a contraindication to immunosuppression; and
7. Member is T- and B-cell crossmatch assay negative; and
8. Member must not have any of the following:
   a. Severe cardiac disease defined by 1 of the following:
      i. Recent, within the past 6 months, myocardial infarction; or
      ii. Angiographic evidence of non-correctable coronary artery disease; or
      iii. Evidence of ischemia on functional cardiac exam (with a stress echo test recommended for members with a history of ischemic disease); or
      iv. Heart failure > New York Heart Association (NYHA) II; or
      v. History of stroke within the past 6 months; and
   b. No active infections, including hepatitis C, hepatitis B, human immunodeficiency virus (HIV), or tuberculosis; and
   c. No history of malignancy except squamous or basal skin cancer; and
   d. No concomitant disease or condition that contradicts the procedure or immunosuppression; and
   e. No history of liver disease or renal failure and has not been the recipient of a renal transplant; and
   f. No history of a prior portal vein thrombosis excluding thrombosis limited to second- or third-order portal vein branches; and
   g. C-peptide ≥0.3ng/mL following a 5g arginine intravenous (IV) infusion challenge; and
   h. Insulin requirements >0.7 IU/kg/day; and
   i. Recent hemoglobin A1C (HbA1c) >12%; and
9. Female members of reproductive potential must not be pregnant or breastfeeding and must agree to use effective contraception prior to initiation of immunosuppression and thereafter; and
10. Initial approvals will be for 12 months. Reauthorization may be granted if the prescriber documents the member has not achieved independence from exogenous insulin within 1 year of infusion or may be granted within 1 year after losing independence from exogenous insulin after a previous infusion; and

    a. Prescriber must verify the member is still receiving concomitant immunosuppression; and
11. Lantidra™ must be administered at a manufacturer approved transplant center; and
12. Approvals will be for a maximum of 3 infusions per member per lifetime.

Next, the College of Pharmacy recommends the following changes to the Anti-Diabetic Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following tier chart):

1. Prior authorization of Zituvio™ (sitagliptin) and Zituvimet™ (sitagliptin/metformin) and placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of glipizide 2.5mg tablets and placement into the Special PA Tier with the following additional criteria; and
3. Prior authorization of Inpefa® (sotagliflozin) and placement into the Special PA Tier with the following additional criteria; and
4. Prior authorization of metformin 625mg tablet and placement into the Special PA Tier; and
5. Prior authorization of generic dapagliflozin and dapagliflozin/metformin ER and placement into the Special PA Tier with the following additional criteria; and
6. Making Farxiga® (dapagliflozin) and Xigduo® XR (dapagliflozin/metformin ER) brand preferred based on net costs; and
7. Moving Invokana® (canagliflozin), Invokamet® (canagliflozin/metformin), and Invokamet® XR (canagliflozin/metformin ER) to Tier-2 based on net costs; and
8. Moving generic saxagliptin and saxagliptin/metformin to Special PA Tier based on net costs and the discontinuation of the brand formulations.

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/			metformin ER susp

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
glipizide (Metaglip®)			(Riomet ER™)
metformin/ glyburide (Glucovance®)			**metformin 625mg tab**
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	**saxagliptin (Onglyza®)**
	linagliptin/ metformin (Jentadueto®)	alogliptin/ metformin (Kazano®)	**saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)**
	linagliptin/ metformin ER (Jentadueto® XR)	alogliptin/ pioglitazone (Oseni®)	**sitagliptin (Zituvio™)***
	~~**saxagliptin (Onglyza®)**~~		**sitagliptin/metformin (Zituvimet™)***
	~~**saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)**~~		
	sitagliptin (Januvia®)		
	sitagliptin/ metformin (Janumet®)		
	sitagliptin/ metformin ER (Janumet XR®)		
DPP-4 Inhibitors/SGLT-2 Inhibitors			
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/ sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	dulaglutide (Trulicity®)	exenatide ER autoinjector (Bydureon BCise®)	lixisenatide (Adlyxin®)*
	exenatide (Byetta®)	semaglutide (Ozempic®)	tirzepatide (Mounjaro®)*
	liraglutide (Victoza®)	semaglutide (Rybelsus®)	
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)+	
		insulin glargine/ lixisenatide (Soliqua® 100/33)+	
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®) **– Brand Preferred**	**canagliflozin (Invokana®)**	~~**canagliflozin (Invokana®)**~~	bexagliflozin (Brenzavvy®)
empagliflozin (Jardiance®)	**canagliflozin/ metformin (Invokamet®)**	~~**canagliflozin/ metformin (Invokamet®**~~	~~**canagliflozin/ metformin ER (Invokamet® XR)**~~
	canagliflozin/ metformin ER (Invokamet® XR)		**dapagliflozin (generic)**
	dapagliflozin/ metformin ER (Xigduo® XR) **– Brand Preferred**		**dapagliflozin/ metformin ER (generic)**
	empagliflozin/ metformin (Synjardy®)		ertugliflozin (Steglatro®)
	empagliflozin/ metformin ER (Synjardy® XR)		ertugliflozin/ metformin (Segluromet®)
	dapagliflozin/ metformin ER (Xigduo® XR)		**sotagliflozin (Inpefa®)***
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)
Sulfonylureas			
glimepiride (Amaryl®)			**glipizide 2.5mg immediate-release tablet***

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

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release; susp = suspension

Anti-Diabetic Medications Special PA Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
2. ~~Use of Invokamet XR [canagliflozin/metformin extended-release (ER)] will require a patient-specific, clinically significant reason why the member cannot take the immediate-release formulation(s); and~~
3. Use of Adlyxin® (lixisenatide) or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 receptor agonists (GLP-1 agonists); and
4. Use of generic dapagliflozin or dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why they member cannot use brand name Farxiga® (dapagliflozin) or Xigduo® XR (dapagliflozin/metformin ER) and all available lower-tiered sodium-glucose cotransporter-2 (SGLT-2) inhibitors; and
5. Use of glipizide 2.5mg immediate-release tablet will require a patient-specific, clinically significant reason why the member cannot use other

appropriate Tier-1 products including splitting a glipizide 5mg tablet to achieve a 2.5mg dose; and
6. Use of Zituvio™ (sitagliptin) and Zituvimet™ (sitagliptin/metformin) will require a patient-specific, clinically significant reason why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors).

Inpefa® (Sotagliflozin) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use all other lower tiered SGLT-2 inhibitors that have a similar indication must be provided.

Next, the College of Pharmacy recommends the prior authorization of insulin degludec U-100 and U-200 and insulin glargine U-300 with the following criteria (shown in red):

Insulin Degludec U-100 and U-200 (Unbranded Tresiba®) Approval Criteria:

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

Insulin Glargine U-300 and U-200 (Unbranded Toujeo®) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use brand name Toujeo® (the brand formulation of Toujeo® is preferred); and
3. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or insulin glargine-yfgn (generic Semglee®) must be provided, and the member must be using a minimum of 100 units of insulin glargine per day.

Finally, the College of Pharmacy recommends the following changes to the Basaglar® (insulin glargine), Rezvoglar™ (insulin glargine-aglr), Ryzodeg® (insulin degludec/insulin aspart), Soliqua® 100/33 (insulin glargine/lixisenatide), Toujeo® (insulin glargine), Tresiba® (insulin degludec), and Xultophy® 100/3.6 (insulin degludec/liraglutide) approval criteria based the discontinuation of Levemir® (insulin detemir) and removing the prior

authorization of generic Semglee® (insulin glargine-ygfn) due to net costs (changes shown in red):

Basaglar® (Insulin Glargine) Approval Criteria:

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

Rezvoglar™ (Insulin Glargine-aglr) and Semglee® (Insulin Glargine-yfgn) Approval Criteria:

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

Ryzodeg® (Insulin Degludec/Insulin Aspart) Approval Criteria:

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

Soliqua® 100/33 (Insulin Glargine/Lixisenatide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or insulin glargine-yfgn (generic Semglee®) with an alternative glucagon-like peptide 1 (GLP-1) receptor agonist must be provided; and
3. Current Tier-3 criteria will apply.

Toujeo® (Insulin Glargine) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or insulin glargine-yfgn (generic Semglee®) must be provided, and the member must be using a minimum of 100 units of ~~Lantus® (~~insulin glargine~~)~~ per day.

Tresiba® (Insulin Degludec) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and

2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or ~~Levemir® (insulin detemir)~~ insulin glargine-yfgn (generic Semglee®) must be provided.

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

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

Utilization Details of Anti-Diabetic Medications and Kerendia® (Finerenone): Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BIGUANIDE PRODUCTS						
TIER-1 PRODUCTS						
METFORMIN TAB 500MG	34,518	13,466	$331,941.96	$9.62	2.56	0.32%
METFORMIN TAB 1000MG	23,258	8,455	$240,690.98	$10.35	2.75	0.23%
METFORMIN TAB 500MG ER	17,752	7,303	$191,235.99	$10.77	2.43	0.19%
METFORMIN TAB 750MG ER	1,731	746	$20,583.25	$11.89	2.32	0.02%
METFORMIN TAB 850MG	1,397	583	$13,850.38	$9.91	2.4	0.01%
TIER-1 SUBTOTAL	**78,656**	**30,553**	**$798,302.56**	**$10.15**	**2.57**	**0.77%**
SPECIAL PA PRODUCTS						
METFORMIN SOL 500MG/5ML	54	11	$15,560.97	**$288.17**	4.91	0.02%
SPECIAL PA SUBTOTAL	**54**	**11**	**$15,560.97**	**$288.17**	**4.91**	**0.02%**
BIGUANIDE TOTAL	**78,710**	**30,564**	**$813,863.53**	**$10.34**	**2.58**	**0.79%**
GLP-1/GIP AGONIST PRODUCTS						
TIER-2 PRODUCTS						
TRULICITY INJ 1.5MG/0.5ML	14,199	4,688	$15,977,029.41	$1,125.22	3.03	15.60%
TRULICITY INJ 0.75MG/0.5ML	14,148	5,396	$14,878,001.29	$1,051.60	2.62	14.52%
TRULICITY INJ 3MG/0.5ML	7,977	2,665	$9,192,606.81	$1,152.39	2.99	8.97%
TRULICITY INJ 4.5MG/0.5ML	5,051	1,369	$6,127,227.56	$1,213.07	3.69	5.98%
VICTOZA INJ 18MG/3ML	4,976	1,456	$5,388,663.77	$1,082.93	3.42	5.26%
BYETTA INJ 5MCG	34	20	$33,604.34	$988.36	1.7	0.03%
BYETTA INJ 10MCG	20	8	$19,221.43	$961.07	2.5	0.02%
TIER-2 SUBTOTAL	**46,405**	**15,602**	**$51,616,354.61**	**$1,112.30**	**2.97**	**50.38%**
TIER-3 PRODUCTS						
OZEMPIC INJ 4MG/3ML	3,087	830	$2,744,573.58	$889.07	3.72	2.68%
OZEMPIC INJ 8MG/3ML	2,533	573	$2,238,233.15	$883.63	4.42	2.18%
OZEMPIC INJ 2MG/3ML	1,831	664	$1,641,056.74	$896.26	2.76	1.60%
OZEMPIC INJ 2MG/1.5ML	697	401	$617,289.24	$885.64	1.74	0.60%
RYBELSUS TAB 7MG	179	48	$157,218.69	$878.32	3.73	0.15%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RYBELSUS TAB 14MG	147	31	$125,283.64	$852.27	4.74	0.12%
BYDUREON BC INJ 2MG/0.85ML	50	14	$39,125.40	$782.51	3.57	0.04%
RYBELSUS TAB 3MG	49	23	$44,543.36	$909.05	2.13	0.04%
TIER-3 SUBTOTAL	**8,573**	**2584**	**$7,607,323.80**	**$887.36**	**3.32**	**7.41%**
SPECIAL PA PRODUCTS						
MOUNJARO INJ 5MG/0.5ML	1,379	453	$1,340,743.67	$972.26	3.04	1.31%
MOUNJARO INJ 7.5MG/0.5ML	1,159	390	$1,130,961.20	$975.81	2.97	1.10%
MOUNJARO INJ 10MG/0.5ML	908	297	$886,134.44	$975.92	3.06	0.86%
MOUNJARO INJ 12.5MG/0.5ML	636	200	$616,744.42	$969.72	3.18	0.60%
MOUNJARO INJ 2.5MG/0.5ML	613	260	$597,963.28	$975.47	2.36	0.58%
MOUNJARO INJ 15MG/0.5ML	467	113	$446,862.83	$956.88	4.13	0.44%
SPECIAL PA SUBTOTAL	**5,162**	**1713**	**$5,019,409.84**	**$972.38**	**3.01**	**4.89%**
GLP-1/GIP AGONIST TOTAL	**60,140**	**19,899**	**$64,243,088.25**	**$1,0680.23**	**3.02**	**62.68%**
SGLT-2 INHIBITOR PRODUCTS						
TIER-1 PRODUCTS						
JARDIANCE TAB 25MG	8,670	2,926	$9,812,936.78	$1,131.83	2.96	9.58%
JARDIANCE TAB 10MG	7,524	2,914	$7,515,966.98	$998.93	2.58	7.34%
FARXIGA TAB 10MG	6,979	2,275	$6,970,494.53	$998.78	3.07	6.80%
FARXIGA TAB 5MG	1,704	631	$1,534,546.98	$900.56	2.7	1.50%
TIER-1 SUBTOTAL	**24,877**	**8,746**	**$25,833,945.27**	**$1,038.47**	**2.84**	**25.22%**
TIER-3 PRODUCTS						
INVOKANA TAB 300MG	152	53	$206,813.22	$1,360.61	2.87	0.20%
INVOKANA TAB 100MG	126	38	$140,759.36	$1,117.14	3.32	0.14%
TIER-3 SUBTOTAL	**278**	**91**	**$347,572.58**	**$1,250.26**	**3.05**	**0.34%**
SPECIAL PA PRODUCTS						
STEGLATRO TAB 15MG	47	9	$15,778.45	$335.71	5.22	0.02%
STEGLATRO TAB 5MG	20	4	$6,742.30	$337.12	5	0.01%
SPECIAL PA SUBTOTAL	**67**	**13**	**$22,520.75**	**$336.13**	**5.15**	**0.03%**
SGLT-2 INHIBITOR TOTAL	**25,222**	**8,850**	**$26,204,038.60**	**$1,038.94**	**2.58**	**25.29%**
SULFONYLUREA PRODUCTS						
TIER-1 PRODUCTS						
GLIPIZIDE TAB 10MG	4,578	1,663	$52,810.31	$11.54	2.75	0.05%
GLIPIZIDE TAB 5MG	3,928	1,589	$39,433.92	$10.04	2.47	0.04%
GLYBURIDE TAB 5MG	2,191	756	$34,025.10	$15.53	2.9	0.03%
GLIMEPIRIDE TAB 4MG	2,019	714	$23,331.51	$11.56	2.83	0.02%
GLIPIZIDE ER TAB 10MG	2,001	806	$44,748.44	$22.36	2.48	0.04%
GLIPIZIDE ER TAB 5MG	1,507	657	$23,103.86	$15.33	2.29	0.02%
GLIMEPIRIDE TAB 2MG	1,460	544	$15,360.40	$10.52	2.68	0.01%
GLIMEPIRIDE TAB 1MG	559	222	$4,870.04	$8.71	2.52	0.00%
GLIPIZIDE ER TAB 2.5MG	533	227	$8,826.14	$16.56	2.35	0.01%
GLYBURIDE TAB 2.5MG	426	185	$6,390.79	$15.00	2.3	0.01%
GLYBURIDE TAB 1.25MG	92	28	$1,094.42	$11.90	3.29	0.00%
GLIPIZIDE XL TAB 10MG	38	23	$881.78	$23.20	1.65	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLYBURIDE MCR TAB 3MG	23	7	$435.28	$18.93	3.29	0.00%
GLYBURIDE MCR TAB 6MG	8	3	$251.45	$31.43	2.67	0.00%
GLIPIZIDE XL TAB 2.5MG	7	6	$137.76	$19.68	1.17	0.00%
GLIPIZIDE XL TAB 5MG	6	3	$82.31	$13.72	2	0.00%
GLYBURIDE MCR TAB 1.5MG	2	2	$30.83	$15.42	1	0.00%
SULFONYLUREA TOTAL	**19,378**	**7,435**	**$255,814.34**	**$13.20**	**2.61**	**0.23%**
DPP-4 INHIBITOR PRODUCTS						
TIER-2 PRODUCTS						
JANUVIA TAB 100MG	3,724	1,101	$3,694,786.80	$992.16	3.38	3.61%
TRADJENTA TAB 5MG	2,096	381	$1,056,005.60	$503.82	5.5	1.03%
JANUVIA TAB 50MG	1,018	323	$967,499.52	$950.39	3.15	0.94%
JANUVIA TAB 25MG	425	137	$353,750.14	$832.35	3.1	0.35%
ONGLYZA TAB 5MG	86	23	$72,426.51	$842.17	3.74	0.07%
SAXAGLIPTIN TAB 5MG	20	8	$1,367.45	$68.37	2.5	0.00%
ONGLYZA TAB 2.5MG	13	4	$16,380.49	$1,260.04	3.25	0.02%
SAXAGLIPTIN TAB 2.5MG	1	1	$63.21	$63.21	1	0.00%
TIER-2 SUBTOTAL	**7,383**	**1,978**	**$6,162,279.72**	**$834.66**	**3.73**	**6.02%**
TIER-3 PRODUCTS						
ALOGLIPTIN TAB 25MG	30	6	$8,075.67	$269.19	5	0.01%
ALOGLIPTIN TAB 12.5MG	24	5	$7,261.12	$302.55	4.8	0.01%
ALOGLIPTIN TAB 6.25MG	1	1	$158.64	$158.64	1	0.00%
NESINA TAB 25MG	1	1	$405.46	$405.46	1	0.00%
TIER-3 SUBTOTAL	**56**	**13**	**$15,900.89**	**$283.94**	**4.31**	**0.02%**
DPP-4 INHIBITOR TOTAL	**7,439**	**1,991**	**$6,178,180.61**	**$830.51**	**3.74**	**6.04%**
TZD PRODUCTS						
TIER-1 PRODUCTS						
PIOGLITAZONE TAB 30MG	2,322	795	$37,272.41	$16.05	2.92	0.04%
PIOGLITAZONE TAB 15MG	1,849	720	$26,520.20	$14.34	2.57	0.03%
PIOGLITAZONE TAB 45MG	1,073	383	$18,959.97	$17.67	2.8	0.02%
TZD TOTAL	**5,244**	**1898**	**$82,752.58**	**$15.78**	**2.76**	**0.09%**
DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						
TIER-2 PRODUCTS						
JANUMET TAB 50-1000MG	1,028	328	$974,945.79	$948.39	3.13	0.95%
JANUMET XR TAB 50-1000MG	338	90	$274,843.45	$813.15	3.76	0.27%
JANUMET XR TAB 100-1000MG	291	79	$251,758.36	$865.15	3.68	0.25%
JENTADUETO TAB 2.5-1000MG	285	105	$340,892.16	$1,196.11	2.71	0.33%
JANUMET TAB 50-500MG	150	53	$138,904.39	$926.03	2.83	0.14%
JANUMET XR TAB 50-500MG	35	11	$13,933.59	$398.10	3.18	0.01%
KOMBIGLYZE XR TAB 2.5-1000MG	26	7	$14,777.23	$568.36	3.71	0.01%
JENTADUETO TAB 2.5-500	8	4	$11,163.59	$1,395.45	2	0.01%
SAXA/METFOR TAB 2.5-1000	6	3	$3,621.84	$603.64	2	0.00%
KOMBIGLYZE XR TAB 5-1000MG	5	2	$7,023.45	$1,404.69	2.5	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DPP-4 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**2,172**	**682**	**$2,031,863.85**	**$935.48**	**3.18**	**1.98%**
SGLT-2 INHIBITOR/BIGUANIDE PRODUCTS						
TIER-2 PRODUCTS						
SYNJARDY TAB	393	131	$432,386.58	$1,100.22	3	0.42%
SYNJARDY XR TAB 25-1000MG	370	132	$481,729.49	$1,301.97	2.8	0.47%
XIGDUO XR TAB 10-1000MG	343	88	$337,106.41	$982.82	3.9	0.33%
SYNJARDY XR TAB 12.5-1000MG	267	93	$235,686.96	$882.72	2.87	0.23%
XIGDUO XR TAB 5-1000MG	178	55	$156,789.54	$880.84	3.24	0.15%
SYNJARDY TAB 5-1000MG	131	54	$148,107.90	$1,130.59	2.43	0.14%
SYNJARDY XR TAB 10-1000MG	84	31	$85,959.11	$1,023.32	2.71	0.08%
SYNJARDY XR TAB 5-1000MG	33	15	$22,619.63	$685.44	2.2	0.02%
XIGDUO XR TAB 10-500MG	20	7	$16,429.19	$821.46	2.86	0.02%
SYNJARDY TAB 12.5-500MG	20	8	$18,744.53	$937.23	2.5	0.02%
XIGDUO XR TAB 2.5-1000MG	19	3	$7,109.51	$374.18	6.33	0.01%
SYNJARDY TAB 5-500MG	19	5	$13,051.62	$686.93	3.8	0.01%
XIGDUO XR TAB 5-500MG	10	5	$12,708.82	$1,270.88	2	0.01%
TIER-2 SUBTOTAL	**1,887**	**627**	**$1,968,429.29**	**$1,043.15**	**3.01**	**1.91%**
TIER-3 PRODUCTS						
INVOKAMET TAB 150-1000MG	16	4	$16,086.63	$1,005.41	4	0.02%
INVOKAMET TAB 50-1000MG	1	1	$1,734.34	$1,734.34	1	0.00%
TIER-3 SUBTOTAL	**17**	**5**	**$17,820.97**	**$1,048.29**	**3.4**	**0.02%**
SPECIAL PA PRODUCTS						
SEGLUROMET TAB 7.5-1000MG	16	2	$5,367.04	$335.44	8	0.01%
SEGLUROMET TAB 2.5-1000MG	12	1	$2,056.20	$171.35	12	0.00%
INVOKAMET XR TAB 150-1000MG	5	1	$6,250.98	$1,250.20	5	0.01%
INVOKAMET XR TAB 50-1000MG	2	1	$3,462.88	$1,731.44	2	0.00%
SPECIAL PA SUBTOTAL	**35**	**5**	**$17,137.10**	**$489.63**	**7**	**0.02%**
SGLT-2 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**1,939**	**637**	**$2,003,387.36**	**$1,033.21**	**3.04**	**1.95%**
SULFONYLUREA/BIGUANIDE COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
GLYB/METFOR TAB 5-500MG	228	70	$3,691.06	$16.19	3.26	0.00%
GLIP/METFOR TAB 5-500MG	160	60	$6,862.17	$42.89	2.67	0.01%
GLIP/METFOR TAB 2.5-500MG	76	36	$4,023.30	$52.94	2.11	0.00%
GLYB/METFOR TAB 2.5-500MG	68	24	$1,122.68	$16.51	2.83	0.00%
GLIP/METFOR TAB 2.5-250MG	9	5	$276.72	$30.75	1.8	0.00%
GLYB/METFOR TAB 1.25-250MG	5	2	$112.56	$22.51	2.5	0.00%
SULFONYLUREA/BIGUANIDE COMBINATION TOTAL	**546**	**197**	**$16,088.49**	**$29.47**	**2.77**	**0.01%**
SGLT-2 INHIBITOR/DPP-4 INHIBITOR COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
GLYXAMBI TAB 25-5MG	257	43	$137,919.62	$536.65	5.98	0.13%
GLYXAMBI TAB 10-5MG	98	23	$51,781.92	$528.39	4.26	0.05%
TIER-1 SUBTOTAL	**355**	**66**	**$189,701.54**	**$534.37**	**5.38**	**0.18%**
SPECIAL PA PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
STEGLUJAN TAB 5-100MG	10	1	$5,554.59	$555.46	10	0.01%
STEGLUJAN TAB 15-100MG	2	1	$1,074.76	$537.38	2	0.00%
SPECIAL PA SUBTOTAL	**12**	**2**	**$6,629.35**	**$552.45**	**6**	**0.01%**
SGLT-2/DPP-4 INHIBITOR COMBINATION TOTAL	**367**	**68**	**$196,330.89**	**$534.96**	**5.4**	**0.19%**
SGLT-2/DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
TRIJARDY XR TAB 25-5-1000MG	243	50	$138,741.85	$570.95	4.86	0.14%
TRIJARDY XR TAB 12.5-2.5-1000MG	49	19	$25,719.44	$524.89	2.58	0.03%
TRIJARDY XR TAB 5-2.5-1000MG	30	11	$10,808.01	$360.27	2.73	0.01%
TRIJARDY XR TAB 10-5-1000MG	22	7	$18,997.87	$863.54	3.14	0.02%
SGLT-2/DPP-4/BIGUANIDE COMBINATION TOTAL	**344**	**87**	**$194,267.17**	**$564.73**	**3.95**	**0.20%**
ALPHA-GLUCOSIDASE INHIBITOR PRODUCTS						
TIER-1 PRODUCTS						
ACARBOSE TAB 25MG	176	58	$5,075.77	$28.84	3.03	0.00%
ACARBOSE TAB 50MG	77	19	$2,160.83	$28.06	4.05	0.00%
ACARBOSE TAB 100MG	50	21	$2,203.97	$44.08	2.38	0.00%
ALPHA-GLUCOSIDASE INHIBITOR TOTAL	**303**	**98**	**$9,440.57**	**$31.16**	**3.09**	**0.00%**
GLP-1 AGONIST/INSULIN COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
SOLIQUA INJ 100U/33MCG	189	35	$142,345.87	$753.15	5.4	0.14%
XULTOPHY INJ 100U/3.6MCG	27	7	$28,769.35	$1,065.53	3.86	0.03%
GLP-1 AGONIST/INSULIN COMBINATION TOTAL	**216**	**42**	**$171,115.22**	**$792.20**	**5.14**	**0.17%**
GLINIDE PRODUCTS						
TIER-1 PRODUCTS						
REPAGLINIDE TAB 1MG	41	13	$1,074.46	$26.21	3.15	0.00%
REPAGLINIDE TAB 2MG	18	5	$490.20	$27.23	3.6	0.00%
REPAGLINIDE TAB 0.5MG	9	5	$221.86	$24.65	1.8	0.00%
TIER-1 SUBTOTAL	**68**	**23**	**$1,786.52**	**$26.27**	**2.96**	**0.00%**
TIER-2 PRODUCTS						
NATEGLINIDE TAB 120MG	18	8	$603.99	$33.56	2.25	0.00%
NATEGLINIDE TAB 60MG	14	7	$625.45	$44.68	2	0.00%
TIER-2 SUBTOTAL	**32**	**15**	**$1,229.44**	**$38.42**	**2.13**	**0.00%**
GLINIDE TOTAL	**100**	**38**	**$3,015.96**	**$30.16**	**2.63**	**0.00%**
FINERENONE PRODUCTS						
KERENDIA TAB 10MG	46	14	$27,706.34	$602.31	3.29	0.03%
KERENDIA TAB 20MG	13	3	$7,900.45	$607.73	4.33	0.01%
FINERENONE TOTAL	**59**	**17**	**$35,606.79**	**$603.50**	**3.47**	**0.04%**
TZD/BIGUANIDE COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
PIOG/METFOR TAB 15-850MG	34	6	$968.21	$28.48	5.67	0.00%
PIOG/METFOR TAB 15-500MG	3	1	$129.08	$43.03	3	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TZD/BIGUANIDE COMBINATION TOTAL	**37**	**7**	**$1,097.29**	**$29.66**	**5.29**	**0.00%**
DPP-4 INHIBITOR/TZD COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
ALOG/PIOG TAB 25-45MG	4	1	$2,373.64	$593.41	4	0.00%
OSENI TAB 25-30MG	3	1	$3,703.41	$1,234.47	3	0.00%
DPP-4 INHIBITOR/TZD COMBINATION TOTAL	**7**	**2**	**$6,077.05**	**$868.15**	**3.50**	**0.00%**
TOTAL	**202,223**	**38,694***	**$102,446,028.55**	**$506.60**	**5.23**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members
ALOG = alogliptin; DPP-4 = dipeptidyl peptidase-4; ER, XL, XR = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLIP = glipizide; GLP-1 = glucagon-like peptide 1; GLYB = glyburide; INJ = injection; MCR = micronized; MET = metformin; PIOG = pioglitazone; SAXA = saxagliptin; SGLT-2 = sodium-glucose cotransporter-2; SOL = solution; TZD = thiazolidinedione; TAB = tablet; U = unit

Utilization Details of Insulin Medication: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INSULIN GLARGINE PRODUCTS						
LANTUS SOLOS INJ 100U/ML	26,076	7,938	$15,453,403.31	$592.63	3.28	29.69%
LANTUS INJ 100U/ML	4,454	1,388	$2,353,758.45	$528.46	3.21	4.52%
INSULIN GLARGINE INJ 100U/ML	2,273	1,085	$475,049.73	$209.00	2.09	0.91%
TOUJEO MAX INJ 300U/ML	564	106	$562,976.39	$998.19	5.32	1.08%
TOUJEO SOLO INJ 300U/ML	317	75	$244,218.88	$770.41	4.23	0.47%
BASAGLAR INJ 100U	128	42	$48,555.36	$379.34	3.05	0.09%
SEMGLEE INJ 100U/ML	35	7	$12,352.46	$352.93	5	0.02%
GLARGIN YFGN INJ 100U/ML	20	9	$2,859.20	$142.96	2.22	0.01%
GLARGIN YFGN SOL 100U/ML	5	1	$1,001.57	$200.31	5	0.00%
INSULIN GLARGINE SOL 100U/ML	4	1	$806.77	$201.69	4	0.00%
BASAGLAR INJ TEMPO PEN	1	1	$324.93	$324.93	1	0.00%
SUBTOTAL	**33,877**	**10,653**	**$19,155,307.05**	**$565.44**	**3.18**	**36.79%**
INSULIN ASPART PRODUCTS						
NOVOLOG INJ FLEXPEN	6,094	2,244	$4,571,868.15	$750.22	2.72	8.78%
INSULIN ASP INJ FLEXPEN	4,364	1,712	$1,650,024.66	$378.10	2.55	3.17%
NOVOLOG INJ 100U/ML	3,196	766	$2,355,253.22	$736.94	4.17	4.52%
NOVOLOG INJ FLEX RELION	2,855	1,173	$369,360.99	$129.37	2.43	0.71%
INSULIN ASP INJ 100U/ML	1,862	579	$814,228.40	$437.29	3.22	1.56%
NOVOLOG INJ RELION	667	211	$155,309.91	$232.85	3.16	0.30%
NOVOLOG INJ PENFILL	266	76	$173,918.74	$653.83	3.5	0.33%
FIASP FLEX INJ TOUCH	238	56	$181,797.45	$763.85	4.25	0.35%
FIASP INJ 100U/ML	73	12	$55,527.26	$760.65	6.08	0.11%
INSULIN ASP INJ PENFILL	62	24	$25,293.54	$407.96	2.58	0.05%
FIASP PENFILL INJ 100U	34	14	$25,901.87	$761.82	2.43	0.05%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**19,711**	**6,867**	**$10,378,484.19**	**$526.53**	**2.87**	**19.93%**
INSULIN LISPRO PRODUCTS						
HUMALOG KWIK INJ 100U/ML	8,010	2,682	$6,004,558.22	$749.63	2.99	11.54%
HUMALOG INJ 100U/ML	4,734	1,095	$3,530,944.85	$745.87	4.32	6.78%
HUMALOG JR INJ 100U/ML	680	189	$397,642.97	$584.77	3.6	0.76%
HUMALOG KWIK INJ 200U/ML	451	70	$852,022.86	$1,889.19	6.44	1.64%
INSULIN LISP INJ JR	330	89	$64,312.76	$194.89	3.71	0.12%
HUMALOG INJ 100U/ML	149	50	$114,074.51	$765.60	2.98	0.22%
LYUMJEV INJ 100U/ML	67	21	$98,915.98	$1,476.36	3.19	0.19%
LYUMJEV KWIK INJ 100U/ML	20	11	$17,580.31	$879.02	1.82	0.03%
INSULIN LISP KWIK INJ 100U/ML	18	8	$5,691.89	$316.22	2.25	0.01%
INSULIN LISP INJ 100U/ML	11	5	$1,936.04	$176.00	2.2	0.00%
ADMELOG INJ 100U/ML	10	1	$506.40	$50.64	10	0.00%
HUMALOG TMPO INJ 100/ML	5	4	$2,360.58	$472.12	1.25	0.00%
ADMELOG SOLO INJ 100U/ML	5	1	$1,950.55	$390.11	5	0.00%
LYUMJEV TEMPO PEN	2	1	$3,197.22	$1,598.61	2	0.01%
LYUMJEV KWIK INJ 200U/ML	1	1	$4,069.01	$4,069.01	1	0.01%
SUBTOTAL	**14,493**	**4,228**	**$11,099,764.15**	**$765.87**	**3.43**	**21.31%**
INSULIN DETEMIR PRODUCTS						
LEVEMIR INJ FLEXPEN	7,371	2,778	$4,527,533.83	$614.24	2.65	8.70%
LEVEMIR INJ	2,112	669	$1,201,580.12	$568.93	3.16	2.31%
LEVEMIR INJ FLEXTOUCH	1,259	948	$739,112.49	$587.06	1.33	1.42%
SUBTOTAL	**10,742**	**4,395**	**$6,468,226.44**	**$602.14**	**2.44**	**12.43%**
INSULIN DEGLUDEC PRODUCTS						
TRESIBA FLEX INJ 200U	1,356	322	$1,183,996.04	$873.15	4.21	2.27%
TRESIBA FLEX INJ 100U	1,154	337	$621,399.37	$538.47	3.42	1.19%
INS DEGLUDEC FLEX INJ 200U	81	36	$24,225.48	$299.08	2.25	0.05%
INS DEGLUDEC FLEX INJ 100U	77	35	$17,015.10	$220.98	2.2	0.03%
TRESIBA INJ 100U	14	6	$9,600.02	$685.72	2.33	0.02%
SUBTOTAL	**2,682**	**736**	**$1,856,236.01**	**$692.11**	**3.64**	**3.56%**
REGULAR INSULIN PRODUCTS						
HUMULIN R INJ 100U	580	191	$160,750.94	$277.16	3.04	0.31%
HUMULIN R KWIK INJ 500U	483	107	$628,291.00	$1,300.81	4.51	1.21%
NOVOLIN R FLEX INJ 100U	417	156	$106,760.00	$256.02	2.67	0.21%
NOVOLIN R INJ 100U	337	138	$81,129.99	$240.74	2.44	0.16%
NOVOLIN R INJ RELION	304	93	$24,518.71	$80.65	3.27	0.05%
HUMULIN R INJ 500U	25	6	$41,610.23	$1,664.41	4.17	0.08%
SUBTOTAL	**2,146**	**691**	**$1,043,060.87**	**$486.05**	**3.11**	**2.02%**
REGULAR/NPH INSULIN COMBINATION PRODUCTS						
NOVOLIN INJ FLEX 70/30	499	139	$163,030.41	$326.71	3.59	0.31%
NOVOLIN INJ 70/30	306	111	$111,932.40	$365.79	2.76	0.22%
HUMULIN INJ KWIK 70/30	304	118	$241,005.78	$792.78	2.58	0.46%
HUMULIN INJ 70/30	292	97	$95,973.72	$328.68	3.01	0.18%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NOVOLIN 70/30 INJ RELION	287	95	$30,586.52	$106.57	3.02	0.06%
SUBTOTAL	**1,688**	**560**	**$642,528.83**	**$380.65**	**3.01**	**1.23%**
NPH INSULIN PRODUCTS						
NOVOLIN N FLEX INJ 100U	339	166	$66,643.19	$196.59	2.04	0.13%
HUMULIN N KWIK INJ 100U	316	167	$175,398.04	$555.06	1.89	0.34%
HUMULIN N INJ 100U	290	106	$88,412.24	$304.87	2.74	0.17%
NOVOLIN N INJ RELION	271	80	$17,519.70	$64.65	3.39	0.03%
NOVOLIN N INJ 100U	227	82	$69,063.99	$304.25	2.77	0.13%
SUBTOTAL	**1,443**	**601**	**$417,037.16**	**$289.01**	**2.4**	**0.80%**
INSULIN ASPART/NPH COMBINATON PRODUCTS						
NOVOLOG MIX INJ FLEX	396	127	$339,613.30	$857.61	3.12	0.65%
INS ASP PROT INJ FLEX	187	61	$91,556.11	$489.60	3.07	0.18%
NOVOLOG MIX INJ FLEX RELION	144	59	$23,058.47	$160.13	2.44	0.04%
NOVOLOG MIX INJ 70/30	95	28	$78,568.32	$827.03	3.39	0.15%
NOVOLOG INJ 70/30 RELION	40	13	$4,949.58	$123.74	3.08	0.01%
INSULIN ASP INJ 70/30	30	14	$11,701.00	$390.03	2.14	0.02%
SUBTOTAL	**892**	**302**	**$549,446.78**	**$615.97**	**2.95**	**1.05%**
INSULIN GLULISINE PRODUCTS						
APIDRA INJ SOLOSTAR	294	96	$221,205.57	$752.40	3.06	0.42%
APIDRA INJ U-100	62	18	$44,710.02	$721.13	3.44	0.09%
SUBTOTAL	**356**	**114**	**$265,915.59**	**$746.95**	**3.12**	**0.51%**
INSULIN LISPRO/NPH COMBINATION PRODUCTS						
HUMALOG MIX KWIK INJ 75/25	101	36	$94,968.64	$940.28	2.81	0.18%
HUMALOG MIX SUS 75/25	65	13	$44,119.77	$678.77	5	0.08%
INSULIN LISP INJ PROT	34	11	$6,468.56	$190.25	3.09	0.01%
HUMALOG MIX KWIK INJ 50/50	32	13	$27,854.00	$870.44	2.46	0.05%
HUMALOG MIX INJ 50/50	5	2	$3,143.76	$628.75	2.5	0.01%
SUBTOTAL	**237**	**75**	**$176,554.73**	**$744.96**	**3.16**	**0.33%**
TOTAL	**88,267**	**15,637***	**$52,052,561.80**	**$589.72**	**5.64**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASP = aspart; FLEX = FlexPen; GLAR = glargine; INJ = injection; INS = insulin; JR = junior; KWIK = KwikPen; LISP = lispro; POW = powder; PROT = protamine; SOL = solution; SUS = suspension; U = unit

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Appendix N

Calendar Year 2023 Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Izervay™ (Avacincaptad Pegol)

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Lucentis® (Ranibizumab Intravitreal Injection) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Byooviz™ (ranibizumab-nuna intravitreal injection) or Cimerli® (ranibizumab-eqrn intravitreal injection) 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.

Susvimo™ (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of neovascular (wet) age-related macular degeneration (AMD) in adults; 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® (aflibercept)] must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

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); 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. A patient-specific, clinically significant reason why the member cannot use VEGF inhibitor injection products (appropriate to the disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea® (aflibercept)] must be provided; and
8. A quantity limit of 0.05mL per 28 days will apply.

Utilization of AMD Medications: Calendar Year 2023

Comparison of Calendar Years: Medical Claims

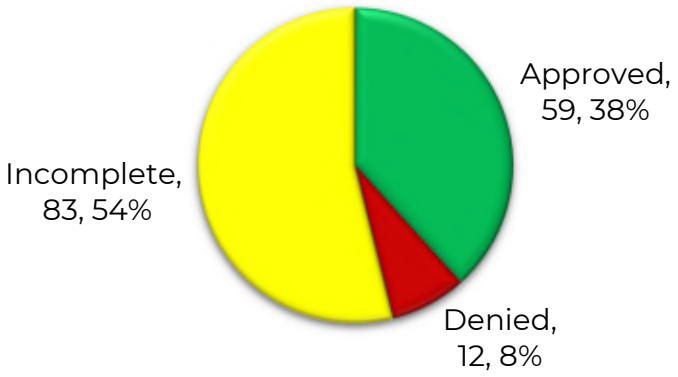
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	160	559	$1,165,736.35	$2,085.40	3.49
2023	333	927	$1,956,571.34	$2,110.65	2.78
% Change	**108.13%**	**65.83%**	**67.84%**	**1.21%**	**-20.34%**
Change	**173**	**368**	**$790,834.99**	**$25.25**	**-0.71**

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

Prior Authorization of AMD Medications

There were 154 prior authorization requests submitted for AMD medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Izervay™ (avacincaptad pegol): July 2034
- Syfovre® (pegcetacoplan injection): February 2037

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

- **August 2023:** The FDA approved Eylea® HD (aflibercept) 8mg injection for the treatment of wet AMD, diabetic macular edema (DME), and diabetic retinopathy (DR) based on the PULSAR and PHOTON studies. Both studies met their primary endpoint, with Eylea® HD demonstrating non-inferior and clinically equivalent vision gains at 48 weeks when compared to Eylea®. Eylea® HD is a higher dose of the already commercially available Eylea® 2mg injection that allows for less frequent injections with the potential to dose every 16 weeks after the

initial 3 monthly doses. The Wholesale Acquisition Cost (WAC) for Eylea® HD is $2,625 per vial resulting in a cost per year of $21,000 for the FDA approved maximum dosing for 1 eye compared to Eylea® whose WAC is $1,850 per vial resulting in a cost per year of $24,050 for the FDA approved maximum dosing for 1 eye.

- **August 2023:** The FDA approved Izervay™ (avacincaptad pegol) for the treatment of geographic atrophy (GA) secondary to AMD.
- **October 2023:** The FDA approved an expanded indication for Vabysmo® (faricimab-svoa) for the treatment of macular edema following retinal vein occlusion (RVO). It was previously FDA approved for wet AMD and DME only.

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 used off-label and repackaged via a compounding pharmacy for use in the eye. The NORSE EIGHT clinical trial is currently underway with results expected at the end of calendar year 2024.
- **Xlucane®:** Xlucane® is a biosimilar candidate for the vascular endothelial growth factor (VEGF) inhibitor, Lucentis® (ranibizumab). A supplemental Biologics License Application (sBLA) has been submitted to the FDA for Xlucane® and a Biosimilar User Fee Amendment (BsUFA) date of April 21, 2024 has been set.

Izervay™ (Avacincaptad Pegol) Product Summary[9]

Therapeutic Class: Complement inhibitor

Indication(s): For the treatment of GA secondary to AMD

How Supplied: 20mg/mL in a single dose vial

Dosing and Administration:

- The recommended dose is 2mg (0.1mL of 20mg/mL solution) administered by intravitreal injection to each affected eye once monthly (approximately every 28 days ± 7 days) for up to 12 months.

Cost Comparison: Complement Inhibitors

Product	Cost Per Dose	Cost Per Year
Izervay™ (avacincaptad pegol inj) 2mg/0.1mL*	**$2,100**	**$27,300**
Syfovre® (pegcetacoplan inj) 15mg/0.1mL*	$2,190	$28,470

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)., Please note: The cost per dose is based on treatment of 1 eye, and the cost per year is based on the maximum number of doses needed for the treatment of 1 eye.
*Cost is based on 0.1mL every 4 weeks.
inj = injection

Recommendations

The College of Pharmacy recommends the prior authorization of Izervay™ (avacincaptad pegol) with the following criteria (shown in red):

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 patient specific, clinically significant reason why the member cannot use Syfovre® (pegcetacoplan) must be provided; and
6. A quantity limit of (1) 0.1mL single-dose vial per eye once monthly for up to 12 months will apply.

Additionally, the College of Pharmacy recommends the removal of the prior authorization for Lucentis® (ranibizumab intravitreal injection) and updating the approval criteria for Susvimo™ (ranibizumab intravitreal implant) based on net costs (changes shown in red):

~~**Lucentis® (Ranibizumab Intravitreal Injection) Approval Criteria:**~~

~~1. An FDA approved diagnosis; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use Byooviz™ (ranibizumab-nuna intravitreal injection) or Cimerli® (ranibizumab-eqrn intravitreal injection) 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.~~

Susvimo™ (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of neovascular (wet) age-related macular degeneration (AMD) in adults; 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)] must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

Finally, the College of Pharmacy recommends updating the approval criteria for Vabysmo® (faricimab-svoa) based on the new FDA approval and net cost (changes shown in red):

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); ~~and~~ 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. A patient-specific, clinically significant reason why the member cannot use VEGF inhibitor injection products (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)] must be provided; and
8. A quantity limit of 0.05mL per 28 days will apply.

Utilization Details of AMD Medications: Calendar Year 2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J0178 AFLIBERCEPT (EYLEA)	642	225	$1,377,889.06	$2,146.24	2.85
Q5128 RANIBIZUMAB-EQRN (CIMERLI)	137	76	$181,613.14	$1,325.64	1.8
J2777 FARICIMAB-SVOA (VABYSMO)	131	50	$379,349.10	$2,895.79	2.62
J2778 RANIBIZUMAB (LUCENTIS)	12	7	$10,891.59	$907.63	1.71
Q5124 RANIBIZUMAB-NUNA (BYOOVIZ)	3	3	$2,993.25	$997.75	1
J0179 BROLUCIZUMAB-DBLL (BEOVU)	2	1	$3,835.20	$1,917.60	2
TOTAL	**927**	**333**	**$1,956,571.34**	**$2,110.65**	**2.78**

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

[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 03/2024. Last accessed 03/28/2024.
[2] Regeneron Pharmaceuticals, Inc. Eylea® HD (Aflibercept) Injection 8mg Approved by FDA for Treatment of Wet Age-Related Macular Degeneration (WAMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR). Available online at: https://investor.regeneron.com/news-releases/news-release-details/eylea-hd-aflibercept-injection-8-mg-approved-fda-treatment-wet. Issued 08/18/2023. Last accessed 03/15/2024.
[3] Eylea® HD (Aflibercept) Prescribing Information. Regeneron Pharmaceuticals, Inc. Available online at: https://www.regeneron.com/downloads/eyleahd_fpi.pdf. Last revised 12/2023. Last accessed 03/15/2024.
[4] Astellas Pharma, Inc. Iveric Bio Receives U.S. FDA Approval for Izervay™ (Avacincaptad Pegol Intravitreal Solution), a New Treatment for Geographic Atrophy. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/iveric-bio-receives-us-fda-approval-for-izervay-avacincaptad-pegol-intravitreal-solution-a-new-treatment-for-geographic-atrophy-301894042.html. Issued 08/04/2023. Last accessed 03/15/2024.
[5] Genentech, Inc. FDA Approves Genentech's Vabysmo® for the Treatment of Retinal Vein Occlusion (RVO). Available online at: https://www.gene.com/media/press-releases/15009/2023-10-26/fda-approves-genentechs-vabysmo-for-the-. Issued 10/26/2023. Last accessed 03/15/2024.
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[7] Outlook Therapeutics®. Outlook Therapeutics® Doses First Subject in NORSE EIGHT. Available online at: https://ir.outlooktherapeutics.com/news-releases/news-release-details/outlook-therapeuticsr-doses-first-subject-norse-eight. Issued 01/31/2024. Last accessed 03/20/2024.
[8] Xbrane BioPharma. Xbrane Announces U.S. FDA Filing Acceptance for Lucentis® (Ranibizumab) Biosimilar Candidate. Available online at: https://xbrane.com/en/mfn_news/xbrane-announce-u-s-fda-filing-acceptance-for-a-lucentis-ranibizumab-biosimilar-candidate/. Issued 06/21/2023. Last accessed 03/20/2024.
[9] Izervay™ (Avacincaptad Pegol Intravitreal Injection) Prescribing Information. Iveric bio, Inc. Available online at: https://ivericbio.com/wp-content/uploads/IZERVAY-avacincaptad-pegol-intravitreal-solution-PI_Final_8.4.23.pdf. Last revised 08/2023. Last accessed 03/15/2024.

Appendix O

Calendar Year 2023 Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin), Voquezna® (Vonoprazan), Voquezna® Dual Pak® (Vonoprazan/Amoxicillin), and Voquezna® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin)

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® caps) – **Brand Preferred**	pantoprazole (Protonix® I.V.)	esomeprazole (Nexium® I.V.)	cimetidine (Tagamet® tabs)
dexlansoprazole (Dexilant® caps)		esomeprazole strontium caps	esomeprazole kit (ESOMEP-EZS™)
esomeprazole (Nexium® caps)		omeprazole (Prilosec® susp, powder)	famotidine (Pepcid® susp)
esomeprazole (Nexium® packet) – **Brand Preferred**		pantoprazole (Protonix® susp)	glycopyrrolate (Glycate® tabs)
lansoprazole (Prevacid® caps)		rabeprazole (Aciphex® sprinkles)	glycopyrrolate ODT (Dartisla® ODT)
lansoprazole ODT (Prevacid® ODT) – **Brand Preferred**			nizatidine (Axid® caps & soln)
omeprazole (Prilosec® caps)			omeprazole/amoxicillin/ rifabutin (Talicia® caps)
pantoprazole (Protonix® tabs)			omeprazole/sodium bicarbonate (Konvomep® for oral suspension)
rabeprazole (Aciphex® tabs)			omeprazole/sodium bicarbonate (Zegrid® caps & pack)
sucralfate susp (Carafate®)			

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
⁺Individual criteria specific to each product applies.
caps = capsules; I.V. = intravenous; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tabs = tablet

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications; and
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reasoning for use.

Proton Pump Inhibitors for Pediatric Members Approval Criteria:

1. A recent 14-day trial of an H_2 receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
    a. Gastrointestinal (GI) bleed; or
    b. Zollinger-Ellison Syndrome or similar disease; and
3. Tier structure rules still apply.

Axid® (Nizatidine Capsules) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Axid® (Nizatidine Solution) Approval Criteria:

1. A previous 14-day trial of famotidine suspension or a patient-specific, clinically significant reason why famotidine suspension is not appropriate for the member must be provided; and
2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

Dartisla® ODT [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and

2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided; and
3. A quantity limit of 120 tablets per 30 days will apply.

Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:

1. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors, including omeprazole and esomeprazole, along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and
2. Current Tier structure rules will also apply.

Glycate® (Glycopyrrolate Tablets) Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.

Konvomep® (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Zegerid® (Omeprazole/Sodium Bicarbonate Capsules) Approval Criteria:

1. Member must be 18 years of age or older; and
2. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided; and
3. For Konvomep™, requests for the 90mL or 150mL package will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size.

Pepcid® (Famotidine Suspension) Approval Criteria:

1. Famotidine suspension will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.

Tagamet® (Cimetidine Tablets) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsules) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and

clarithromycin) or Pylera® (bismuth subcitrate potassium/ metronidazole/tetracycline), which are available without prior authorization, must be provided; and

3. A quantity limit of 168 capsules per 14 days will apply.

Utilization of Anti-Ulcer Medications: Calendar Year 2023

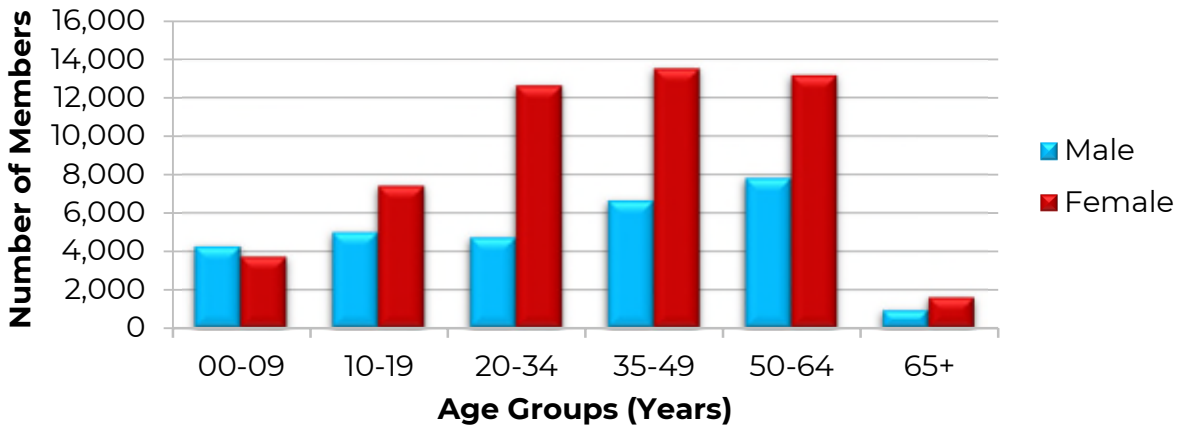
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	73,492	224,005	$5,977,223.87	$26.68	$0.59	13,994,278	10,101,477
2023	81,137	242,099	$6,033,636.16	$24.92	$0.53	15,782,399	11,401,774
% Change	**10.40%**	**8.10%**	**0.90%**	**-6.60%**	**-10.20%**	**12.80%**	**12.90%**
Change	**7,645**	**18,094**	**$56,412.29**	**-$1.76**	**-$0.06**	**1,788,121**	**1,300,297**

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

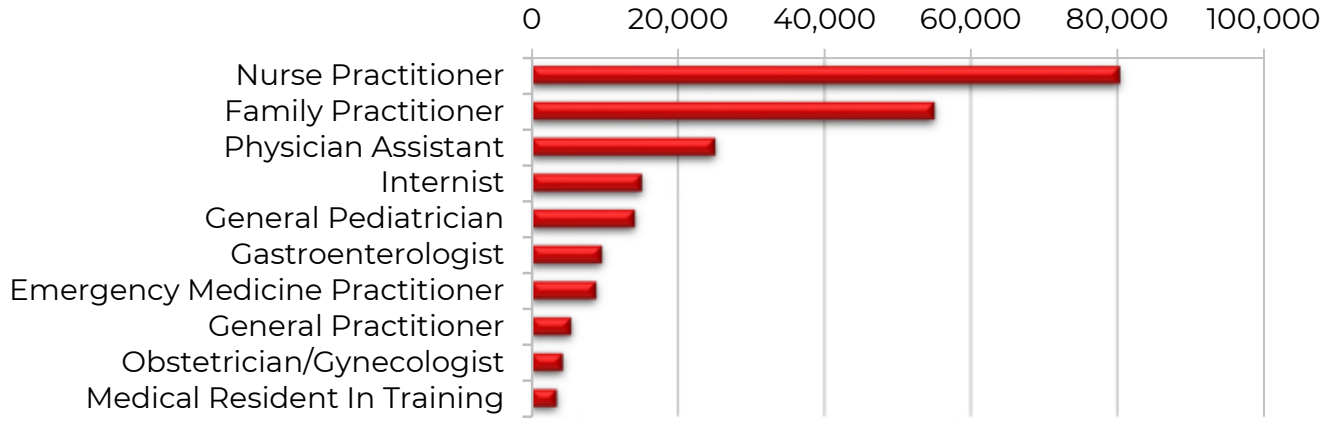
- Aggregate drug rebates collected during fiscal year 2023 (07/01/2022 to 06/30/2023) for antiulcer medications totaled $1,142,241.06.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for calendar year 2023 are still being collected at this time. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Anti-Ulcer Medications



[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.

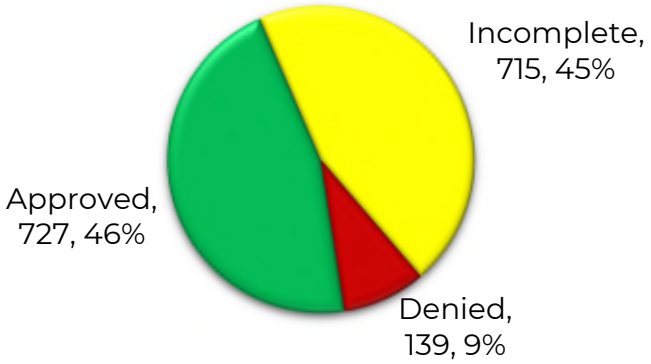
Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



Prior Authorization of Anti-Ulcer Medications

There were 1,581 prior authorization requests submitted for anti-ulcer medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Voquezna® (vonoprazan): August 2030
- Voquezna® Triple Pak® (vonoprazan/amoxicillin/clarithromycin): August 2030
- Voquezna® Dual Pak® (vonoprazan/amoxicillin): August 2030
- Dexilant® (dexlansoprazole): March 2032
- Konvomep® (omeprazole/sodium bicarbonate for oral suspension): March 2040
- Talicia® (omeprazole/amoxicillin/rifabutin): May 2042

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

- **October 2023:** The FDA approved a Prior Approval Supplement (PAS) for the reformulation of vonoprazan tablets for the Voquezna® Triple Pak® and Dual Pak® for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. The Voquezna® Triple Pak® and Dual Pak® were originally FDA approved on May 3, 2022 but market launch was delayed due to the presence of nitrosamine impurities.
- **November 2023:** The FDA approved Voquezna® (vonoprazan tablets) for the healing of all grades of erosive gastroesophageal reflux disease (GERD), maintenance of healing of erosive GERD, and relief of heartburn associated with erosive GERD in adults.

Pipeline:

- **Vonoprazan:** Vonoprazan is also currently being studied for heartburn associated with non-erosive GERD. A New Drug Application (NDA) was accepted by the FDA and a Prescription Drug User Fee Act (PDUFA) date of July 19, 2024 has been set.

Voquezna® (Vonoprazan) Product Summary[8]

Therapeutic Class: Potassium-competitive acid blocker

Indication(s):

- Healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
- Maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
- Treatment of *H. pylori* infection in adults in combination with amoxicillin ± clarithromycin

How Supplied: 10mg and 20mg tablets

Dosing and Administration:

- Healing of erosive esophagitis: 20mg once daily for 8 weeks
- Maintenance of healed erosive esophagitis: 10mg once daily for up to 6 months
- Treatment of *H. pylori*: 20mg twice daily in combination with amoxicillin ± clarithromycin

Cost Comparison: Anti-Ulcer Medications

Product	Cost Per Unit	Cost Per 8-Week Course*
Voquezna® (vonoprazan) 20mg	**$21.67**	**$1,213.52**
esomeprazole 40mg (generic)	$0.16	$8.96
pantoprazole 40mg (generic)	$0.06	$3.36

omeprazole 20mg (generic)	$0.03	$1.68

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 = tablet or capsule
*Cost per 8-week treatment course is based on the FDA approved dosing for the healing of erosive esophagitis for each product

Voquezna® Dual Pak® (Vonoprazan/Amoxicillin) and Voquezna® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin) Product Summary[9]

Therapeutic Class: Potassium-competitive acid blocker (vonoprazan) in combination with penicillin class antibacterial (amoxicillin) ± a macrolide (clarithromycin)

Indication(s): Treatment of *H. pylori* infection in adults

How Supplied: Carton of 14 daily administration packs for morning and evening dosing, each containing the following:

- Voquezna® Dual Pak®: Vonoprazan 20mg tablets and amoxicillin 500mg capsules
- Voquezna® Triple Pak®: Vonoprazan 20mg tablets, amoxicillin 500mg capsules, and clarithromycin 500mg tablets

Dosing and Administration:

- Voquezna® Dual Pak®: Vonoprazan 20mg twice daily (morning and evening) plus amoxicillin 1,000mg 3 times daily (morning, mid-day, and evening), with or without food, for 14 days.
- Voquezna® Triple Pak®: Vonoprazan 20mg plus amoxicillin 1,000mg plus clarithromycin 500mg, each given twice daily (morning and evening, 12 hours apart), with or without food, for 14 days.

Cost Comparison: *H. Pylori* Treatments

Product	Cost Per Tablet	Cost Per Course*
Voquezna® Dual Pak® (vonoprazan/amoxicillin)	**$7.25**	**$812.00**
Voquezna® Triple Pak® (vonoprazan/amoxicillin/ clarithromycin)	**$7.25**	**$812.00**
lansoprazole/amoxicillin/clarithromycin (generic PrevPac®)	$7.92	$887.04
Talicia® (omeprazole/amoxicillin/rifabutin)	$4.59	$771.12
Pylera® (bismuth/metronidazole/tetracycline)	$2.43	$291.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per treatment course is based on the FDA approved dosing of a 14-day treatment course for each product.

Recommendations

The College of Pharmacy recommends the following changes to the Anti-Ulcer medications Product Based Prior Authorization (PBPA) category with the following additional criteria (changes shown in red):

1. The prior authorization of PrevPac® (lansoprazole/amoxicillin/ clarithromycin) and placement into the Special Prior Authorization (PA) Tier; and
2. The prior authorization of Voquezna® (vonoprazan), Voquezna® Dual Pak® (vonoprazan/amoxicillin), and Voquezna® Triple Pak® (vonoprazan/ amoxicillin/clarithromycin) and placement into the Special PA Tier; and
3. Removing the brand preferred status of Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline) and moving it to the Special PA Tier based on product availability and net costs.

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
~~**bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® caps) – Brand Preferred**~~	pantoprazole (Protonix® I.V.)	esomeprazole (Nexium® I.V.)	**bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® caps)**
dexlansoprazole (Dexilant® caps)		esomeprazole strontium caps	cimetidine (Tagamet® tabs)
esomeprazole (Nexium® caps)		omeprazole (Prilosec® susp, powder)	esomeprazole kit (ESOMEP-EZS™)
esomeprazole (Nexium® packet) – **Brand Preferred**		pantoprazole (Protonix® susp)	famotidine (Pepcid® susp)
lansoprazole (Prevacid® caps)		rabeprazole (Aciphex® sprinkles)	glycopyrrolate (Glycate® tabs)
lansoprazole ODT (Prevacid® ODT) – **Brand Preferred**			glycopyrrolate ODT (Dartisla® ODT)
omeprazole (Prilosec® caps)			**lansoprazole/amoxicillin/ clarithromycin (PrevPac®)**
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/amoxicillin/ rifabutin (Talicia® caps)
sucralfate susp (Carafate®)			omeprazole/sodium bicarbonate (Konvomep™ for oral suspension)
			omeprazole/sodium bicarbonate

			(Zegrid® caps & pack)
			vonoprazan (Voquezna® tabs)
			vonoprazan fumarate/ amoxicillin trihydrate (Voquezna® Dual Pak®)
			vonoprazan fumarate/ amoxicillin trihydrate/ clarithromycin (Voquezna® Triple Pak®)

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
†Individual criteria specific to each product applies.
caps = capsules; I.V. = intravenous; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tabs = tablet

PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin) Approval Criteria:

1. An FDA approved indication for the eradication of *Helicobacter pylori* (*H. pylori)* infection and to reduce the risk of duodenal ulcer recurrence; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components, which are available without prior authorization, must be provided; and
3. A quantity limit of 112 tablets/capsules per 14 days will apply.

Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus an histamine type 2 receptor (H2) antagonist], must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
5. A quantity limit of 120 capsules per 10 days will apply.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsules) Approval Criteria:

1. An FDA approved diagnosis; and

2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin) ~~or Pylera® (bismuth subcitrate potassium/ metronidazole/tetracycline),~~ which are available without prior authorization, must be provided; and
3. A quantity limit of 168 capsules per 14 days will apply.

Voquezna® (Vonoprazan Fumarate) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate) and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/ Clarithromycin) Approval Criteria:

1. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/ H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin) which are available without prior authorization, must be provided; and
5. A quantity limit of 112 tablets/capsules per 14 days will apply.

Utilization Details of Anti-Ulcer Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
OMEPRAZOLE PRODUCTS						
OMEPRAZOLE CAP 20MG	48,286	19,619	$555,503.89	$11.50	2.46	9.21%
OMEPRAZOLE CAP 40MG	44,490	17,303	$576,422.61	$12.96	2.57	9.55%
OMEPRAZOLE CAP 10MG	2,135	928	$29,711.14	$13.92	2.3	0.49%
SUBTOTAL	**94,911**	**37,850**	**$1,161,637.64**	**$12.24**	**2.51**	**19.25%**
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE TAB 40MG	57,182	22,603	$744,931.66	$13.03	2.53	12.35%
PANTOPRAZOLE TAB 20MG	8,259	3,670	$104,814.77	$12.69	2.25	1.74%
SUBTOTAL	**65,441**	**26,273**	**$849,746.43**	**$12.98**	**2.49**	**14.09%**
FAMOTIDINE PRODUCTS						
FAMOTIDINE TAB 20MG	24,188	12,145	$297,821.81	$12.31	1.99	4.94%
FAMOTIDINE TAB 40MG	8,118	3,912	$109,289.17	$13.46	2.08	1.81%
FAMOTIDINE INJ 200MG/20ML	142	10	$2,784.66	$19.61	14.2	0.05%
FAMOTIDINE INJ 10MG/ML	93	7	$1,367.68	$14.71	13.29	0.02%
FAMOTIDINE INJ 20MG/2ML	74	6	$1,378.68	$18.63	12.33	0.02%
FAMOTIDINE INJ 40MG/4ML	59	5	$1,549.82	$26.27	11.8	0.03%
SUBTOTAL	**32,674**	**16,085**	**$414,191.82**	**$12.68**	**2.03**	**6.87%**
SUCRALFATE PRODUCTS						
SUCRALFATE TAB 1GM	11,483	6,954	$262,178.86	$22.83	1.65	4.35%
SUCRALFATE SUS 1GM/10ML	975	627	$212,560.50	$218.01	1.56	3.52%
CARAFATE SUS 1GM/10ML	510	264	$205,175.07	$402.30	1.93	3.40%
SUBTOTAL	**12,968**	**7,845**	**$679,914.43**	**$52.43**	**1.65**	**11.27%**
ESOMEPRAZOLE PRODUCTS						
ESOMEPRAZOLE CAP 40MG DR	5,837	1,943	$109,435.31	$18.75	3	1.81%
ESOMEPRAZOLE CAP 20MG DR	2,192	855	$43,515.17	$19.85	2.56	0.72%
NEXIUM GRA 10MG DR	629	195	$187,790.93	$298.55	3.23	3.11%
NEXIUM GRA 20MG DR	552	131	$164,084.20	$297.25	4.21	2.72%
NEXIUM GRA 5MG DR	339	134	$97,154.16	$286.59	2.53	1.61%
NEXIUM GRA 40MG DR	221	49	$63,472.64	$287.21	4.51	1.05%
NEXIUM GRA 2.5MG DR	133	75	$38,002.72	$285.73	1.77	0.63%
NEXIUM CAP 40MG	2	1	$1,601.50	$800.75	2	0.03%
ESOMEPRAZOLE GRA 10MG DR	1	1	$409.63	$409.63	1	0.01%
SUBTOTAL	**9,906**	**3,384**	**$705,466.26**	**$71.22**	**2.93**	**11.69%**
DEXLANSOPRAZOLE PRODUCTS						
DEXLANSOPRAZOLE CAP 60MG DR	3,610	644	$776,200.00	$215.01	5.61	12.86%
DEXLANSOPRAZOLE CAP 30MG DR	940	185	$208,840.08	$222.17	5.08	3.46%
DEXILANT CAP 60MG DR	625	133	$182,076.77	$291.32	4.7	3.02%
DEXILANT CAP 30MG DR	152	35	$46,077.22	$303.14	4.34	0.76%
SUBTOTAL	**5,327**	**997**	**$1,213,194.07**	**$227.74**	**5.34**	**20.10%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LANSOPRAZOLE PRODUCTS						
LANSOPRAZOLE CAP 30MG DR	2,469	829	$36,465.95	$14.77	2.98	0.60%
LANSOPRAZOLE CAP 15MG DR	504	190	$9,719.81	$19.29	2.65	0.16%
LANSOPRAZOLE ODT 15MG	324	84	$39,326.64	$121.38	3.86	0.65%
PREVACID TAB 30MG STB	313	44	$133,147.43	$425.39	7.11	2.21%
PREVACID TAB 15MG STB	86	25	$40,536.96	$471.36	3.44	0.67%
LANSOPRAZOLE ODT 30MG	38	26	$5,353.93	$140.89	1.46	0.09%
LANSOPRAZOLE TAB 30MG	1	1	$137.86	$137.86	1	0.00%
SUBTOTAL	**3,735**	**1,199**	**$264,688.58**	**$70.87**	**3.12**	**4.38%**
GLYCOPYRROLATE PRODUCTS						
GLYCOPYRROLATE TAB 1MG	1,770	409	$30,934.77	$17.48	4.33	0.51%
GLYCOPYRROLATE TAB 2MG	1,098	178	$24,744.62	$22.54	6.17	0.41%
SUBTOTAL	**2,868**	**587**	**$55,679.39**	**$19.41**	**4.89**	**0.92%**
RABEPRAZOLE PRODUCTS						
RABEPRAZOLE TAB 20MG	697	245	$15,357.34	$22.03	2.84	0.25%
SUBTOTAL	**697**	**245**	**$15,357.34**	**$22.03**	**2.84**	**0.25%**
CIMETIDINE PRODUCTS						
CIMETIDINE SOL 300MG/5ML	65	49	$3,260.71	$50.16	1.33	0.05%
SUBTOTAL	**65**	**49**	**$3,260.71**	**$50.16**	**1.33**	**0.05%**
TRIPLE THERAPY COMBINATIONS						
PYLERA CAP 140-125-125MG	37	35	$26,565.08	$717.98	1.06	0.44%
BISMTH/METR/TETRA 140-125-125MG	3	3	$2,536.81	$845.60	1	0.04%
SUBTOTAL	**40**	**38**	**$29,101.89**	**$727.55**	**1.05**	**0.48%**
TIER-1 TOTAL	**228,632**	**94,552**	**$5,392,238.56**	**$23.58**	**2.42**	**89.35%**
TIER-2 UTILIZATION						
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE INJ 40MG	109	4	$3,306.29	$30.33	27.25	0.05%
SUBTOTAL	**109**	**4**	**$3,306.29**	**$30.33**	**27.25**	**0.05%**
TIER-2 TOTAL	**109**	**4**	**$3,306.29**	**$30.33**	**27.25**	**0.05%**
TIER-3 UTILIZATION						
PANTOPRAZOLE PRODUCTS						
PROTONIX PAK 40MG	11	1	$5,596.80	$508.80	11	0.09%
PANTOPRAZOLE PAK 40MG	6	4	$7,092.65	$1,182.11	1.5	0.12%
SUBTOTAL	**17**	**5**	**$12,689.45**	**$746.44**	**3.4**	**0.21%**
OMEPRAZOLE PRODUCTS						
PRILOSEC POW 10MG	4	1	$1,637.72	$409.43	4	0.03%
PRILOSEC POW 2.5MG	2	1	$820.24	$410.12	2	0.01%
SUBTOTAL	**6**	**2**	**$2,457.96**	**$409.66**	**3**	**0.04%**
TIER-3 TOTAL	**23**	**7**	**$15,147.41**	**$658.58**	**3.29**	**0.25%**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
FAMOTIDINE PRODUCTS						
FAMOTIDINE SUS 40MG/5ML	13,254	5,628	$618,953.59	$46.70	2.36	10.26%
SUBTOTAL	**13,254**	**5,628**	**$618,953.59**	**$46.70**	**2.36**	**10.26%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CIMETIDINE PRODUCTS						
CIMETIDINE TAB 400MG	34	20	$1,146.13	$33.71	1.7	0.02%
CIMETIDINE TAB 800MG	19	6	$886.25	$46.64	3.17	0.01%
CIMETIDINE TAB 300MG	15	4	$416.84	$27.79	3.75	0.01%
CIMETIDINE TAB 200MG	10	3	$250.30	$25.03	3.33	0.00%
SUBTOTAL	**78**	**33**	**$2,699.52**	**$34.61**	**2.36**	**0.04%**
OMEPRAZOLE/SODIUM BICARBONATE PRODUCTS						
KONVOMEP SUS 2-84MG/ML	3	2	$1,290.79	$430.26	1.5	0.02%
SUBTOTAL	**3**	**2**	**$1,290.79**	**$430.26**	**1.5**	**0.02%**
SPECIAL PA TOTAL	**13,335**	**5,663**	**$622,943.90**	**$46.71**	**2.35**	**10.32%**
TOTAL	**242,099**	**81,137***	**$6,033,636.16**	**$24.92**	**2.98**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BICARB = bicarbonate; BISMTH = bismuth subcitrate; CAP = capsule; DR = delayed-release; GRA = granules; INJ = injection; METR = metronidazole; ODT = orally disintegrating tablet; PAK = pack; POW = powder; SOD = sodium; SOL = solution; SPR = sprinkle; STB = solutab; SUS = suspension; TAB = tablet; TETRA = tetracycline

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Appendix P

Calendar Year 2023 Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Rezzayo™ (Rezafungin Injection)

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Ancobon® (Flucytosine) Approval Criteria:

1. An FDA approved indication for treatment of systemic fungal infections (e.g., sepsis, endocarditis, urinary tract infection, meningitis, pulmonary) caused by strains of *Candida* or *Cryptococcus*.

Brexafemme® (Ibrexafungerp) Approval Criteria [Recurrent Vulvovaginal Candidiasis (RVVC) Diagnosis]:

1. An FDA approved indication to reduce the incidence of RVVC; and
2. Member must be an adult female or post-menarchal pediatric female; and
3. Member has a history of RVVC with at least 3 symptomatic episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months; and
4. Member has experienced a recurrence of VVC during or following 6 months of fluconazole-only maintenance treatment for RVVC or member has a contraindication to fluconazole (e.g., hypersensitivity, drug-drug interactions); and
5. Prescriber must verify member is not pregnant, not lactating, and is currently using reliable contraception and will continue to use throughout the treatment duration and 4 days after last dose; and
6. Member must not be taking concurrent strong CYP3A inducers (e.g., carbamazepine, phenobarbital, phenytoin, rifampin); and
7. A quantity limit of 24 tablets per 180 days will apply.

Brexafemme® (Ibrexafungerp) Approval Criteria [Vulvovaginal Candidiasis (VVC) Diagnosis]:

1. An FDA approved diagnosis of VVC; and
2. Member must be an adult female or a post-menarchal pediatric female; and
3. Prescriber must verify that female members are not pregnant and are currently using reliable contraception; and
4. Member must not be taking concurrent strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, long-acting barbiturates, bosentan, efavirenz, etravirine); and

5. Authorization consideration requires a patient-specific, clinically significant reason why oral fluconazole and all topical antifungals [prescription and over-the-counter (OTC)] FDA approved for the treatment of VVC are not appropriate for the member; and
6. A quantity limit for 4 tablets for 1 day will apply.

Cresemba® (Isavuconazonium Sulfate) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Invasive aspergillosis; or
   b. Invasive mucormycosis; and
2. For the treatment of invasive aspergillosis, a patient-specific, clinically significant reason why voriconazole cannot be used must be provided.

Ketoconazole Oral Tablets Approval Criteria:

1. An FDA approved indication of systemic fungal infections with 1 of the following:
   a. Blastomycosis; or
   b. Coccidioidomycosis; or
   c. Histoplasmosis; or
   d. Chromomycosis; or
   e. Paracoccidioidomycosis; and
2. Member is 3 years of age or older; and
3. Member does not have underlying hepatic disease; and
4. Trials with other effective oral antifungal therapies, including fluconazole, itraconazole, and voriconazole, have failed to resolve infection; or
5. Other effective oral antifungal therapies are not tolerated or potential benefits outweigh the potential risks; and
6. Hepatic function tests must be done at baseline and weekly during treatment; and
7. A clinical exception may apply for members with a diagnosis of Cushing's disease when other modalities are not available.

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk patients due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy with product use as follows:
      i. <u>Delayed-release (DR) tablets:</u> Adults and pediatric members 2 years of age and older who weigh >40kg; or
      ii. <u>Intravenous (IV) injection:</u> Adults and pediatric members 2 years of age and older; or

iii. Oral suspension: Adults and pediatric members 13 years of age and older; or
iv. PowderMix for DR oral suspension: Pediatric members 2 years of age and older who weigh ≤40kg; or

b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric members 13 years of age and older with product use as follows:
   i. For the treatment of OPC, including rOPC to itraconazole and/or fluconazole, only the oral suspension may be used; or
c. Treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older with product use as follows:
   i. For the treatment of invasive aspergillosis only the IV injection or DR tablets may be used; or

2. Treatment of invasive mucormycosis; or
3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization.

Oravig® (Miconazole Buccal Tablets) Approval Criteria:

1. An FDA approved diagnosis of oropharyngeal candidiasis in adult members 18 years of age and older; and
2. Recent trials (within the last month) of the following medications at the recommended dosing and duration of therapy:
   a. Clotrimazole troches; and
   b. Nystatin suspension; and
   c. Fluconazole tablets; or
3. Contraindication(s) to all available alternative medications.

Tolsura® (Itraconazole Oral Capsules) Approval Criteria:

1. An FDA approved indication of 1 of the following fungal infections in immunocompromised and non-immunocompromised adult members:
   a. Blastomycosis, pulmonary and extrapulmonary; or
   b. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; or
   c. Aspergillosis, pulmonary and extrapulmonary, in members who are intolerant of or who are refractory to amphotericin B therapy; and
2. A patient-specific, clinically significant reason why the member cannot use itraconazole 100mg capsules, which are available without prior authorization, must be provided.

Vivjoa® (Oteseconazole) Approval Criteria:

1. An FDA approved indication to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC); and
2. Member must be a female who is not pregnant, lactating, or not of reproductive potential; and

3. Member has a history of RVVC with at least 3 symptomatic episodes of acute vulvovaginal candidiasis (VVC) in the previous 12 months; and
4. Member has experienced a recurrence of VVC during or following 6 months of fluconazole-only maintenance treatment for RVVC or member has a contraindication to fluconazole (e.g., hypersensitivity, drug-drug interactions); and
5. Prescriber must verify member will be monitored if taking breast cancer resistance protein (BCRP) substrates (e.g., rosuvastatin, mitoxantrone, methotrexate, topotecan, imatinib, irinotecan); and
6. A quantity limit of 18 capsules per 84 days will apply.

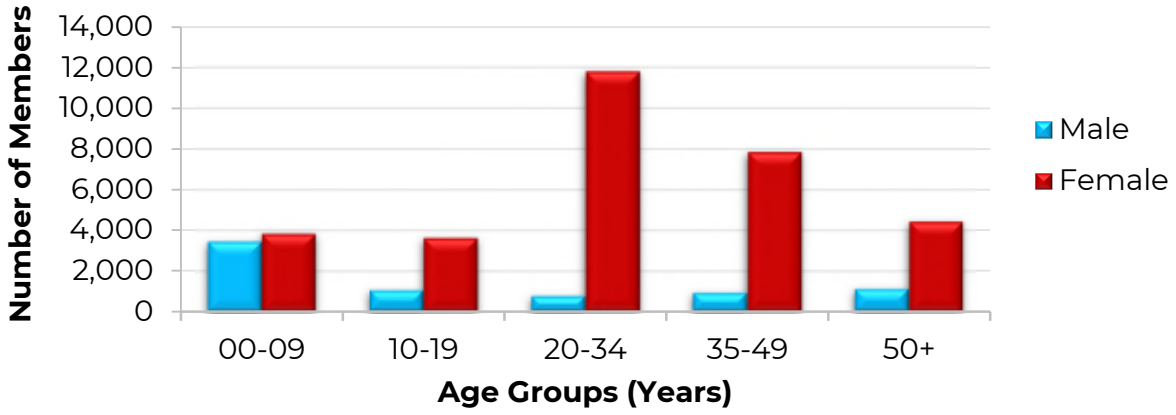
Utilization of Systemic Antifungal Medications: Calendar Year 2023

Comparison of Calendar Years

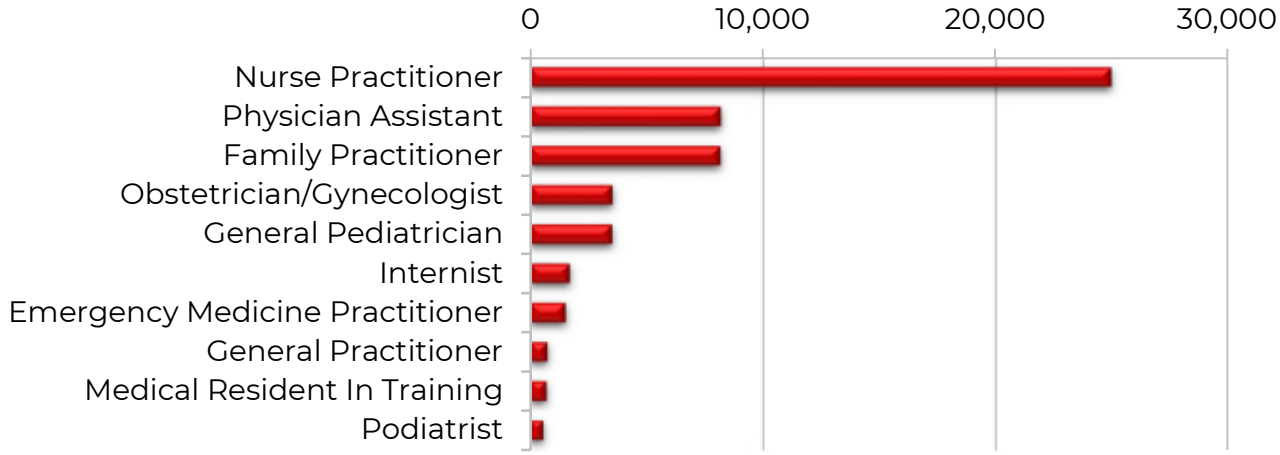
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	36,150	53,885	$2,397,764.49	$44.50	$4.05	2,108,984	592,660
2023	38,685	56,940	$1,637,636.06	$28.76	$2.65	2,103,798	618,962
% Change	**7.0%**	**5.7%**	**-31.7%**	**-35.4%**	**-34.6%**	**-0.3%**	**4.4%**
Change	**2,532**	**3,051**	**-$760,192.68**	**-$15.74**	**-$1.40**	**-5,393**	**26,204**

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

Demographics of Members Utilizing Systemic Antifungal Medications



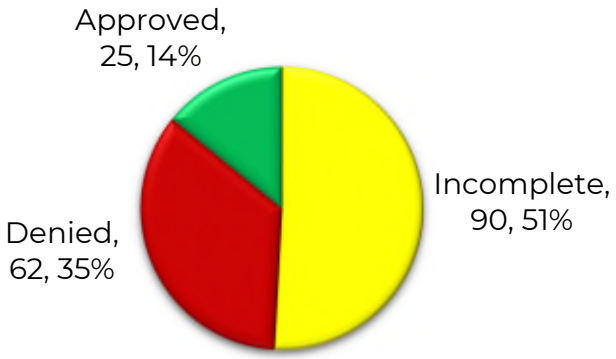
Top Prescriber Specialties of Systemic Antifungal Medications by Number of Claims



Prior Authorization of Systemic Antifungal Medications

There were 177 prior authorization requests submitted for systemic antifungal medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Cresemba® [isavuconazonium intravenous (IV) powder for solution]: October 2025
- Cresemba® (isavuconazonium capsule): September 2027
- Noxafil® (posaconazole IV solution): February 2033
- Tolsura® (itraconazole capsule): June 2033
- Vivjoa® (oteseconazole capsule): March 2036
- Rezzayo™ (rezafungin injection): July 2038
- Brexafemme® (ibrexafungerp tablet): June 2039

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

- **March 2023:** The FDA approved Rezzayo™ (rezafungin injection) for the treatment of candidemia and invasive candidiasis in patients with limited or no treatment options. The approval was based on the ReSTORE Phase 3 clinical trial which was found to meet the primary endpoint. Studies are continuing on rezafungin for other indications including prevention of invasive fungal diseases in patients undergoing allogenic blood and bone marrow transplant.

Rezzayo™ (Rezafungin Injection) Product Summary[3]

Therapeutic Class: Echinocandin antifungal

Indication(s): Treatment of candidemia and invasive candidiasis in patients 18 years of age or older who have limited or no alternative options

- **Limitation(s) of Use:** Has not been studied in patients with endocarditis, osteomyelitis, or meningitis due to *Candida*

How Supplied: 200mg rezafungin powder for reconstitution in a single-dose glass vial

Dosing and Administration:

- Administered as a weekly IV infusion over 1 hour up to a maximum of 4 total doses
  - Loading dose (week 1): 400mg
  - Subsequent doses (week 2 and thereafter up to a maximum of 4 total weeks): 200mg once weekly
- Rate can be slowed down or paused and restarted if infusion related reactions occur

Cost Comparison: Echinocandin Medications

Medication	Cost Per Vial*	Cost Per Treatment†
Rezzayo™ (rezafungin) 200mg	**$1,950.00**	**$9,750.00**
Eraxis® (anidulafungin) 100mg	$190.89	$5,535.81
micafungin 100mg (generic)	$187.00[α]	$5,236.00
caspofungin 50mg (generic)	$54.27	$1,573.83

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

[α]Cost per vial varies per NDC

†Cost per treatment is based on the FDA recommended dosing for each medication, including loading doses, for a patient with candidiasis resulting in 5 vials of Rezzayo™, 29 vials of Eraxis®, 28 vials of micafungin, and 29 vials of caspofungin.

Recommendations

The College of Pharmacy recommends the prior authorization of Rezzayo™ (rezafungin injection) with the following criteria (shown in red):

Rezzayo™ (Rezafungin Injection) Approval Criteria:

1. An FDA approved diagnosis of candidemia or invasive candidiasis; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that limited or no alternative treatment options are available; and
4. A patient-specific, clinically significant reason why the member cannot use anidulafungin, caspofungin, or micafungin, which are available without a prior authorization, must be provided; and
5. Member must not have endocarditis, osteomyelitis, or meningitis due to *Candida*; and
6. Must be administered by a health care provider in a setting that is appropriately equipped to administer Rezzayo™; and
7. A quantity limit of 5 vials for 28 days will apply; and
8. A limit of 4 weeks of treatment will apply.

Utilization Details of Systemic Antifungal Medications: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FLUCONAZOLE PRODUCTS						
FLUCONAZOLE TAB 150MG	31,264	21,835	$330,224.56	$10.56	1.43	20.16%
FLUCONAZOLE TAB 200MG	4,133	3,129	$56,245.17	$13.61	1.32	3.43%
FLUCONAZOLE TAB 100MG	3,010	2,497	$33,049.31	$10.98	1.21	2.02%
FLUCONAZOLE SUS 40MG/ML	1,355	1,112	$43,827.55	$32.35	1.22	2.68%
FLUCONAZOLE SUS 10MG/ML	808	709	$18,868.66	$23.35	1.14	1.15%
FLUCONAZOLE TAB 50MG	40	34	$531.27	$13.28	1.18	0.03%
FLUCONAZOLE INJ 200MG	11	2	$700.85	$63.71	5.5	0.04%
FLUCONAZOLE INJ 400MG	2	2	$96.01	$48.01	1	0.01%
SUBTOTAL	**40,623**	**29,320**	**$483,543.38**	**$11.90**	**1.39**	**29.53%**
NYSTATIN PRODUCTS						
NYSTATIN SUS 100,000U/ML	8,725	7,340	$144,569.34	$16.57	1.19	8.83%
NYSTATIN TAB 500,000U	64	32	$1,957.85	$30.59	2	0.12%
SUBTOTAL	**8,789**	**7,372**	**$146,527.19**	**$16.67**	**1.19**	**8.95%**
TERBINAFINE PRODUCTS						
TERBINAFINE TAB 250MG	4,782	3,332	$74,746.21	$15.63	1.44	4.56%
SUBTOTAL	**4,782**	**3,332**	**$74,746.21**	**$15.63**	**1.44**	**4.56%**
GRISEOFULVIN PRODUCTS						
GRISEOFULVIN SUS 125MG/5ML	998	759	$130,130.56	$130.39	1.31	7.95%
GRISEOFULVIN TAB MICRO 500MG	410	327	$118,649.68	$289.39	1.25	7.25%
GRISEOFULVIN TAB ULTR 250MG	129	99	$24,862.22	$192.73	1.3	1.52%
GRISEOFULVIN TAB ULTR 125MG	28	23	$5,417.87	$193.50	1.22	0.33%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**1,565**	**1,208**	**$279,060.33**	**$178.31**	**1.3**	**17.04%**
ITRACONAZOLE PRODUCTS						
ITRACONAZOLE CAP 100MG	440	223	$29,420.80	$66.87	1.97	1.80%
ITRACONAZOLE SOL 10MG/ML	94	56	$67,646.35	$719.64	1.68	4.13%
SUBTOTAL	**534**	**279**	**$97,067.15**	**$181.77**	**1.91**	**5.93%**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE TRO 10MG	216	175	$6,010.91	$27.83	1.23	0.37%
SUBTOTAL	**216**	**175**	**$6,010.91**	**$27.83**	**1.23**	**0.37%**
VORICONAZOLE PRODUCTS						
VORICONAZOLE TAB 200MG	107	42	$12,633.40	$118.07	2.55	0.77%
VORICONAZOLE SUS 40MG/ML	20	7	$41,337.69	$2,066.88	2.86	2.52%
VORICONAZOLE TAB 50MG	15	6	$6,975.13	$465.01	2.5	0.43%
SUBTOTAL	**142**	**55**	**$60,946.22**	**$429.20**	**2.58**	**3.72%**
ECHINOCANDIN PRODUCTS						
MICAFUNGIN INJ 100MG	114	45	$193,469.22	$1,697.10	2.53	11.81%
MICAFUNGIN INJ 50MG	1	1	$50.98	$50.98	1	0.00%
ERAXIS INJ 100MG	1	1	$777.57	$777.57	1	0.05%
SUBTOTAL	**116**	**47**	**$194,297.77**	**$1,674.98**	**2.47**	**11.86%**
POSACONAZOLE PRODUCTS						
POSACONAZOLE TAB 100MG DR	112	33	$79,013.16	$705.47	3.39	4.82%
NOXAFIL TAB 100MG	2	1	$4,134.62	$2,067.31	2	0.25%
POSACONAZOLE SUS 40MG/ML	1	1	$5,262.89	$5,262.89	1	0.32%
SUBTOTAL	**115**	**35**	**$88,410.67**	**$768.79**	**3.29**	**5.40%**
ISAVUCONAZONIUM PRODUCTS						
CRESEMBA CAP 186MG	25	8	$145,270.87	$5,810.83	3.13	8.87%
SUBTOTAL	**25**	**8**	**$145,270.87**	**$5,810.83**	**3.13**	**8.87%**
FLUCYTOSINE PRODUCTS						
FLUCYTOSINE CAP 500MG	14	14	$41,251.24	$2,946.52	1	2.52%
SUBTOTAL	**14**	**14**	**$41,251.24**	**$2,946.52**	**1**	**2.52%**
IBREXAFUNGERP PRODUCTS						
BREXAFEMME TAB 150MG	7	6	$3,462.11	$494.59	1.17	0.21%
SUBTOTAL	**7**	**6**	**$3,462.11**	**$494.59**	**1.17**	**0.21%**
AMPHOTERICIN B PRODUCTS						
AMPHOTERICIN POW	3	3	$35.49	$11.83	1	0.00%
AMBISOME INJ 50MG	2	1	$3,923.34	$1,961.67	2	0.24%
AMPHOTERICIN INJ 50MG	1	1	$12,850.81	$12,850.81	1	0.78%
SUBTOTAL	**6**	**5**	**$16,809.64**	**$2,801.61**	**1.2**	**1.03%**
MICONAZOLE PRODUCTS						
MICONAZOLE POWDER	6	5	$232.37	$38.73	1.2	0.01%
SUBTOTAL	**6**	**5**	**$232.37**	**$38.73**	**1.2**	**0.01%**
TOTAL	**56,940**	**38,685***	**$1,637,636.06**	**$28.76**	**1.47**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; INJ = injection; MICRO = microcrystalline; POW = powder; SOL = solution; SUS = suspension; TAB = tablet; TRO = troche; U = units; ULTR = ultramicrocrystalline

[1] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 03/2024. Last accessed 03/19/2024.
[2] Gallagher A. FDA Approves Rezafungin Injection for the Treatment of Candidemia, Invasive Candidiasis. *Pharmacy Times*. Available online at: https://www.pharmacytimes.com/view/fda-approves-rezafungin-injection-for-the-treatment-of-candidemia-invasive-candidiasis. Issued 03/24/2023. Last accessed 03/20/2024.
[3] Rezzayo™ (Rezafungin) Prescribing Information. Cidara Therapeutics Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217417s000lbl.pdf. Last revised 03/2023. Last accessed 03/20/2024.

Appendix Q

Calendar Year 2023 Annual Review of Filspari® (Sparsentan)

Oklahoma Health Care Authority
April 2024

Current Prior Authorization Criteria

Filspari® (Sparsentan) 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 advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite 3 months of maximal supportive care:
   a. Urine protein-to-creatinine (UPCR) ratio ≥1.5g/g; or
   b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) 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); 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.

Utilization of Filspari® (Sparsentan): Calendar Year 2023

There was no SoonerCare utilization of Filspari® (sparsentan) during calendar year 2023.

Prior Authorization of Filspari® (Sparsentan)

There were 2 prior authorization requests submitted for Filspari® (sparsentan) for 1 unique member during calendar year 2023 which were both incomplete due to missing information.

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

Anticipated Patent Expiration(s):

- Filspari® (sparsentan): March 2030

News:

- **September 2023:** Travere Therapeutics, the makers of Filspari®, announced the results of the 2-year Phase 3 confirmatory study, PROTECT, which studied Filspari® in Immunoglobin A nephropathy (IgAN) versus irbesartan. The key confirmatory benchmark in the study was estimated glomerular filtration rate (eGFR) total and chronic slope over the 2-year study period. The results showed that Filspari®-treated patients had a slower rate of kidney decline versus irbesartan-treated patients in eGFR total slope [difference: 1.0mL/min/1.73m^2 (P=0.058)] and in eGFR chronic slope [difference: 1.1mL/min/1.73m^2 (P=0.037)]; however, the results were not statistically significant. Travere Therapeutics did note the results were clinically meaningful as the Filspari®-treated patients showed "one of the slowest annual rates of kidney function decline seen in a clinical trial of IgAN patients (-2.7 to -2.9mL/min/1.73m^2)." The U.S. Food and Drug Administration (FDA) previously granted accelerated approval for Filspari® in February 2023 based on the reduction of proteinuria with continued approval for this indication being contingent upon verification and description of clinical benefit in a confirmatory trial.
- **March 2024:** Travere Therapeutics announced the submission of a supplemental New Drug Application (sNDA) to the FDA to seek full approval of Filspari® for the treatment of IgAN. The submission is being supported by the results of the Phase 3 PROTECT study.

Pipeline:

- **Sibeprenlimab:** Sibeprenlimab is a humanized immunoglobin G2 (IgG2) monoclonal antibody being studied to reduce proteinuria in adults with IgAN. The results of a Phase 2 ENVISION study found that intravenous sibeprenlimab led to significantly greater decrease in 24-hour urinary protein-to-creatinine ratio at 12 months compared to

placebo. In February 2024, the FDA granted Breakthrough Therapy designation for sibeprenlimab. The Phase 3 study is ongoing.

Recommendations

The College of Pharmacy does not recommend any changes to the current Filspari® (sparsentan) 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: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 03/2024. Last accessed 03/27/2024.
[2] Travere Therapeutics, Inc. Travere Therapeutics Announces Confirmatory Data from the Phase 3 PROTECT Study of Filspari® Demonstrating Long-Term Kidney Function Preservation in IgA Nephropathy; Narrowly Missing eGFR Total Slope Endpoint versus Active Control, Irbesartan. Available online at: https://ir.travere.com/news-releases/news-release-details/travere-therapeutics-announces-confirmatory-data-phase-3-protect. Issued 09/21/2023. Last accessed 03/19/2024.
[3] Travere Therapeutics, Inc. Travere Therapeutics Submits Supplemental New Drug Application to the U.S. Food and Drug Administration (FDA) Seeking Full Approval for Filspari® (Sparsentan) for the Treatment of IgA Nephropathy (IgAN). *BioSpace*. Available online at: https://www.biospace.com/article/releases/travere-therapeutics-submits-supplemental-new-drug-application-to-the-u-s-food-and-drug-administration-seeking-full-approval-of-filspari-sparsentan-for-the-treatment-of-iga-nephropathy-igan-/. Issued 03/11/2024. Last accessed 03/19/2024.
[4] Monaco K. Mid-Stage Win for Novel IgA Nephropathy Drug. *Medpage Today*. Available online at: https://www.medpagetoday.com/meetingcoverage/asn/107120. Issued 11/02/2023. Last accessed 03/19/2024.
[5] Otsuka Pharmaceutical, Co. Ltd. Sibeprenlimab Receives U.S. FDA Breakthrough Therapy Designation for the Treatment of Immunoglobulin A Nephropathy. Available online at: https://www.otsuka-us.com/news/sibeprenlimab-receives-us-fda-breakthrough-therapy-designation-treatment-immunoglobulin. Issued 02/16/2024. Last accessed 03/19/2024.

Appendix R

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: April 3, 2024

FDA Approves New Antibiotic for Three Different Uses

The FDA approved Zevtera® (ceftobiprole medocaril sodium for injection) for the treatment of adults with *Staphylococcus aureus* bacteremia (SAB), including those with right-sided infective endocarditis; adults with acute bacterial skin and skin structure infections (ABSSSI); and adult and pediatric patients 3 months to young than 18 years of age with community-acquired bacterial pneumonia (CABP).

Zevtera®'s efficacy in treating SAB was evaluated in a randomized, controlled, double-blind, multinational, multicenter trial. In the trial, researchers randomly assigned 390 subjects to receive Zevtera® (192 subjects) or daptomycin plus optional aztreonam (198 subjects). The primary measure of efficacy for this trial was the overall success (defined as survival, symptom improvement, SAB bloodstream clearance, no new SAB complications, and no use of other potentially effective antibiotics) at the post-treatment evaluation visit, which occurred 70 days after being randomly assigned an antibiotic. A total of 69.8% of subjects who received Zevtera® achieved overall success compared to 68.7% of subjects who received the comparator.

Zevtera®'s efficacy in treating ABSSSI was evaluated in a randomized, controlled, double-blind, multinational trial. In the trial, researchers randomly assigned 679 subjects to receive either Zevtera® (335 subjects) or vancomycin plus aztreonam (344 subjects). The primary measure of efficacy was early clinical response 48-72 hours after start of treatment. Early clinical response required a reduction of the primary skin lesion by at least 20%, survival for at least 72 hours, and the absence of additional antibacterial treatment or unplanned surgery. Of the subjects who received Zevtera®, 91.3% achieved an early clinical response within the necessary timeframe compared to 88.1% of subjects who received the comparator.

Zevtera®'s efficacy in treating adult patients with CABP was evaluated in a randomized, controlled, double-blind, multinational, multicenter trial. In the trial, researchers randomly assigned 638 adults hospitalized with CABP and requiring intravenous (IV) antibacterial treatment for at least 3 days to receive either Zevtera® (314 subjects) or ceftriaxone with optional linezolid (324 subjects). The primary measurement of efficacy was clinical cure rates at test-of-cure visit, which occurred 7-14 days after end-of-treatment. Of the subjects who received Zevtera®, 76.4% achieved clinical cure compared to 79.3% of subjects who received the comparator. An additional analysis considered an earlier timepoint of clinical success at day 3, which was 71% in patients receiving Zevtera® and 71.1% in patients receiving the comparator.

Given the similar course of CABP in adults and pediatric patients, today's approval of Zevtera® in pediatric patients 3 months to younger than 18 years of age with CABP was supported by evidence from the CABP trial of Zevtera® in adults and a trial in 138 pediatric subjects 3 months to younger than 18 years of age with pneumonia.

For adults with SAB, the most common side effects of Zevtera® included anemia, nausea, hypokalemia, vomiting, diarrhea, increased levels of hepatic enzymes and

bilirubin, increased blood creatinine, high blood pressure, leukopenia, fever, abdominal pain, fungal infection, headache, and dyspnea.

For adults with ABSSSI, the most common side effects of Zevtera® included nausea, diarrhea, headache, injection site reaction, increased levels of hepatic enzymes, rash, vomiting, and dysgeusia.

For adults with CABP, the most common side effects of Zevtera® included nausea, increased levels of hepatic enzymes, vomiting, diarrhea, headache, rash, insomnia, abdominal pain, phlebitis, high blood pressure, and dizziness. For pediatric patients with CABP, the most common side effects of Zevtera® included vomiting, headache, increased levels of hepatic enzymes, diarrhea, infusion site reaction, phlebitis, and fever.

Patients should not use Zevtera® if they have a known history of severe hypersensitivity to ceftobiprole or any of the components of Zevtera®, or other members of the cephalosporin antibacterial class.

Zevtera® comes with certain warnings and precautions such as increased mortality in ventilator-associated bacterial pneumonia patients (an unapproved use), hypersensitivity reactions, seizures, and other central nervous system reactions and *Clostridioides difficile*-associated diarrhea.

Zevtera® was granted Priority Review, Fast Track, and Qualified Infectious Disease Product designations for the CABP, ABSSSI, and SAB indications. The FDA granted the approval of Zevtera® to Basilea Pharmaceutica International Ltd.

FDA NEWS RELEASE

For Immediate Release: March 21, 2024

FDA Approves Nonsteroidal Treatment for Duchenne Muscular Dystrophy

The FDA approved Duvyzat™ (givinostat) oral medication for the treatment of Duchenne Muscular Dystrophy (DMD) in patients 6 years of age and older. Duvyzat™ is the first nonsteroidal drug approved to treat patients with all genetic variants of DMD. It is a histone deacetylase (HDAC) inhibitor that works by targeting pathogenic processes to reduce inflammation and loss of muscle.

DMD is the most common childhood form of muscular dystrophy and typically affects males. It is a rare neurological disorder which causes progressive muscle weakness due to a lack of muscle protein called dystrophin. Over time, the muscles deteriorate causing problems with walking and muscle strength and ultimately problems with breathing leading to early death. Life expectancy for those with DMD has increased over the years, with some patients surviving beyond 30 years.

The efficacy of Duvyzat™ for the treatment of DMD was evaluated in a randomized, double-blind, placebo-controlled 18-month Phase 3 study. The primary endpoint was the change from baseline to month 18 using a 4 stair climb to measure muscle function. All participants continued to receive a standard of care steroid regimen throughout the study and, after 18 months of treatment, patients treated with Duvyzat™ showed statistically significant less decline in the time it took to climb 4 stairs compared to placebo. The mean change from baseline to month 18 in time to climb 4 stairs was 1.25 seconds for patients receiving Duvyzat™ compared to 3.03 seconds for patients receiving placebo.

A secondary efficacy endpoint was the change from baseline to month 18 in physical function as assessed by the North Star Ambulatory Assessment (NSAA) – a scale commonly used to rate the motor function in boys with DMD who are capable of walking. Compared to placebo, patients treated with Duvyzat™ saw less worsening in their NSAA score after 18 months.

The most common side effects of Duvyzat™ are diarrhea, abdominal pain, a decrease in platelets, nausea/vomiting, an increase in triglycerides, and fever.

The *Prescribing Information* for Duvyzat™ includes warnings which state that health care providers should evaluate the patient's platelet counts and triglycerides before prescribing Duvyzat™. Patients with a platelet count less than 150 x 10^9/L should not take Duvyzat™. Platelet counts and triglycerides should be monitored as recommended during treatment to determine if changes in dosage are needed. Dosage modifications may also be needed for moderate or severe diarrhea. Duvyzat™ may also cause QTc prolongation, which can increase the risk for irregular heartbeats. Patients taking certain medications that also cause QTc prolongation or have certain types of heart disease should avoid taking Duvyzat™.

The recommended dosage of Duvyzat™ is determined by the individual's body weight. It should be administered orally twice daily with food. The FDA granted this application Priority Review and Fast Track designation. It also received Orphan Drug and Rare Pediatric Disease designations. The approval of Duvyzat™ was granted to Italfarmaco S.p.A.

FDA NEWS RELEASE

For Immediate Release: March 18, 2024

FDA Approves First Gene Therapy for Children with Metachromatic Leukodystrophy

The FDA approved Lenmeldy™ (atidarsagene autotemcel), the first FDA-approved gene therapy indicated for the treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile, or early symptomatic early juvenile metachromatic leukodystrophy (MLD).

MLD is a debilitating, rare genetic disease affecting the brain and nervous system. It is caused by a deficiency of an enzyme called arylsulfatase A (ARSA), leading to a buildup of sulfatides in the cells. This buildup causes damage to the central and peripheral nervous system, manifesting with loss of motor and cognitive function and early death. It is estimated that MLD affects 1 in every 40,000 individuals in the United States. There is no cure for MLD, and treatment typically focuses on supportive care and symptom management.

Lenmeldy™ is a one-time, individualized single-dose infusion made from the patient's own hematopoietic stem cells (HSCs), which have been genetically modified to include functional copies of the *ARSA* gene. The stem cells are collected from the patient and modified by adding a functional copy of the *ARSA* gene. The modified stem cells are transplanted back into the patient where they engraft within the bone marrow. The modified stem cells supply the body with myeloid cells that produce the ARSA enzyme, which helps break down the harmful build-up of sulfatides and may stop the progression of MLD. Prior to treatment, patients must undergo high-dose chemotherapy to remove cells from the bone marrow so they can be replaced with the modified cells in Lenmeldy™.

The safety and effectiveness of Lenmeldy™ were assessed based on data from 37 children who received Lenmeldy™ in 2 single-arm, open-label clinical trials and in an expanded access program. Children who received treatment with Lenmeldy™ were compared to untreated children (natural history). The primary efficacy endpoint was severe motor impairment-free survival, defined as the interval from birth to the first occurrence of loss of locomotion and loss of sitting without support or death. In children with MLD, treatment with Lenmeldy™ significantly reduced the risk of severe motor impairment or death compared with untreated children. All children with pre-

symptomatic late infantile MLD who were treated with Lenmeldy™ were alive at 6 years of age, compared to only 58% of children in the natural history group. At 5 years of age, 71% of treated children were able to walk without assistance. Eighty five percent of the children treated had normal language and performance IQ scores, which has not been reported in untreated children. In addition, children with pre-symptomatic early juvenile and early symptomatic early juvenile MLD showed slowing of motor and/or cognitive disease.

The most common side effects of Lenmeldy™ are fever and low white blood cell count, mouth sores, respiratory infections, rash, medical line infections, viral infections, fever, gastrointestinal infections, and enlarged liver.

After infusion with Lenmeldy™, patients should be monitored for neutrophil counts and risk of delayed platelet engraftment until engraftment has been achieved. Treatment with Lenmeldy™ may be associated with formation of blood clots or encephalitis. There is a potential risk of blood cancer associated with this treatment; however, no cases have been seen in patients treated with Lenmeldy™. Patients receiving this product should have lifelong monitoring for hematologic malignancies, including a complete blood count (with differential) annually and integration site analysis, as warranted, for at least 15 years after treatment.

The application received Priority Review, Orphan Drug, Rare Pediatric Disease, and Regenerative Medicine Advanced Therapy (RMAT) designations. The FDA granted approval of Lenmeldy™ to Orchard Therapeutics.

FDA NEWS RELEASE

For Immediate Release: March 14, 2024

FDA Approves First Treatment for Patients with Liver Scarring Due to Fatty Liver Disease

The FDA approved Rezdiffra™ (resmetirom) for the treatment of adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced liver scarring, to be used along with diet and exercise.

NASH is a result of the progression of nonalcoholic fatty liver disease where liver inflammation, over time, can lead to liver scarring and liver dysfunction. NASH is often associated with other health problems such as hypertension and type 2 diabetes. By at least one estimate, approximately 6-8 million people in the U.S. have NASH with moderate to advanced liver scarring, with that number expected to increase. Rezdiffra™ is a partial activator of a thyroid hormone receptor; activation of this receptor by Rezdiffra™ in the liver reduces liver fat accumulation.

The safety and efficacy of Rezdiffra™ was evaluated based on an analysis of a surrogate endpoint at month 12 in a 54-month, randomized, double-blind placebo-controlled trial. The surrogate endpoint measured the extent of liver inflammation and scarring. The sponsor is required to conduct a post approval study to verify and describe Rezdiffra™'s clinical benefit, which will be done through completing the same 54-month study, which is still ongoing. To enroll in the trial, patients needed to have a liver biopsy showing inflammation due to NASH with moderate or advanced liver scarring. In the trial, 888 subjects were randomly assigned to receive one of the following: placebo (294 subjects); 80 milligrams of Rezdiffra™ (298 subjects); or 100 milligrams of Rezdiffra™ (296 subjects); once daily, in addition to standard care for NASH, which includes counseling for healthy diet and exercise.

At 12 months, liver biopsies showed that a greater proportion of subjects who were treated with Rezdiffra™ achieved NASH resolution or an improvement in liver scarring as

compared with those who received the placebo. A total of 26% to 27% of subjects who received 80 milligrams of Rezdiffra™ and 24% to 36% of subjects who received 100 milligrams of Rezdiffra™ experienced NASH resolution and no worsening of liver scarring, compared to 9% to 13% of those who received placebo and counseling on diet and exercise. The range of responses reflects different pathologists' readings. In addition, a total of 23% of subjects who received 80 milligrams of Rezdiffra™ and 24% to 28% of subjects who received 100 milligrams of Rezdiffra™ experienced an improvement in liver scarring and no worsening of NASH, compared to 13% to 15% of those who received placebo, depending on each pathologist's readings. Demonstration of these changes in the proportion of patients after just 1 year of treatment is notable, as the disease typically progresses slowly with most patients taking years or even decades to show progression.

The most common side effects of Rezdiffra™ included diarrhea and nausea. Rezdiffra™ comes with certain warnings and precautions, such as drug-induced liver toxicity and gallbladder-related side effects.

Use of Rezdiffra™ should be avoided in patients with decompensated cirrhosis. Patients should stop using Rezdiffra™ if they develop signs or symptoms of worsening liver function while on Rezdiffra™ treatment.

Using Rezdiffra™ at the same time as certain other drugs, in particular statins for lowering cholesterol, may result in potentially significant drug interactions. Health care providers should refer to the full *Prescribing Information* for additional information on these potentially significant drug interactions with Rezdiffra™, recommended dosage and administration modifications.

The FDA approved Rezdiffra™ under the accelerated approval pathway, which allows for earlier approval of drugs that treat serious conditions and address an unmet medical need, based on a surrogate or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The required 54-month study, which is ongoing, will assess clinical benefit after 54 months of Rezdiffra™ treatment. Rezdiffra™ received Breakthrough Therapy, Fast Track, and Priority Review designations for this indication. The FDA granted the approval of Rezdiffra™ to Madrigal Pharmaceuticals.

FDA NEWS RELEASE

For Immediate Release: March 8, 2024

FDA Approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight

The FDA approved a new indication for use for Wegovy® (semaglutide) injection to reduce the risk of cardiovascular (CV) death, heart attack, and stroke in adults with CV disease and either obesity or overweight. Wegovy® should be used in addition to a reduced calorie diet and increased physical activity.

Obesity or overweight affect approximately 70% of American adults. Obesity and overweight are serious health issues that increase the risk for premature death and a variety of health problems, including heart attack and stroke.

Wegovy® contains semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist. Therefore, Wegovy® should not be used in combination with other semaglutide-containing products or other GLP-1 receptor agonists.

Wegovy®'s efficacy and safety for this new indication were studied in a multi-national, multi-center, placebo-controlled double-blind trial that randomly assigned over 17,600 participants to receive either Wegovy® or placebo. Participants in both groups also received standard-of-care medical treatment (e.g., management of blood pressure and cholesterol) and healthy lifestyle counseling (including diet and physical activity).

Wegovy® significantly reduced the risk of major adverse CV events (CV death, heart attack, and stroke), which occurred in 6.5% of participants who received Wegovy® compared to 8% of participants who received placebo.

The *Prescribing Information* for Wegovy® contains a boxed warning to inform health care professionals and patients about the risk of thyroid C-cell tumors. Because of this risk, Wegovy® should not be used in patients with a personal or family history of medullary thyroid carcinoma or in patients with a rare condition called Multiple Endocrine Neoplasia syndrome type 2.

Wegovy® should not be used in patients with a history of a severe allergic reaction to semaglutide or to any of the other ingredients. Patients should stop Wegovy® immediately and seek medical help if a severe allergic reaction is suspected.

Wegovy® also contains warnings for inflammation of the pancreas (pancreatitis), gallbladder problems (including gallstones), low blood sugar, acute kidney injury, hypersensitivity reactions, diabetic retinopathy, increased heart rate, and suicidal behavior or thinking. Patients should discuss with their health care provider if they have symptoms of pancreatitis or gallstones. If Wegovy® is used with insulin or with a medication that causes insulin secretion, patients should speak to their health care provider about the risk of low blood sugar. Health care professionals should monitor patients for kidney disease, diabetic retinopathy, and depression or suicidal behaviors or thoughts.

The most common side effects of Wegovy® include nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distension, eructation, hypoglycemia in patients with diabetes, flatulence, and gastroesophageal reflux disease.

Wegovy® received Priority Review designation for this indication. The FDA granted the approval to Novo Nordisk A/S. Wegovy® is also approved to reduce excess weight and maintain weight reduction long term in certain adults with obesity or overweight and certain children with obesity, for use in addition to a reduced calorie diet and increased physical activity.

Current Drug Shortages Index (as of March 26th, 2024):

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***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Capecitabine Tablet	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Collagenase Clostridium Histolyticum Ointment	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Diazepam Gel	***Currently in Shortage***
Difluprednate Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate Capsule	***Currently in Shortage***

Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection, Syringes	***Currently in Shortage***
Erythromycin Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Fluconazole Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methotrexate Sodium Tablet	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Neomycin Sulfate Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***

Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride 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***
Semaglutide Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sodium Chloride 0.9% Irrigation	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sucralfate Tablet	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablet	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***