OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
December 11, 2024
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – December 11, 2024

DATE: December 4, 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 December 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/SoonerCare Opioid Initiative Update – Appendix B

SoonerCare Maintenance Drug List – Appendix C

Action Item – Vote to Prior Authorize Ebglyss™ (Lebrikizumab) and Update the Approval Criteria for the Atopic Dermatitis Medications – Appendix D

Action Item – Vote to Prior Authorize Ohtuvayre™ (Ensifentrine) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications – Appendix E

Action Item – Vote to Prior Authorize Nemluvio® (Nemolizumab-ilto) – Appendix F

Action Item – Annual Review of Skin Cancer Medications – Appendix G

Action Item – Annual Review of Antidepressants – Appendix H

Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan) – Appendix I

Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol) – Appendix J

Annual Review of Parathyroid Medications and 30-Day Notice to Prior Authorize Yorvipath® (Palopegteriparatide) – Appendix K

Annual Review of Osteoporosis Medications and 30-Day Notice to Prior Authorize Jubbonti® (Denosumab-bbdz) – Appendix L

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

Future Business

Action Item – Nomination of DUR Board Officers

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – December 11, 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

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https://oklahoma.zoom.us/webinar/register/WN_94lCoSe9Ty2msgsLMqg2Ww
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: 958 2294 2095
Passcode: 65079339

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. November 13, 2024 DUR Board Meeting Minutes
   B. November 13, 2024 DUR Board Recommendations Memorandum
   C. Correspondence

Items to be presented by Dr. Metts, Dr. Snyder, Dr. Muchmore, Chairman:

4. **Update on Medication Coverage Authorization Unit/SoonerCare Opioid Initiative Update – See Appendix B**
   A. Pharmacy Help Desk Activity for October 2024
   B. Medication Coverage Activity for October 2024
   C. SoonerCare Opioid Initiative Update

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

5. **SoonerCare Maintenance Drug List – See Appendix C**
   A. Introduction
   B. Maintenance Drug List
   C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Ebglyss™ (Lebrikizumab) and Update the Approval Criteria for the Atopic Dermatitis Medications – See Appendix D**

A. Market News and Updates
B. Ebglyss™ (Lebrikizumab) Product Summary
C. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Ohtuvayre™ (Ensifentrine) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications – See Appendix E

A. Market News and Updates
B. Ohtuvayre™ (Ensifentrine) Product Summary
C. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Nemluvio® (Nemolizumab-ilto) – See Appendix F

A. Market News and Updates
B. Nemluvio® (Nemolizumab-ilto) Product Summary
C. College of Pharmacy Recommendations

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

9. Action Item – Annual Review of Skin Cancer Medications – See Appendix G

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

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

10. Action Item – Annual Review of Antidepressants – See Appendix H

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

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

11. Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan) – See Appendix I

A. Current Prior Authorization Criteria
B. Utilization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents

C. Prior Authorization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Complement Inhibitors and Miscellaneous Immunomodulatory Agents

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

12. Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol) – See Appendix J

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

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

13. Annual Review of Parathyroid Medications and 30-Day Notice to Prior Authorize Yorvipath® (Palopegteriparatide) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Parathyroid Medications
C. Prior Authorization of Parathyroid Medications
D. Market News and Updates
E. Yorvipath® (Palopegteriparatide) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Parathyroid Medications

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

14. Annual Review of Osteoporosis Medications and 30-Day Notice to Prior Authorize Jubbonti® (Denosumab-bbdz) – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of Osteoporosis Medications
C. Prior Authorization of Osteoporosis Medications
D. Market News and Updates
E. Jubbonti® (Denosumab-bbdz) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Osteoporosis Medications

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

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

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

16. **Future Business* (Upcoming Product and Class Reviews)**
    No live DUR Board meeting scheduled for January 2025. January 2025 will be a packet-only meeting.
    A. Antihyperlipidemics
    B. Antihypertensive Medications
    C. Miscellaneous Cancer Medications
    D. Non-Steroidal Anti-Inflammatory Drugs
    *Future product and class reviews subject to change.

Items to be presented by Dr. Muchmore, Chairman:

17. **Action Item – Nomination of DUR Board Officers**
    A. Nominations and Approval of DUR Board Chair and Vice Chair

18. **Adjournment**

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

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING NOVEMBER 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

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
Michaela Metts, Pharm.D., MBA, BCPS; Clinical Pharmacist	X	
Regan Moss, Pharm.D.; Clinical Pharmacist		X
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Chinemerem Opara, Pharm.D.; Pharmacy Resident	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: Matthew Dickson, Pharm.D.	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Conner Mulvaney, J.D.; Deputy General Counsel	X	
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	

Michelle Tahah, Pharm.D.; Clinical Pharmacist		**X**
Toney Welborn, M.D., MPH, MS; Medical Director		**X**

OTHERS PRESENT:	
Crystal Burkhardt, AstraZeneca	Danielle Walters, Bluebird Bio
Biron Patel, Bluebird Bio	Bryan Mauk, Vertex
Eardie Curry, Genentech	Rhonda Clark, Indivior
Brent Milovac, LEO Pharma	Chrystal Mayes, Sanofi
Kristen Winters, Centene	Lindsey Baker, Genentech
Deidra Williams, Humana	Irene Chung, Aetna
Brent Parker, Merck	David Prather, Novo Nordisk
Bryan Steffan, Boehringer	Brielle Dozier, Artia Solutions
Jim Semans, SK Life Science	Phil Lohec, Viatris
Roberto Pedraza, Vertex	Matt John, Otsuka
Brent Fushimi, UCB	Rich Junk, Organon
Melissa Abbott, Eisai	Erik Schindler, Sanofi
Bo Han, Takeda	Christine Dube, AstraZeneca
Taha Khan, Vertex	Matt Grewe, LEO Pharma
Alison Davis, Galderma	John Suelzer, LEO Pharma

PRESENT FOR PUBLIC COMMENT:	
Biran Patel, Bluebird Bio	Crystal Burkhardt, AstraZeneca
Brent Milovac, LEO Pharma	

AGENDA ITEM NO. 1: **CALL TO ORDER**
1A: ROLL CALL
Dr. Muchmore called the meeting to order at 4:01pm. Roll call by Dr. Wilcox did not initially establish the presence of a quorum; however, a quorum was established prior to any action items being voted on.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**
2A: AGENDA ITEM NO. 8 BIRAN PATEL
2B: AGENDA ITEM NO. 13 CRYSTAL BURKHARDT
2C: AGENDA ITEM NO. 14 BRENT MILOVAC
ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MEETING MINUTES**
3A: OCTOBER 9, 2024 DUR MINUTES – VOTE
Materials included in agenda packet; presented by Dr. Muchmore
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/ADHERENCE TO ASTHMA MAINTENANCE MEDICATIONS PRIOR TO ADDING ON BIOLOGIC THERAPY**
4A: PHARMACY HELPDESK ACTIVITY FOR OCTOBER 2024
4B: MEDICATION COVERAGE ACTIVITY FOR OCTOBER 2024
4C: ADHERENCE TO ASTHMA MAINTENANCE MEDICATIONS PRIOR TO ADDING ON BIOLOGIC THERAPY
Materials included in agenda packet; presented by Dr. Metts, Dr. O'Halloran

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> APPROVAL OF 2025 DRUG UTILIZATION REVIEW (DUR) BOARD MEETING DATES

5A: 2025 DUR BOARD MEETING DATES

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

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE BIMZELX® (BIMEKIZUMAB-BKZX), LEQSELVI™ (DEURUXOLITINIB), OMVOH™ (MIRIKIZUMAB-MRKZ), OTULFI™ (USTEKINUMAB-AAUZ), PYZCHIVA® (USTEKINUMAB-TTWE), RINVOQ® LQ (UPADACITINIB ORAL SOLUTION), SELARSDI™ (USTEKINUMAB-AEKN), SIMLANDI® (ADALIMUMAB-RYVK), TYENNE® (TOCILIZUMAB-AAZG), VELSIPITY™ (ETRASIMOD), WEZLANA™ (USTEKINUMAB-AUUB), AND ZYMFENTRA™ (INFLIXIMAB-DYYB) AND UPDATE THE APPROVAL CRITERIA FOR THE TARGETED IMMUNOMODULATOR AGENTS

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

Materials included in agenda packet; presented by Dr. Wilson
Mr. Foster moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE RIVFLOZA® (NEDOSIRAN)

7A: MARKET NEWS AND UPDATES
7B: RIVFLOZA® (NEDOSIRAN) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Metts
Mr. Foster moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE CASGEVY™ (EXAGAMGLOGENE AUTOTEMCEL), LYFGENIA® (LOVOTIBEGLOGENE AUTOTEMCEL), VAFSEO® (VADADUSTAT), AND XROMI® (HYDROXYUREA ORAL SOLUTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ANEMIA MEDICATIONS

8A: MARKET NEWS AND UPDATES
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

<u>AGENDA ITEM NO. 9:</u> ANNUAL REVIEW OF MULTIPLE MYELOMA MEDICATIONS

9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF MULTIPLE MYELOMA MEDICATIONS
9C: PRIOR AUTHORIZATION OF MULTIPLE MYELOMA MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: COLLEGE OF PHARMACY RECOMMENDATIONS
9F: UTILIZATION DETAILS OF MULTIPLE MYELOMA MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko

Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF LAMBERT-EATON MYASTHENIC SYNDROME (LEMS) MEDICATIONS
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF LEMS MEDICATIONS
10C: PRIOR AUTHORIZATION OF LEMS MEDICATIONS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF LEMS MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Haymore moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF HAE MEDICATIONS
11C: PRIOR AUTHORIZATION OF HAE MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: COST COMPARISON: ICATIBANT PRODUCTS
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF HAE MEDICATIONS
Materials included in agenda packet; presented by Dr. Metts
Mr. Foster moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: 30-DAY NOTICE TO PRIOR AUTHORIZE NEMLUVIO® (NEMOLIZUMAB-ILTO)
12A: INTRODUCTION
12B: NEMLUVIO® (NEMOLIZUMAB-ILTO) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 13: ANNUAL REVIEW OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE OHTUVAYRE™ (ENSIFENTRINE)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
13C: PRIOR AUTHORIZATION OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: OHTUVAYRE™ (ENSIFENTRINE) PRODUCT SUMMARY
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ATOPIC DERMATITIS (AD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EBGLYSS™ (LEBRIKIZUMAB-LBKZ)

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF AD MEDICATIONS
14C: PRIOR AUTHORIZATION OF AD MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: EBGLYSS™ (LEBRIKIZUMAB-LBKZ) PRODUCT SUMMARY
14F: COST COMPARISONS
14G: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 15: ANNUAL REVIEW OF SOHONOS™ (PALOVAROTENE)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF SOHONOS™ (PALOVAROTENE)
15C: PRIOR AUTHORIZATION OF SOHONOS™ (PALOVAROTENE)
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Metts
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Metts
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
17A: ANTIDEPRESSANTS
17B: COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
17C: LYSOSOMAL STORAGE DISEASE MEDICATIONS
17D: OSTEOPOROSIS MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: ADJOURNMENT
The meeting was adjourned at 5:41pm.

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

Memorandum

Date: November 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 November 13, 2024

Recommendation 1: Update on Medication Coverage Authorization Unit/Adherence to Asthma Maintenance Medications Prior to Adding on Biologic Therapy

NO ACTION REQUIRED.

Recommendation 2: Approval of 2025 Drug Utilization Review (DUR) Board Meeting Dates

MOTION CARRIED by unanimous approval.

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

- January 8, 2025
- February 12, 2025
- March 12, 2025
- April 9, 2025
- May 14, 2025
- June 11, 2025
- July 9, 2025
- August 13, 2025
- September 10, 2025
- October 8, 2025

- November 12, 2025
- December 10, 2025

Recommendation 3: Vote to Prior Authorize Bimzelx® (Bimekizumab-bkzx), Leqselvi™ (Deuruxolitinib), Omvoh™ (Mirikizumab-mrkz), Otulfi™ (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Rinvoq® LQ (Upadacitinib Oral Solution), Selarsdi™ (Ustekinumab-aekn), Simlandi® (Adalimumab-ryvk), Tyenne® (Tocilizumab-aazg), Velsipity™ (Etrasimod), Wezlana™ (Ustekinumab-auub), and Zymfentra™ (Infliximab-dyyb) and Update the Approval Criteria for the Targeted Immunomodulator Agents

MOTION CARRIED by unanimous approval.

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

1. Adding topical corticosteroids as a Tier-1 option for appropriate indications (e.g., plaque psoriasis); and
2. Updating the Special Prior Authorization (PA) approval criteria for clarity to list all the required lower-tiered trials prior to Special PA Tier approval; and
3. Making Humira® (adalimumab) brand preferred; and
4. Moving Hadlima™ (adalimumab-bwwd) and Yusimry™ (adalimumab-aqvh) to Tier-2, and updating the adalimumab approval criteria based on net cost; and
5. Prior authorization and placement of Tyenne® (tocilizumab-aazg) into Tier-3, and updating the tocilizumab approval criteria based on net cost; and
6. Moving Sotyktu™ (deucravacitinib) from the Special PA Tier to Tier-3 based on net cost; and
7. Prior authorization and placement of Bimzelx® (bimekizumab-bkzx), Omvoh™ (mirikizumab-mrkz), Velsipity™ (etrasimod), and Zymfentra™ (infliximab-dyyb) into the Special PA Tier based on net cost; and
8. Moving Siliq® (brodalumab) from Tier-3 to the Special PA Tier based on net cost; and
9. Prior authorization and placement of Leqselvi™ (deuruxolitinib) into the Special PA Tier with additional approval criteria for the diagnosis of alopecia areata; and
10. Prior authorization and placement of Otulfi™ (ustekinumab-auz), Pyzchiva® (ustekinumab-ttwe), Selarsdi™ (ustekinumab-aekn), Simlandi® (adalimumab-ryvk), and Wezlana™ (ustekinumab-auub) into the Special PA Tier with additional criteria for use of a biosimilar product; and

11. Prior authorization and placement of Rinvoq® LQ (upadacitinib oral solution) into the Special PA Tier, based on net cost, with additional criteria for use of a special formulation; and
12. Adding new approval criteria for Cosentyx® (secukinumab) for the diagnosis of hidradenitis suppurativa; and
13. Updating the approval criteria for Entyvio® (vedolizumab) based on the recent FDA approval for CD and moving the sub-Q formulation of Entyvio® to the Special PA Tier based on net cost; and
14. Updating the approval criteria for Lupkynis® (voclosporin) and Spevigo® (spesolimab-sbzo) based on recent FDA approvals and expert consensus recommendations.

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

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

DMARDs = disease modifying anti-rheumatic drugs; NSAIDs = nonsteroidal anti-inflammatory drugs
*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to participate in supplemental rebates.
±Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.

[+]Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.
[β] Unique criteria applies for a diagnosis of Behçet's disease (BD).
[¥]Unique criteria applies for a diagnosis of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor-associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), familial Mediterranean fever (FMF), systemic juvenile idiopathic arthritis (SJIA), adult-onset Still's disease (AOSD), or gout flare.
~Unique criteria applies for a diagnosis of pemphigus vulgaris (PV). Unique criteria applies for a diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).
[π]Unique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS), and systemic sclerosis-associated interstitial lung disease (SSc-ILD).
[¤]Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.
[#]Unique criteria applies for a diagnosis of atopic dermatitis (AD).
[€]Unique criteria applies for a diagnosis of alopecia areata.
[§]Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).
[Δ]Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS).
[**]Unique criteria applies to this medication for approval.

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

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

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

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry™ (adalimumab-aqvh) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if

the net cost changes in comparison to the reference product and/or other available biosimilar products.

Actemra® (Tocilizumab) and Tofidence™ (Tocilizumab-bavi) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use ~~Actemra® (tocilizumab)~~ Tyenne® (tocilizumab-aazg) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. History of erythrocyte sedimentation rate (ESR) of ≥30mm/hr or a history of C-reactive protein (CRP) ≥1mg/dL; and
4. Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and
5. ~~Actemra®~~ Must be taken in combination with a tapering course of corticosteroids upon initiation; and
6. Member must have baseline liver enzymes, absolute neutrophil count (ANC), lipid panel, and platelet count and verification that they are acceptable to prescriber; and
7. Member must not have severe hepatic impairment; and
8. ~~Actemra®~~ Should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
9. Requests for Actemra® or Tofidence™ will require a patient-specific, clinically significant reason why the member cannot use Tyenne®. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
10. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

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

1. A diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 5 abscesses or inflammatory nodules; and
4. Previous failure of at least 2 of the following categories:
    a. Topical or systemic antibiotics; or

b. Oral or intralesional corticosteroids; or
c. Dapsone; or
d. Cyclosporine; or
e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
f. Finasteride; or
g. Surgery; and

5. Previous failure of Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry™ (adalimumab-aqvh) for at least 12 weeks at recommended dosing (or documented intolerance).

Entyvio® (Vedolizumab) Approval Criteria:

1. An FDA approved diagnosis of moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); and
   ~~a. For intravenous (IV) administration: Moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); or~~
   ~~b. For subcutaneous (sub-Q) administration: Moderately-to-severely active UC; and~~
2. Member must be 18 years of age or older; and
3. A minimum of a 4 week trial of a Tier-2 tumor necrosis factor (TNF) blocker indicated for the treatment of CD or UC that did not yield adequate relief of symptoms or resulted in intolerable adverse effects. Current Tier-2 medications include the following:
   a. CD: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or
   b. UC: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or
4. Prior stabilization on the medication documented within the last 100 days; and
5. For Entyvio® subcutaneous (sub-Q) administration, member must have received at least 2 initial intravenous (IV) doses of Entyvio®; and
   a. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue to use the IV formulation must be provided; and
6. A quantity limit of 300mg every 8 weeks will apply for the IV formulation and 108mg every 2 weeks will apply for the sub-Q formulation. Approvals will be granted for titration quantities required for initial dosing; and
7. Initial approvals will be for the duration of 14 weeks as Entyvio® should be discontinued in patients who do not show evidence of therapeutic benefit by week 14.

Hadlima™ (Adalimumab-bwwd), Humira® (Adalimumab), or Yusimry™ (Adalimumab-aqvh) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 3 abscesses or inflammatory nodules; and

4. Previous failure of at least 2 of the following categories:
    a. Topical or systemic antibiotics; or
    b. Oral or intralesional corticosteroids; or
    c. Dapsone; or
    d. Cyclosporine; or
    e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
    f. Finasteride; or
    g. Surgery.

Hadlima™ (Adalimumab-bwwd), Humira® (Adalimumab), or Yusimry™ (Adalimumab-aqvh) Approval Criteria [Noninfectious Intermediate and Posterior Uveitis or Panuveitis Diagnosis]:

1. Diagnosis of noninfectious intermediate uveitis, posterior uveitis, or panuveitis in members 2 years of age and older; and
2. A failed trial with a corticosteroid injection or systemic corticosteroid in which member has had an inadequate response; or
3. A patient-specific, clinically significant reason why a trial of corticosteroid treatment is inappropriate for the member must be provided.

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

1. An FDA approved diagnosis of severe alopecia areata; and
2. For Litfulo™, member must be 12 to 20 years of age; or
3. For Leqselvi™ or Olumiant®, member must be 18 to 20 years of age; and
4. Prescriber must confirm the member or caregiver has been counseled regarding the covered age range for the requested product and that the medication will no longer be covered once the member turns 21 years of age; and
5. Member's baseline Severity of Alopecia Tool (SALT) score must be provided and must be ≥50; and
6. Must be prescribed by a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. Prescriber must agree to screen for tuberculosis and viral hepatitis prior to initiating treatment; and
8. ~~Prescriber must agree to evaluate lymphocyte and platelet counts at baseline, 4 weeks after initiation, and as clinically indicated thereafter; and~~
9. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
10. Prescriber must provide documentation of patient-specific, clinically significant information (e.g., impacting member's mental health or ability to function in day-to-day living, reason why no treatment or

cosmetic solutions are not appropriate) to demonstrate the medical necessity of this medication for this member; and

11. Member must have documented trials within the last 6 months that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance to all alternatives):
    a. Medium potency to very-high potency Tier-1 topical corticosteroid used for at least 12 weeks; or
    b. Oral corticosteroid used for at least 6 weeks; or
    c. Cyclosporine; or
    d. Methotrexate; or
    e. Contact immunotherapy (e.g., diphenylcyclopropenone, squaric acid dibutyl ester); and
12. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
13. Prescriber must verify female members are not breastfeeding; and
14. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the pregnancy registry; and
15. Initial approvals will be for a duration of 24 weeks of treatment; and
16. Reauthorization may be considered if the prescriber documents the member is responding well to treatment as indicated by a reduction in the member's SALT score (current SALT score must be provided).

Lupkynis® (Voclosporin) Approval Criteria:

1. An FDA approved indication for the treatment of adults with active lupus nephritis (LN) in combination with a background immunosuppressive therapy regimen; and
    a. Lupkynis® must be used in combination with mycophenolate mofetil and low dose oral corticosteroids; and
2. Member must be 18 years of age or older; and
3. Lupkynis® must be prescribed by a nephrologist, rheumatologist, or other specialist with expertise in the treatment of LN; and
4. Member's current urine protein-to-creatinine ratio (UPCR) must be provided and must be ≥1.5mg/mg; and
5. Member's current estimated glomerular filtration rate (eGFR) must be provided and must be >45mL/min/1.73m^2 prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor renal function regularly during treatment with Lupkynis® and modify the dose as needed in accordance with the package labeling; and
6. Member's current blood pressure (BP) must be ≤165/105mmHg prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor BP regularly during treatment with Lupkynis® and agree to discontinue treatment if BP is

>165/105mmHg or member experiences a hypertensive emergency; and
7. Member must not be taking strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) concomitantly with Lupkynis®; and
8. Prescriber must verify member has been counseled on proper administration of Lupkynis® including taking it on an empty stomach every 12 hours; and
9. Lupkynis® will not be approved in combination with biologic therapies or cyclophosphamide; and
10. A quantity limit of 180 capsules per 30 days will apply; and
11. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in the member's UPCR. If the member does not experience therapeutic benefit by 6 months, discontinuation of Lupkynis® should be considered.~~; and~~
12. ~~The safety and efficacy of Lupkynis® have not been established beyond 1 year of treatment. For continued authorization consideration after 1 year of treatment, a patient-specific, clinically significant reason why a longer treatment duration is appropriate for the member must be provided.~~

Otulfi™ (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Selarsdi™ (Ustekinumab-aekn), and Wezlana™ (Ustekinumab-auub) Approval Criteria:
1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Stelara® (ustekinumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

Siliq® (Brodalumab) Approval Criteria:
1. Member must meet ~~Tier 3~~ Special Prior Authorization (PA) approval criteria; and
2. Members must also be enrolled in the Siliq® Risk Evaluation and Mitigation Strategy (REMS) program for approval; and

3. Members with a concomitant diagnosis of Crohn's disease will not be approved; and
4. Initial authorizations of Siliq® (brodalumab) will be for the duration of 12 weeks at which time the prescriber must verify the member is responding to treatment. If an adequate response has not been achieved after 12 to 16 weeks of treatment with brodalumab, consideration should be given to discontinuing therapy.

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

1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP) flares ~~(GPP diagnosis should be verifiable in the member's diagnosis history)~~; and
2. Prescriber must verify ~~at least 1 of the following:~~ the member has presence of macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques; and
   ~~a. Member has experienced >1 flare (relapsing GPP); or~~
   ~~b. Member has symptoms persisting for >3 months (persistent GPP); and~~
3. Member must be currently experiencing a moderate-to-severe GPP flare meeting all the following criteria:
   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score must be provided and must be ≥3; and
   b. Presence of fresh pustules (new appearance or worsening of pustules); and
   c. GPPPGA pustulation sub-score must be provided and must be ≥2; and
   d. ≥5% of body surface area (BSA) covered with erythema and the presence of pustules; and
4. Member must be ~~21~~ 12 years of age or older; and
5. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and
6. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo®; and
7. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections prior to each dose of Spevigo®; and
8. Approvals will be for 1 dose of Spevigo®. A second dose of Spevigo® may be approved 1 week after the first dose if the prescriber submits documentation that the member has been evaluated and continues to experience GPP flare symptoms; and

9. A quantity limit of 2 doses per year will apply (the safety and efficacy of additional doses of Spevigo® have not been assessed); and
    a. Requests for additional doses of Spevigo® to treat new GPP flares occurring within 1 year (after successful resolution of the previous flare) will be reviewed on a case-by-case basis and will require the prescriber to submit patient-specific, clinically significant information documenting the clinical necessity of additional treatment despite the lack of adequate safety and efficacy data; and
10. Subsequent requests for new GPP flares (after 1 year) will require the member to meet all initial approval criteria, and information regarding the member's response to previous treatment with Spevigo® must be submitted. Members who did not experience resolution of pustules after previous treatment will not be approved for additional use of Spevigo®.

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

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

Recommendation 4: Vote to Prior Authorize Rivfloza® (Nedosiran)

MOTION CARRIED by unanimous approval.

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

Rivfloza® (Nedosiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels. Diagnosis of PH1 must be confirmed by:
    a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene (results of genetic testing must be submitted); or
    b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and
2. Member must be 9 years of age or older; and
3. Rivfloza® must be prescribed by a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1); and
4. Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2 prior to starting Rivfloza® and must agree to monitor renal function regularly during treatment; and
5. Prescriber must confirm the member has not undergone a liver or kidney transplant; and
6. Member must not have evidence of systemic oxalosis; and
7. Prescriber must verify that Rivfloza® will be administered by a health care professional or, if appropriate, the member or caregiver have been trained on the subcutaneous administration and proper storage of Rivfloza®; and
8. Rivfloza® will not be approved for concomitant use with Oxlumo® (lumasiran); and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion.

The College of Pharmacy also recommends updating the approval criteria for Oxlumo® (lumasiran) based on clinical practice and net costs (changes shown in red):

Oxlumo® (Lumasiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels. Diagnosis of PH1 must be confirmed by:
    a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene (results of genetic testing must be submitted); or

b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and

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

Recommendation 5: Vote to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution) and Update the Approval Criteria for the Anemia Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Casgevy™ (exagamglogene autotemcel), Lyfgenia® (lovotibeglogene autotemcel), Vafseo® (vadadustat), and Xromi® (hydroxyurea solution) with the following criteria (shown in red):

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

1. An FDA approved diagnosis of SCD with recurrent vaso-occlusive crises (VOCs); and
2. Member must be 12 years of age or older; and
3. Member must have evidence of severe disease as demonstrated by ≥2 severe vaso-occlusive events (VOEs) per year in the last 2 years; and
4. Casgevy™ must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Casgevy™; and
5. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and

6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Lyfgenia™ (lovotibeglogene autotemcel); and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Casgevy™); and
11. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
12. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
13. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy™ administration; and
14. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy™; and
15. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member; and
16. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy™; and
17. Casgevy™ must be administered at a Casgevy™ authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy™ dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

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

1. An FDA approved diagnosis of TDT; and
2. Member must be 12 years of age or older; and
3. Member must require regular red blood cell (RBC) transfusions as demonstrated by the following:
    a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
    b. 10 units of packed RBCs per year in the last 2 years; and
4. Casgevy™ must be prescribed by a hematologist with expertise in the treatment of TDT and the administration of Casgevy™; and

5. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
6. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
7. Member must not have previously received treatment with Zynteglo™ (betibeglogene autotemcel); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
9. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Casgevy™); and
10. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy™ administration; and
11. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Casgevy™; and
12. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member; and
13. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy™; and
14. Member will not be approved for treatment with Reblozyl® (luspatercept-aamt) following Casgevy™ infusion (current authorizations for luspatercept-aamt will be discontinued upon Casgevy™ approval); and
15. Casgevy™ must be administered at a Casgevy™ authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy™ dose from receipt to storage to administration; and
16. Approvals will be for 1 dose per member per lifetime.

Lyfgenia® (Lovotibeglogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of sickle cell disease (SCD) with a history of vaso-occlusive events (VOEs); and
2. Member must be 12 years of age or older; and
3. Member must have evidence of severe disease as demonstrated by ≥4 severe VOEs in the last 2 years; and
4. Member must not have >2 α-globin gene deletions; and
5. Lyfgenia® must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Lyfgenia®; and
6. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and

7. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
8. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
9. Member must not have previously received treatment with Casgevy™ (exagamglogene autotemcel); and
10. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
11. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Lyfgenia®); and
12. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
13. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
14. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lyfgenia® administration; and
15. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lyfgenia®; and
16. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member; and
17. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Lyfgenia®; and
18. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Lyfgenia®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
19. Lyfgenia® must be administered at a Lyfgenia® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Lyfgenia® dose from receipt to storage to administration; and
20. A patient-specific, clinically significant reason why the member cannot use Casgevy™ (exagamglogene autotemcel) must be provided; and
21. Approvals will be for 1 dose per member per lifetime.

Vafseo® (Vadadustat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia due to chronic kidney disease (CKD) in adults; and
2. Member must currently be on dialysis and must have been receiving dialysis for ≥3 months; and

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

Xromi® (Hydroxyurea Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Xromi® will not require prior authorization for members 6 years of age and younger. For members 7 years of age and older, a patient-specific, clinically significant reason why the member cannot use hydroxyurea capsules or tablets must be provided; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and
5. Prescriber must agree to monitor the member for the development of secondary malignancies; and

6. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
7. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Xromi® for at least 6 months after therapy; and
8. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Additionally, the College of Pharmacy recommends the following changes to the Reblozyl® (luspatercept-aamt) and Zynteglo™ (betibeglogene autotemcel) criteria based on the FDA approval of Casgevy™ (changes shown in red):

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

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

Zynteglo™ (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must be 4 years of age or older; and
3. Member must weigh ≥6kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
   a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
   b. ≥8 transfusions of packed RBCs per year in the last 2 years; and
5. Zynteglo™ must be prescribed by a hematologist with expertise in the treatment of beta thalassemia and the administration of Zynteglo™; and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Casgevy™ (exagamglogene autotemcel) for the transfusion-dependent beta thalassemia (TDT) indication; and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Zynteglo™); and
11. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo™ administration; and
12. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6months after administration of Zynteglo™; and
13. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member; and
14. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo™; and
15. Member will not be approved for treatment with Reblozyl® (luspatercept-aamt) following Zynteglo™ infusion (current authorizations for luspatercept-aamt will be discontinued upon Zynteglo™ approval); and
16. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Zynteglo™,

then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
17. Zynteglo™ must be administered at a Zynteglo™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zynteglo™ dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Next, the College of Pharmacy recommends the following changes to the Jesduvroq® (daprodustat) criteria based on the FDA approval of Vafseo® (vadadustat) (changes shown in red):

Jesduvroq® (Daprodustat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia due to chronic kidney disease (CKD) in adults; and
2. Member must currently be on dialysis and must have been receiving dialysis for ≥4 months; and
3. Prescriber must verify that member does not have uncontrolled hypertension; and
4. Prescriber must verify that member does not have an active malignancy; and
5. Member must not be concurrently taking strong CYP2C8 inhibitors (i.e., gemfibrozil); and
6. Member's pre-treatment hemoglobin (Hgb) must be <11g/dL. Recent Hgb levels must be provided; and
7. Member must be hyporesponsive to an erythropoiesis-stimulating agent (ESA) (or have a contraindication to use), defined as:
    a. No increase in Hgb after 1 month of weight-based dosing; or
    b. 2 increases in ESA dose up to 50% more than previous dose to maintain current Hgb level; and
8. Prescriber must verify that member will not use Jesduvroq® concomitantly with an ESA or another hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor; and
9. Initial and subsequent approvals will be for the duration of 12 weeks of treatment. Subsequent approvals will granted if the member meets 1 of the following:
    a. Member has achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL and the member's Hgb level is <12g/dL; or
    b. If the member has not achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL, then all of the following will be required:
        i. The dose will be increased as tolerated to a maximum of 24mg per day; and
        ii. The member has not received 24mg per day for >12 weeks without achieving a clinically meaningful increase in hemoglobin of ≥1g/dL; and

iii. The member's Hgb is <12g/dL; and

10. Jesduvroq® should be discontinued in members who do not show evidence of a clinically meaningful increase in Hgb by 24 weeks.

Next, the College of Pharmacy recommends the prior authorization of generic Endari® (L-glutamine) based on net costs with the following criteria (shown in red):

Endari® (L-Glutamine) Approval Criteria:

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

Finally, the College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for Oxbryta® (voxelotor) based on the withdrawal of the medication from the market (changes noted in red):

~~**Oxbryta® (Voxelotor) Approval Criteria:**~~

~~1. An FDA approved indication for the treatment of sickle cell disease (SCD) in members 4 years of age and older; and~~
~~2. Member must have baseline hemoglobin ≤10.5g/dL; and~~
~~3. Oxbryta® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and~~
~~4. Member must not be taking concomitant strong or moderate CYP3A4 inducers (e.g., rifampin) or the prescriber must verify the dose of Oxbryta® will be adjusted during concomitant use according to package labeling; and~~
~~5. Prescriber must verify that the dose of Oxbryta® will be reduced in accordance with package labeling for members with severe hepatic impairment; and~~

~~6. For members younger than 12 years of age, the member's recent weight (kg)must be provided on the prior authorization request to ensure accurate dosing in accordance with package labeling; and~~
~~7. Oxbryta® tablets for oral suspension will have an age restriction of 4 to 10 years of age; and~~
~~a. Members older than 10 years of age requesting Oxbryta® tablets for oral suspension will require a patient-specific, clinically significant reason why the member cannot use Oxbryta® oral tablets; and~~
~~8. The following quantity limits will apply:~~
~~a. (3) 500mg tablets per day; and~~
~~b. (5) 300mg tablets for oral suspension per day; and~~
~~9. Initial approvals will be for the duration of 6months. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.~~

Recommendation 6: Annual Review of Multiple Myeloma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Abecma® (idecabtagene vicleucel), Carvykti® (ciltacabtagene autoleucel), and Sarclisa® (isatuximab-irfc) based on recent FDA approvals (changes shown in red):

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

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ~~≥4~~ ≥2 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma; and

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

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

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
   a. ~~Member has received ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody; and~~
      i. ~~Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and~~
      ii. ~~Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and~~
   b. Member has received ≥1 prior line of therapy, including an immunomodulatory agent and a proteasome inhibitor; and
      i. Member must be refractory to lenalidomide; and
      ii. Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
   c. Member must have measurable disease, including at least 1 of the following:
      i. Serum M-protein ≥0.5g/dL; or
      ii. Urine M-protein ≥200mg/24hr; or
      iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
      iv. Bone marrow plasma cells >30% of total bone marrow cells; and
   d. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

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

1. Diagnosis of multiple myeloma; and
   a. Used in the first line setting; and

b. Used in combination with bortezomib, lenalidomide, and dexamethasone; and
c. Member is considered ineligible for autologous stem cell transplantation; or

2. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
   a. Used in 1 of the following settings:
      i. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
      ii. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

Recommendation 7: Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Firdapse® (amifampridine) approval criteria to be consistent with the recent FDA approval to increase the maximum daily dose (changes shown in red):

Firdapse® (Amifampridine) Approval Criteria:

1. An FDA approved diagnosis of Lambert-Eaton myasthenic syndrome (LEMS); and
2. LEMS diagnosis must be confirmed by 1 of the following:
   a. A high titer anti-P/Q-type voltage-gated calcium channel (VGCC) antibody assay; or
   b. A confirmatory electrodiagnostic study [e.g., repetitive nerve stimulation (RNS), needle electromyography (EMG), single-fiber electromyography (SFEMG)]; and
3. The requested medication must be prescribed by, or in consultation with, a neurologist or oncologist; and
4. Member must not have a history of seizures or be taking medications that lower the seizure threshold (e.g., bupropion, tramadol, amphetamines, theophylline); and
5. A quantity limit of ~~240~~ 300 tablets per 30 days will apply; and
6. Initial approvals will be for 6 months. Continued authorization will require the prescriber to indicate that the member is responding well to treatment and continues to require treatment with the requested medication.

Recommendation 8: Annual Review of Hereditary Angioedema (HAE) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the icatibant approval criteria based on net costs (changes shown in red):

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

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

The College of Pharmacy recommends updating the Cinryze® (C1 esterase inhibitor) approval criteria to be consistent with clinical practice (changes shown in red):

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

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

a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); ~~or~~ and
    i. For requests exceeding the quantity limit, clinical documentation supporting the need for the dose increase (i.e., up to a maximum of 16,000 units per month) must be provided for a quantity limit override; or

9. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
    b. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
    c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or
10. Orladeyo® Dosing:
    a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and
    b. A quantity limit of 28 capsules per 28 days will apply; or
11. Takhzyro® Dosing:
    a. For members 12 years of age of older: The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    b. For members 6-11 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    c. For members 2 to 5 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 4 weeks; and
    d. Prescriber must verify member or caregiver has been trained by a health professional on proper storage and sub-Q administration of Takhzyro®; and
    e. A quantity limit of (2) vials per 28 days will apply.

Recommendation 9: 30-Day Notice to Prior Authorize Nemluvio® (Nemolizumab-ilto)

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

Recommendation 10: Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Ohtuvayre™ (Ensifentrine)

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

Recommendation 11: Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Ebglyss™ (Lebrikizumab-lbkz)

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

Recommendation 12: Annual Review of Sohonos™ (Palovarotene)

NO ACTION REQUIRED.

Recommendation 13: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

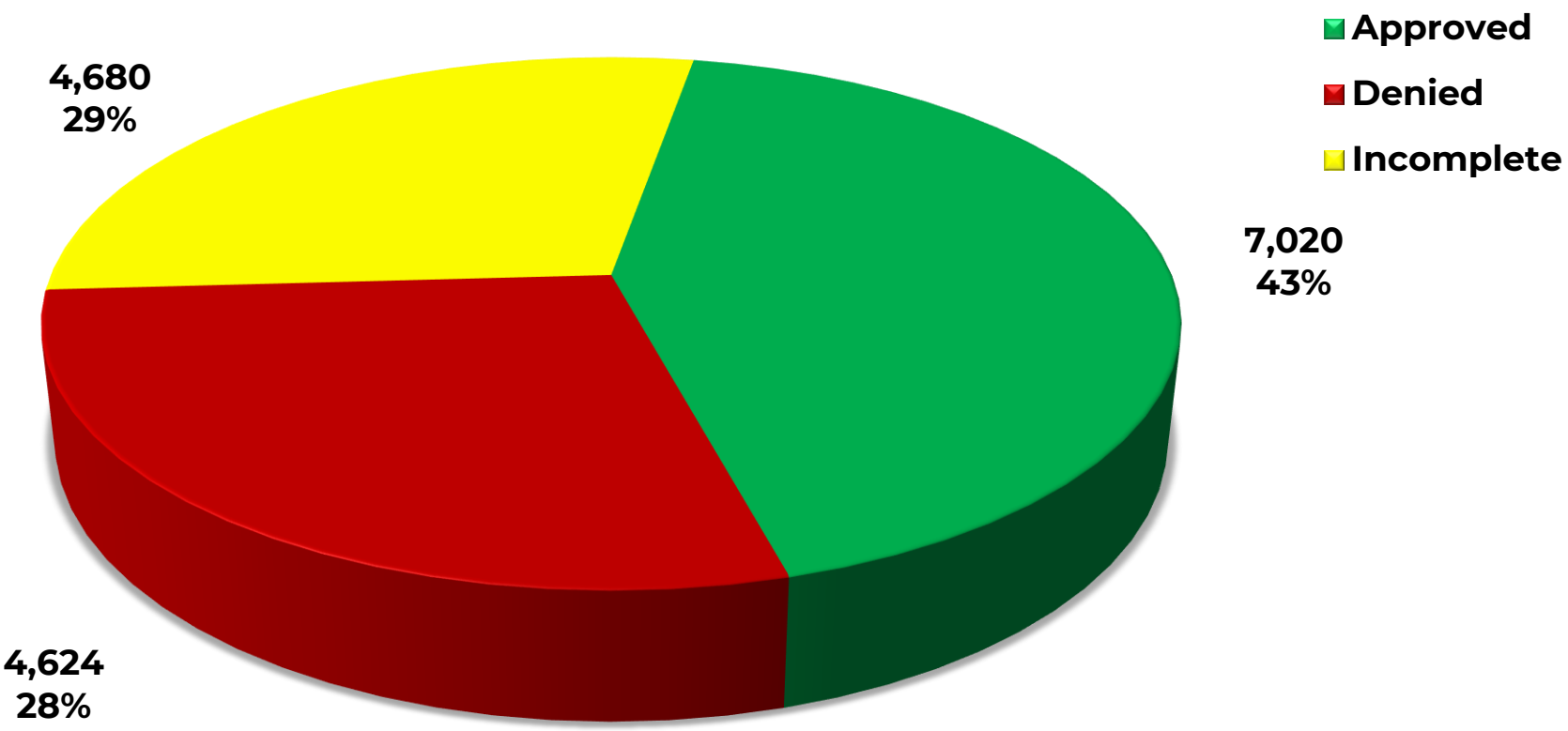
NO ACTION REQUIRED.

Recommendation 14: Future Business

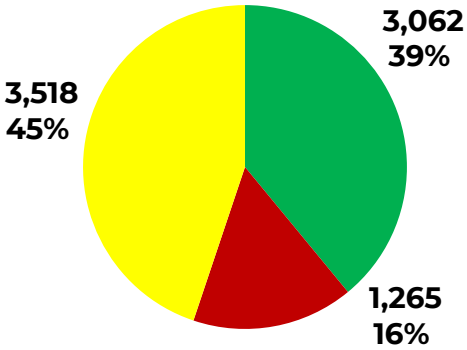
NO ACTION REQUIRED.

Appendix B

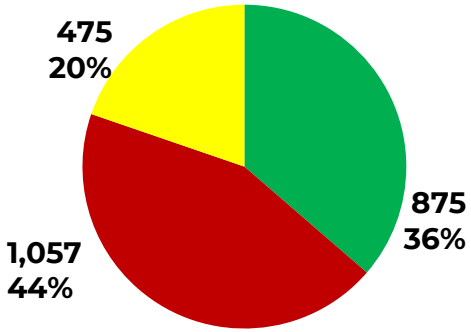
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: NOVEMBER 2024



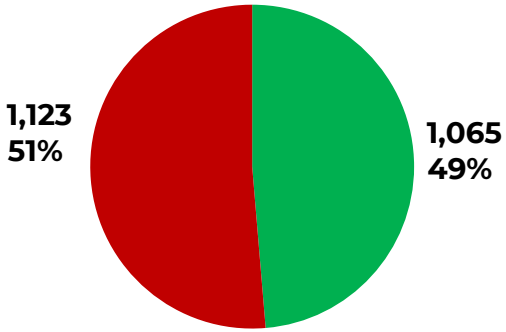
SoonerCare FFS



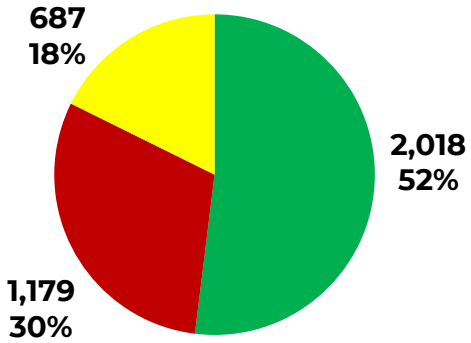
SoonerSelect Aetna



SoonerSelect Humana

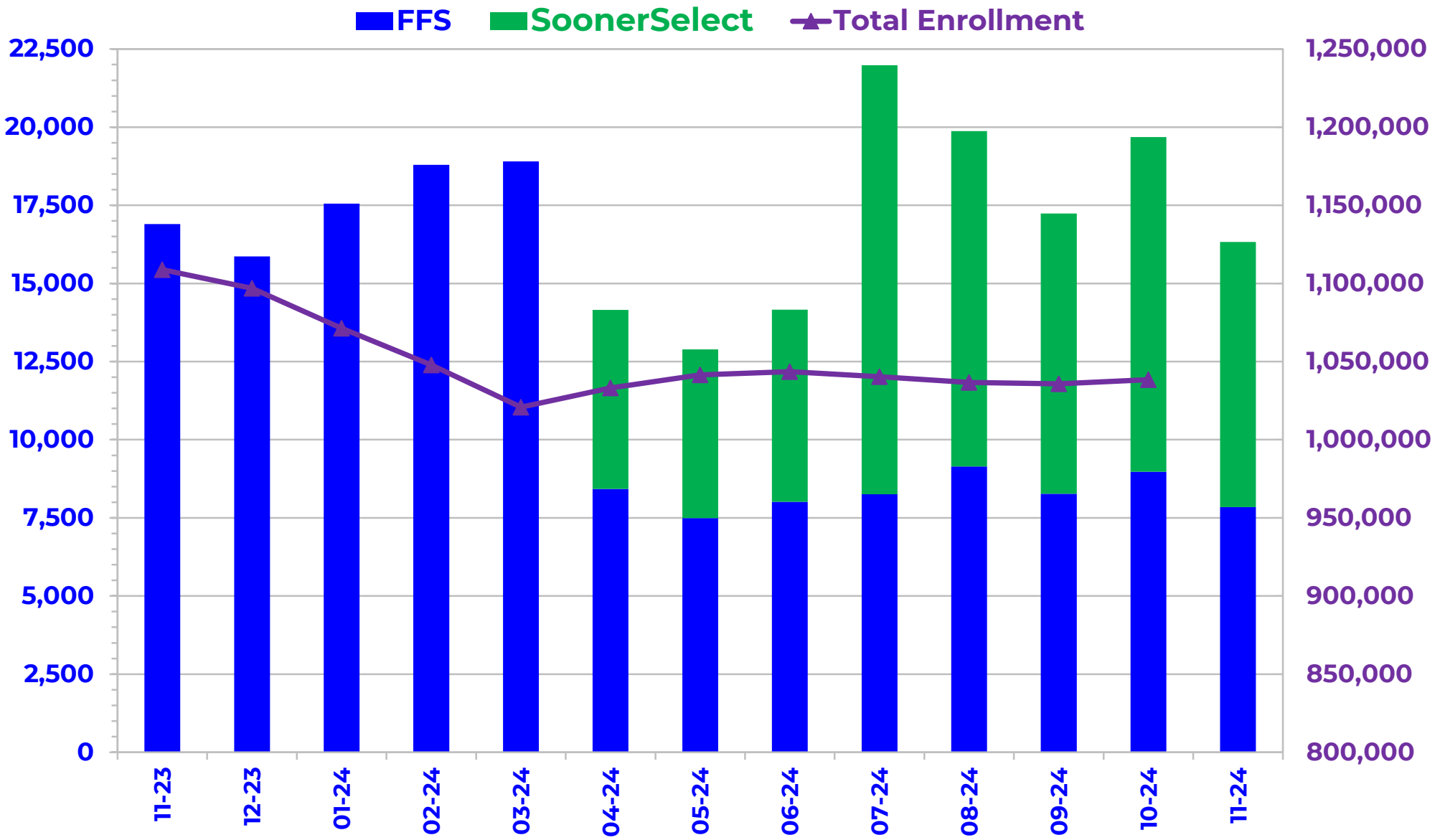


SoonerSelect OK Complete Health



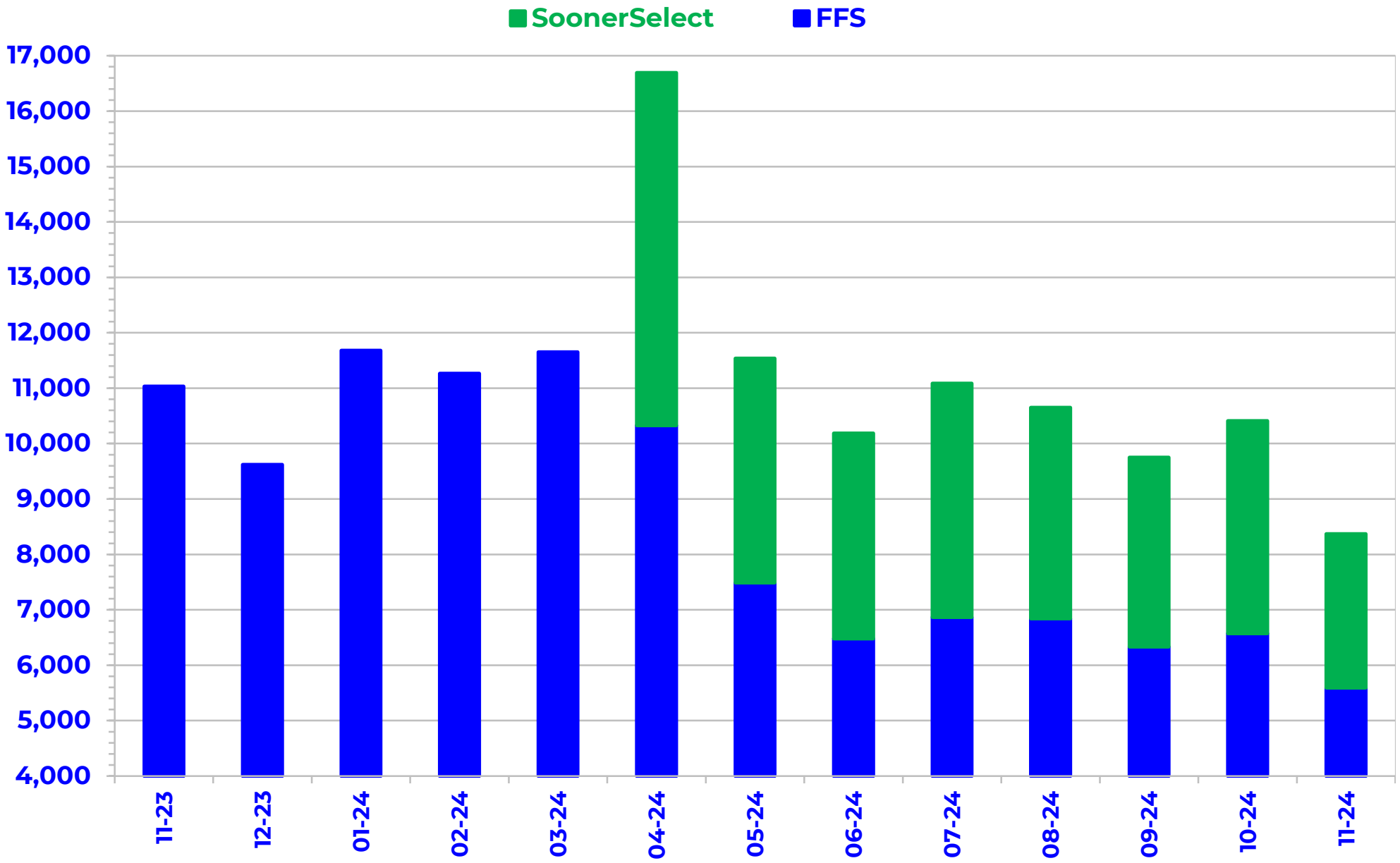
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: NOVEMBER 2023 – NOVEMBER 2024



SoonerCare FFS Prior Authorization Activity

11/1/2024 Through 11/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	2	0	1	1	0
Amphetamines	550	351	6	193	353
Analgesics - Anti-Inflammatory	192	70	26	96	300
Analgesics - Nonnarcotic	8	0	5	3	0
Analgesics - Opioid	299	135	26	138	134
Androgens - Anabolic	66	16	18	32	346
Anorectal and Related Products	2	0	1	1	0
Anorexiants Non-Amphetamine	1	0	1	0	0
Antacids	1	1	0	0	361
Anthelmintics	15	4	2	9	10
Anti-Infective Agents - Misc.	29	9	2	18	172
Anti-Obesity Agents	98	12	54	32	81
Antianginal Agents	2	2	0	0	360
Antianxiety Agents	17	4	1	12	270
Antiasthmatic and Bronchodilator Agents	455	93	85	277	335
Antibiotics	28	11	0	17	284
Anticoagulants	13	2	2	9	340
Anticonvulsants	195	89	11	95	324
Antidepressants	211	45	44	122	298
Antidiabetics	1,127	337	235	555	354
Antidiarrheal/Probiotic Agents	2	2	0	0	17
Antidotes and Specific Antagonists	2	2	0	0	360
Antiemetics	14	2	2	10	100
Antifungals	5	1	1	3	25
Antihistamines	26	4	5	17	360
Antihyperlipidemics	49	19	10	20	222
Antihypertensives	23	6	1	16	359
Antimalarials	2	0	0	2	0
Antimyasthenic/Cholinergic Agents	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	194	129	10	55	180
Antiparkinson and Related Therapy Agents	14	7	0	7	359
Antipsychotics/Antimanic Agents	296	113	36	147	347
Antivirals	21	7	2	12	8
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	204	130	18	56	352
Beta Blockers	9	5	1	3	359
Calcium Channel Blockers	4	1	0	3	271
Cardiovascular Agents - Misc.	90	34	10	46	319
Contraceptives	37	15	3	19	325
Corticosteroids	10	4	0	6	186

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Cough/Cold/Allergy	1	1	0	0	24
Dermatologicals	447	119	104	224	230
Diagnostic Products	39	24	2	13	125
Digestive Aids	8	5	1	2	288
Diuretics	2	2	0	0	351
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	0	0	2	0
Emergency PA	1	1	0	0	0
Endocrine and Metabolic Agents - Misc.	151	80	16	55	224
Estrogens	12	3	4	5	358
Gastrointestinal Agents - Misc.	261	62	60	139	236
Genitourinary Agents - Misc.	3	2	0	1	361
Gout Agents	11	4	0	7	360
Hematological Agents - Misc.	12	6	0	6	329
Hematopoietic Agents	34	9	11	14	126
Histamine H3-Receptor Antagonist/Inverse Agonists	5	4	0	1	187
Hypnotics/Sedatives/Sleep Disorder Agents	49	1	7	41	360
Laxatives	26	11	1	14	234
Medical Devices and Supplies	206	47	46	113	234
Migraine Products	301	62	104	135	274
Minerals and Electrolytes	6	4	1	1	270
Miscellaneous Therapeutic Classes	53	18	5	30	321
Multivitamins	3	0	0	3	0
Musculoskeletal Therapy Agents	27	9	4	14	226
Nasal Agents - Systemic And Topical	16	0	6	10	0
Neuromuscular Agents	104	36	48	20	310
Nutrients	1	1	0	0	360
Ophthalmic Agents	52	8	10	34	274
Other*	39	10	4	25	257
Otic Agents	19	1	3	15	25
Passive Immunizing and Treatment Agents	1	0	0	1	0
Pharmaceutical Adjuvants	5	2	0	3	223
Progestins	3	2	1	0	226
Psychotherapeutic and Neurological Agents - Misc.	226	78	49	99	206
Respiratory Agents - Misc.	20	13	1	6	277
Stimulants - Misc.	228	88	28	112	301
Thyroid Agents	15	5	1	9	359
Ulcer Drugs/Antispasmodics/Anticholinergics	42	7	9	26	246
Urinary Antispasmodics	84	15	24	45	341
Vaccines	1	1	0	0	360
Vaginal and Related Products	4	0	1	3	0
Vasopressors	2	2	0	0	361
Vitamins	29	4	21	4	252
Total	**6,865**	**2,409**	**1,191**	**3,265**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	21	11	0	10	305
Compound	11	9	0	2	12
Dosage Change	183	162	3	18	14
High Dose	2	0	0	2	0
Lost/Broken Rx	44	40	2	2	18
MAT Override	15	9	1	5	103
NDC vs Age	156	96	20	40	285
NDC vs Sex	25	15	4	6	246
Nursing Home Issue	32	30	0	2	7
Opioid MME Limit	66	19	3	44	107
Opioid Quantity	11	9	1	1	136
Other	44	32	7	5	21
Prescriber Temp Unlock	1	0	0	1	0
Quantity vs Days Supply	304	185	22	97	275
STBS/STBSM	16	7	3	6	63
Step Therapy Exception	11	5	5	1	286
Stolen	10	10	0	0	30
Third Brand Request	28	14	3	11	19
Overrides Total	**980**	**653**	**74**	**253**	
Total Regular PAs + Overrides	**7,845**	**3,062**	**1,265**	**3,518**	

Denial Reasons	
Unable to verify required trials.	3,020
Does not meet established criteria.	1,287
Lack required information to process request.	512
Other PA Activity	
Duplicate Requests	804
Letters	29,627
No Process	2
Helpdesk Initiated Prior Authorizations	328
PAs Missing Information	393
Pharmacotherapy	89
Changes to Existing PAs	518

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

SoonerSelect Aetna Prior Authorization Activity

11/1/2024 Through 11/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	1	1	0	0	181
Amphetamines	212	153	32	27	364
Analgesics - Anti-Inflammatory	70	51	11	8	354
Analgesics - Nonnarcotic	3	0	2	1	0
Analgesics - Opioid	122	52	54	16	159
Androgens - Anabolic	42	8	33	1	365
Anorectal and Related Products	2	0	1	1	0
Anthelmintics	5	4	1	0	11
Antianginal Agents	2	0	0	2	0
Antianxiety Agents	12	2	5	5	365
Antiasthmatic and Bronchodilator Agents	136	26	70	40	335
Antibiotics	6	3	1	2	28
Anticoagulants	4	3	0	1	242
Anticonvulsants	42	16	13	13	298
Antidepressants	130	39	58	33	328
Antidiabetics	386	98	228	60	335
Antidiarrheal/Probiotic Agents	1	1	0	0	365
Antiemetics	1	0	0	1	0
Antifungals	4	0	2	2	0
Antihistamines	13	2	10	1	365
Antihyperlipidemics	21	2	7	12	229
Antihypertensives	14	0	1	13	0
Anti-Infective Agents - Misc.	9	5	3	1	365
Antineoplastics and Adjunctive Therapies	12	8	0	4	260
Anti-Obesity Agents	36	0	33	3	0
Antiparkinson and Related Therapy Agents	2	0	0	2	0
Antipsychotics/Antimanic Agents	121	47	56	18	356
Antivirals	8	3	4	1	140
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	69	54	12	3	365
Beta Blockers	7	1	0	6	131
Calcium Channel Blockers	11	1	1	9	365
Cardiovascular Agents - Misc.	21	8	10	3	226
Chemicals	4	1	1	2	365
Contraceptives	12	4	4	4	365
Corticosteroids	1	0	0	1	0
Dermatologicals	183	71	81	31	218
Diagnostic Products	42	20	9	13	331
Dietary Products/Dietary Management Products	1	0	0	1	0
Diuretics	3	0	0	3	0
Endocrine and Metabolic Agents - Misc.	26	17	9	0	314
Estrogens	6	3	2	1	365
Gastrointestinal Agents - Misc.	69	25	41	3	225
Gout Agents	1	0	0	1	0
Hematological Agents - Misc.	3	2	0	1	351
Hematopoietic Agents	7	4	2	1	229
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	1	0	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	24	3	15	6	181
Laxatives	10	0	8	2	0
Medical Devices and Supplies	76	20	26	30	350
Migraine Products	136	36	88	12	257
Minerals and Electrolytes	6	0	1	5	0
Miscellaneous Therapeutic Classes	4	3	0	1	365
Multivitamins	5	4	1	0	332
Musculoskeletal Therapy Agents	29	6	4	19	265
Nasal Agents - Systemic and Topical	18	1	10	7	92
Neuromuscular Agents	3	0	1	2	0
Ophthalmic Agents	11	6	5	0	275
*Other	13	3	8	2	319
Otic Agents	12	1	11	0	92
Passive Immunizing and Treatment Agents	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	23	6	12	5	255
Respiratory Agents - Misc.	5	5	0	0	319
Stimulants - Misc.	62	39	19	4	348
Thyroid Agents	7	1	2	4	317
Ulcer Drugs/Antispasmodics/Anticholinergics	33	1	14	18	365
Urinary Antispasmodics	9	1	7	1	181
Vaccines	1	1	0	0	181
Vaginal and Related Products	3	0	0	3	0
Vasopressors	7	1	4	2	14
Vitamins	25	2	23	0	229
****Total**	**2,407**	**875**	**1,057**	**475**	

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

Overrides					
Brand	2	2	0	0	365
Other	475	0	0	475	0
Quantity Level Limit	18	18	0	0	250
Overrides Total	**495**	**20**	**0**	**475**	

Denial Reason	
Benefit	80
Experimental/Investigational	118
Lack Required Infomation to Process Request	69
Medical Necessity	790
Other PA Activity	
Duplicate Requests	12
Letters	3,067
No Process	204
Changes to existing PAs	0
Helpdesk initiated PA	4
PAs missing info	4

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

SoonerSelect Humana Prior Authorization Activity

11/1/2024 Through 11/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	3	0	3	0	0
Analgesics - Anti-Inflammatory	58	44	14	0	368
Analgesics - Nonnarcotic	6	2	4	0	365
Analgesics - Opioid	74	30	44	0	306
Androgens - Anabolic	41	9	32	0	365
Anthelmintics	5	2	3	0	365
Antiasthmatic and Bronchodilator Agents	111	41	70	0	338
Antibiotics	5	1	4	0	365
Anticonvulsants	6	3	3	0	365
Antidepressants	36	24	12	0	358
Antidiabetics	166	58	108	0	366
Antiemetics	2	0	2	0	0
Antihyperlipidemics	8	2	6	0	229
Antineoplastics and Adjunctive Therapies	43	33	10	0	251
Anti-Obesity Agents	46	3	43	0	456
Antiparkinson and Related Therapy Agents	1	0	1	0	0
Antivirals	4	1	3	0	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	16	5	11	0	365
Cardiovascular Agents - Misc.	16	11	5	0	365
Contraceptives	14	9	5	0	342
Corticosteroids	2	2	0	0	365
Dermatologicals	89	58	31	0	307
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	3	1	2	0	730
Endocrine and Metabolic Agents - Misc.	32	16	16	0	288
Gastrointestinal Agents - Misc.	75	33	42	0	253
Gout Agents	1	0	1	0	0
Hematological Agents - Misc.	6	2	4	0	411
Hematopoietic Agents	16	4	12	0	273
Histamine H3-Receptor Antagonist/Inverse Agonists	3	0	3	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	9	3	6	0	304
Laxatives	8	3	5	0	365
Migraine Products	95	54	41	0	270
Miscellaneous Therapeutic Classes	5	3	2	0	365
Multivitamins	1	1	0	0	730
Musculoskeletal Therapy Agents	21	8	13	0	365
Nasal Agents - Systemic and Topical	3	0	3	0	0
Neuromuscular Agents	19	13	6	0	365
Ophthalmic Agents	20	9	11	0	365
*Other	16	7	9	0	242
Otic Agents	4	0	4	0	0
Psychotherapeutic and Neurological Agents - Misc.	22	10	12	0	211
Stimulants - Misc.	11	3	8	0	365
Thyroid Agents	8	2	6	0	195
Ulcer Drugs/Antispasmodics/Anticholinergics	7	2	5	0	365
Urinary Antispasmodics	18	5	13	0	365
Vaginal And Related Products	1	0	1	0	0
Vitamins	28	3	25	0	380
Total	**1,184**	**520**	**664**	**0**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Ingredient Duplication	70	33	37	0	416
MAT Override	98	77	21	0	413
NDC vs Age	211	157	54	0	364
Opioid MME Limit	3	3	0	0	487
Opioid Quantity	12	12	0	0	403
Other	89	35	54	0	352
Quantity vs Days Supply	144	100	44	0	372
STBS/STBSM	100	21	79	0	370
Step Therapy Exception	277	107	170	0	386
Overrides Total	**1,004**	**545**	**459**	**0**	
Total Regular PAs + Overrides	**2,188**	**1,065**	**1,123**	**0**	

Denial Reasons	
Benefit	302
Medical Necessity	821

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

SoonerSelect Oklahoma Complete Health Prior Authorization Activity

11/1/2024 Through 11/30/2024

	Total	Approved	Denied	Incomplete	Average Length
Amphetamines	130	101	8	21	143
Analgesics - Anti-Inflammatory	69	41	17	11	333
Analgesics - Nonnarcotic	5	1	2	2	365
Analgesics - Opioid	255	84	136	35	184
Androgens - Anabolic	60	18	38	4	350
Anorectal and Related Products	1	0	1	0	0
Anthelmintics	7	2	4	1	365
Antianginal Agents	4	3	0	1	48
Antianxiety Agents	82	56	13	13	82
Antiasthmatic and Bronchodilator Agents	233	109	87	37	145
Antibiotics	15	5	7	3	319
Anticoagulants	2	1	0	1	55
Anticonvulsants	268	186	19	63	107
Antidepressants	319	200	46	73	147
Antidiabetics	646	363	198	85	220
Antidotes and Specific Antagonists	1	0	1	0	0
Antiemetics	10	4	5	1	258
Antifungals	1	1	0	0	55
Antihistamines	17	9	6	2	365
Antihyperlipidemics	38	22	6	10	98
Antihypertensives	73	53	3	17	90
Anti-Infective Agents - Misc.	6	2	4	0	365
Antimyasthenic/Cholinergic Agents	1	0	1	0	0
Antineoplastics and Adjunctive Therapies	28	17	5	6	284
Anti-Obesity Agents	66	4	57	5	140
Antiparkinson and Related Therapy Agents	4	3	1	0	53
Antipsychotics/Antimanic Agents	201	105	50	46	223
Antivirals	5	2	3	0	50
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	56	24	20	12	206
Beta Blockers	52	36	3	13	63
Calcium Channel Blockers	21	15	0	6	88
Cardiovascular Agents - Misc.	37	19	14	4	365
Contraceptives	11	5	5	1	365
Corticosteroids	3	2	1	0	365
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	209	95	87	27	268
Diagnostic Products	38	21	12	5	307
Dietary Products/Dietary Management Products	3	1	2	0	365
Diuretics	19	13	0	6	48
Endocrine and Metabolic Agents - Misc.	26	10	13	3	326
Estrogens	2	1	1	0	730
Gastrointestinal Agents - Misc.	52	19	27	6	336
Genitourinary Agents - Misc.	7	4	0	3	46
Gout Agents	2	1	1	0	365
Hematological Agents - Misc.	11	2	3	6	365
Hematopoietic Agents	5	3	1	1	283
Hypnotics/Sedatives/Sleep Disorder Agents	29	8	16	5	198
Laxatives	2	1	1	0	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Medical Devices and Supplies	101	58	37	6	335
Migraine Products	131	37	81	13	300
Miscellaneous Therapeutic Classes	8	2	1	5	365
Multivitamins	4	1	2	1	365
Musculoskeletal Therapy Agents	15	1	13	1	365
Nasal Agents - Systemic and Topical	5	1	2	2	365
Neuromuscular Agents	5	0	0	5	0
Ophthalmic Agents	18	4	8	6	121
*Other	59	15	12	32	227
Otic Agents	50	24	17	9	246
Psychotherapeutic and Neurological Agents - Misc.	40	9	23	8	195
Respiratory Agents - Misc.	6	4	2	0	365
Stimulants - Misc.	179	110	34	35	275
Thyroid Agents	29	21	3	5	43
Ulcer Drugs/Antispasmodics/Anticholinergics	78	50	9	19	90
Urinary Antispasmodics	20	9	8	3	86
Vaginal and Related Products	3	0	2	1	0
****Total**	**3,884**	**2,018**	**1,179**	**687**	

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

Denial Reasons	
Benefit	58
Medical Necessity	1,121

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

Academic Detailing Program Update

Oklahoma Health Care Authority
December 2024

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

The Academic Detailing (AD) program is an educational initiative combining standards of care with the most current peer-reviewed studies and presenting them in an unbiased, independent, evidence-based manner. AD programs link prescribers with an educator, resulting in improved patient health and cost outcomes. Historically, AD programs that focus specifically on prescribing patterns are shown to reduce inappropriate prescribing to a modest, but significant degree, with a median difference of up to 7%. While not specifically designed to be a tool of cost containment, traditionally AD programs save $2 for every dollar spent.

Since July 2015, under the direction of the Oklahoma Health Care Authority (OHCA), Pharmacy Management Consultants (PMC) has operated an AD program to improve implementation of published guidelines and standards of care. In consultation with OHCA, PMC clinical pharmacists, data analysts, and pharmacy graduate students analyze prescription claims data to determine AD topics, identify providers who may benefit from individualized support from an AD pharmacist, and assess outcomes. Previous AD interventions have focused mainly on topics with particular relevance to the care of pediatric members; however, in June 2023, PMC added adult AD topics with a grant from the Oklahoma State Department of Health (OSDH). The focus of this grant concerns safety and harm reduction with opioid prescribing practices.

For each topic, the PMC-AD pharmacist prepares educational materials in consultation with the National Resource Center for Academic Detailing (NaRCAD) and offers the program to providers. Educational materials include the following:

- Clinical treatment guidelines
- Provider resources
- Patient and parent resources
- Diagnostic and treatment tools
- Topic-specific continuing medical education (CME) course listings
- Drug alerts and statements from the U.S. Food and Drug Administration (FDA)
- National quality measures [e.g., Healthcare Effectiveness Data and Information Set (HEDIS)]
- OHCA Product Based Prior Authorization (PBPA) coverage criteria

To date, AD services have been provided to nearly 1,100 health care providers and/or their administrative staff. As previously reported, changes in prescribing patterns and associated improvements in health care utilization have led to cost savings to OHCA in the amount of $3,377,207 through December 2023. This amount is inclusive of all federal and supplemental rebates for the analysis periods following AD on the following topics for pediatric SoonerCare members:

- Attention-deficit/hyperactivity disorder (ADHD)
- Use of second generation/atypical antipsychotic medications (SGAs)
- Upper respiratory infections (URIs)
- Persistent asthma
- Diabetes
- Prenatal vitamins

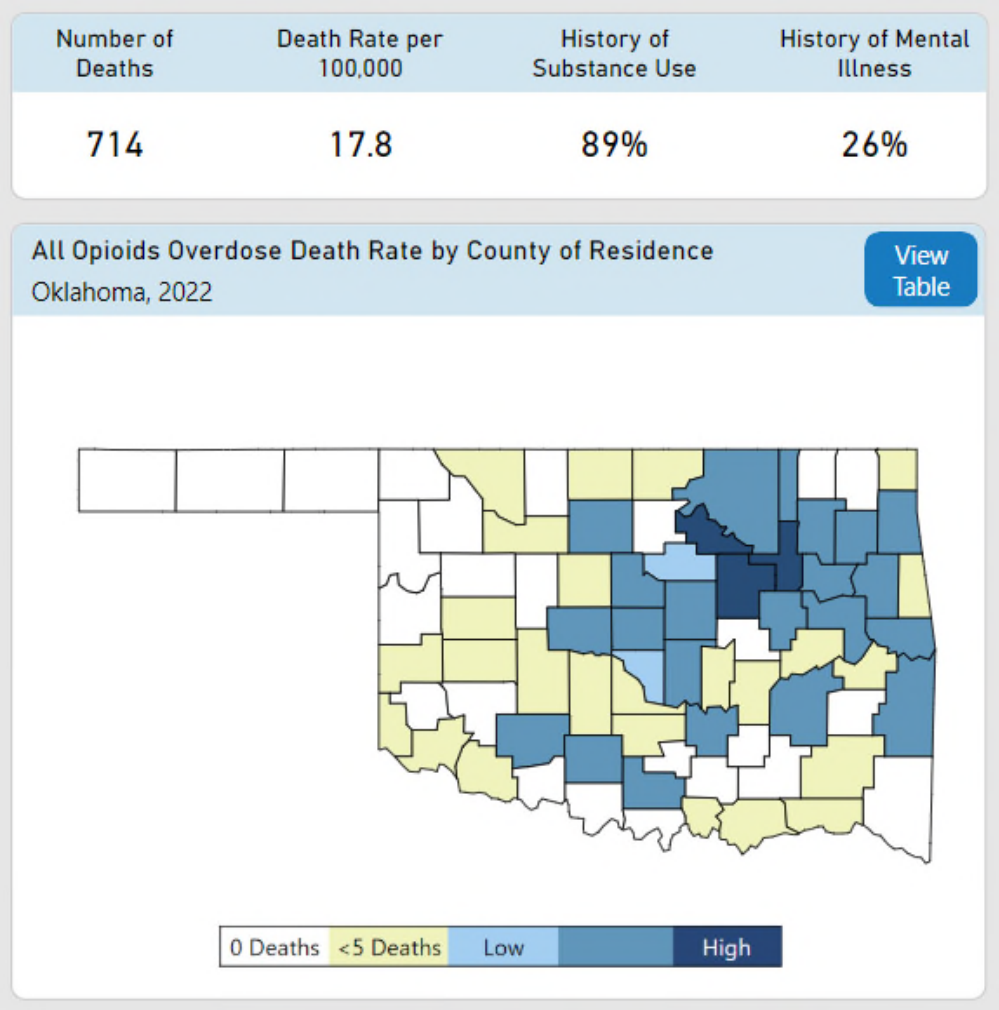
Current Topic: Co-Prescribing Naloxone with Opioid Medications[6,7,8,9,10]

The State Unintentional Drug Overdose Reporting System (SUDORS) sponsored by the Centers for Disease Control and Prevention (CDC) reported drug overdose data from 30 jurisdictions (29 U.S. states and the District of Columbia) for calendar year 2022. The SUDORS database collects information from death certificates, coroner or medical examiner reports, and postmortem toxicology reports to provide information on the number of overdose-related deaths and the medications involved. Of the 30 jurisdictions included for calendar year 2022, it was reported that 51,435 overdose deaths occurred overall, of which 1,298 occurred in Oklahoma.

The OSDH Oklahoma Drug Overdose Dashboard reported 714 of these deaths involved at least 1 opioid (see Figure 1 below). According to the CDC, approximately 5% of overdose deaths involved only prescription opioids (no other opioids or stimulants). Potential bystanders were present in at least 40% of Oklahoma overdose deaths as recorded by medical examiner or coroner report; however, of those deaths with a potential bystander present, no response was provided in 84% of the deaths. A person was considered a potential bystander if they were 11 years of age or older, physically nearby either during or shortly preceding the overdose, and potentially had an opportunity to intervene or respond to the overdose. The reasons for bystander nonresponse included:

- Was unaware of substance use; or
- Did not recognize signs of overdose; or
- Was using substances or alcohol; or
- Was not close enough to provide aid.

Figure 1: OSDH Oklahoma Drug Overdose Dashboard: Overdose Deaths from all Opioids in 2022



The 2022 CDC guidelines for prescribing opioids for pain recommend the following patients taking opioids should be prescribed naloxone:

- Prescribed high-dose opioids (i.e., ≥50 MME/day)
- Concomitant use with benzodiazepines
- With sleep-disordered breathing (e.g., sleep apnea)
- History of substance use disorder
- History of drug overdose
- At risk of returning to a high dose for which they have lost tolerance (e.g., incarceration or recently leaving a rehab facility)

According to national trends, only 1 naloxone prescription is written for every 70 high-dose opioid prescriptions. It is difficult to determine which patients taking opioid medications are at risk for accidental overdose, so it is recommended that ideally, all patients on opioids are prescribed naloxone.

Prescriber Mailing: Co-Prescribing Naloxone with Opioid Medications

PMC, OHCA, and OSDH are working to improve the safety of Oklahomans who are currently prescribed an opioid medication and who may not have immediate access to naloxone in the event of an opioid emergency. While there are currently no requirements regarding co-prescribing of naloxone with opioid medications, there is convincing evidence supporting this co-prescribing as a benefit to patients.

In May 2024, 49 prescribers received an educational outreach letter addressing the potential lack of naloxone dispensing based on paid claims from January 1, 2023, to April 4, 2024, with the following selection criteria:

- ≥1 high-dose opioid prescription(s) (i.e., ≥50 MME/day), irrespective of treatment length, lacking a paid claim for naloxone; or
- ≥1 opioid medication(s) lasting ≥30 days, irrespective of dose, lacking a paid claim for naloxone.

All 49 prescribers have previously received at least 1 educational mailing related to their opioid prescribing history since September 2022, with an average of 6.6 letters per prescriber prior to this outreach.

Results: Co-Prescribing Naloxone with Opioid Medications

Starting in May 2024, contact has been attempted with all prescribers who received an educational outreach letter, and AD has been completed with 11 prescribers to date. Before AD, these prescribers had an average of 2.91% paid claims of naloxone in 16 months with a range of 0 – 47%. After AD, these prescribers had an average of 9.73% dispensing of naloxone in 6 months with a range of 1 – 48%. This was a total increase of 6.82% of naloxone paid claims. Member counts and naloxone paid claims are represented in Table 1.

Table 1: Prescribers Who Accepted AD – Naloxone Use Before and After AD

Prescriber	Pre-AD Period			Post-AD Period			% Change
	Member Count	Naloxone Rx	Naloxone Rx %	Member Count	Naloxone Rx	Naloxone Rx %	
A	103	3	2.91%	57	4	7.02%	4.11%
B	189	4	2.12%	114	2	1.75%	-0.37%
C	15	7	46.67%	13	2	15.38%	-31.29%
D	554	2	0.36%	192	3	1.56%	1.20%
E	375	13	3.47%	180	32	17.78%	14.31%
F	94	23	24.47%	71	34	47.89%	23.42%
G	150	29	19.33%	106	27	25.47%	6.14%
H	354	1	0.28%	85	1	1.18%	0.90%
I	317	1	0.32%	78	1	1.28%	0.96%
J	717	1	0.14%	249	5	2.01%	1.87%
K	21	0	0.00%	6	1	16.67%	16.67%

Total	**2,889**	**84**	**2.91%**	**1,151**	**112**	**9.73%**	**6.82%**

Pre-AD Period = 01/01/2023 to 04/24/2024; Post-AD Period = 04/25/2024 to 10/31/2024
AD = Academic Detailing; N/A = not applicable; Rx = paid claims

In 2014, the CDC conducted a survey based on naloxone distribution from organizations providing naloxone kits to laypersons from 1999 to 2014 to determine the number of overdose reversals to kits provided. It was determined that for every documented overdose reversal, 5.75 kits had been provided. In 2013, it was estimated that the direct medical cost for an overdose was $6,000. When adjusted for the cost of inflation, the cost saving of naloxone AD is over $36,000.

AD was offered and deferred by 3 prescribers. These prescribers had an average of 14% paid claims of naloxone in the 16 months before the offer of AD with a range of 1 – 50%. After AD was offered (and deferred), these prescribers had an average of 22% paid claims of naloxone, which was an increase of over 8%. Thus, these prescribers showed an increase in paid claims of naloxone merely with the offer of AD, as shown in Table 2 below.

Table 2: Prescribers Who Were Offered AD – Naloxone Use Before and After AD

Prescriber	Pre-AD Period			Post-AD Period			% Change
	Member Count	Naloxone Rx	Naloxone Rx %	Member Count	Naloxone Rx	Naloxone Rx %	
A	420	4	0.95%	225	10	4.44%	3.49%
B	44	2	4.55%	4	1	25.00%	20.45%
C	164	82	50.00%	120	66	55.00%	5.00%
Total	**628**	**88**	**14.01%**	**349**	**77**	**22.06%**	**8.05%**

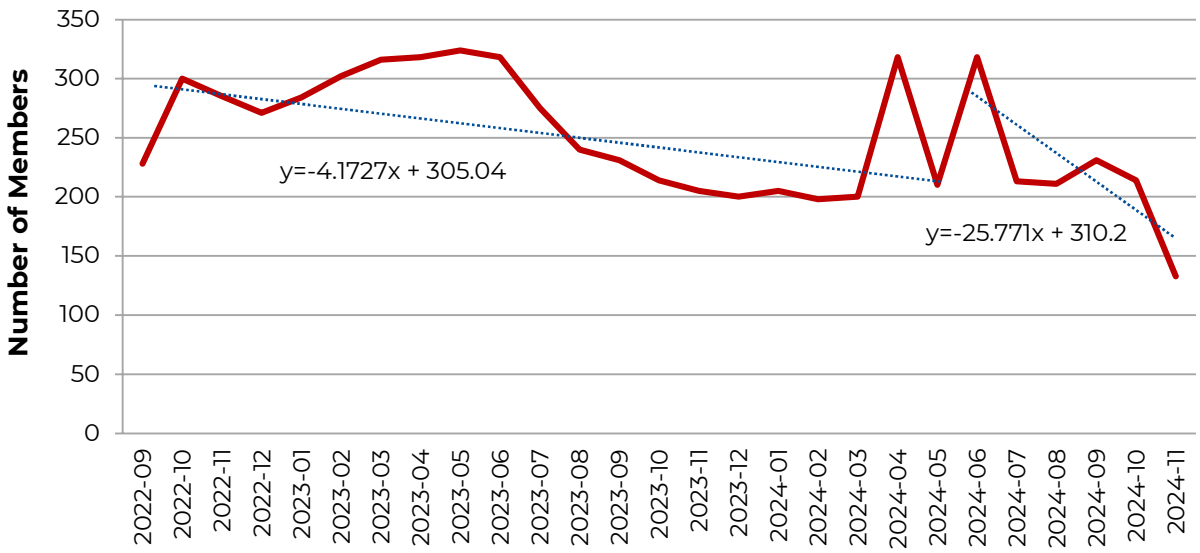
Pre-AD = 01/01/2023 to 04/24/2024; Post AD = 04/25/2024 to 10/31/2024
AD = Academic Detailing; Rx = paid claims

The goal of this outreach has been to increase the safety of Oklahomans who are members of SoonerCare fee-for-service and SoonerSelect managed care by providing access to naloxone. The data shows that there has been a change in prescribing practices in a short amount of time. This data does not reflect members who obtained naloxone from other sources, which could include the following:

- Over-the-counter (OTC) products
- Provided in prescriber's office
- OK I'm Ready – mail order provided by the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS)

As these prescribers have previously received 2 educational mailings related to their opioid prescribing history, the total number of members with high MME (i.e., ≥50 MME/day) was reviewed. The following graph (Figure 2) demonstrates a dramatic decline in total members after the start of naloxone AD in May 2024.

Figure 2: Monthly Total Members with High MME (≥50 MME/day)



Summary: Co-Prescribing Naloxone with Opioid Medications

As demonstrated in the results, it is shown that providing AD to prescribers increased the endpoint of more naloxone prescriptions. The naloxone AD project is ongoing, and providers who have not responded will continue to be contacted, as the data shows that there have been positive impacts related to naloxone co-prescribing. Future topics for AD such as co-prescribing of opioids with benzodiazepines, opioid prescribing in pregnancy, and stigma associated with opioids will increase the numbers of conversations for naloxone co-prescribing. The goal is to increase the amount of naloxone that is in the hands of both members and bystanders. In the right hands, naloxone can prevent overdose deaths and potentially save lives.

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Appendix C

SoonerCare Maintenance Drug List

Oklahoma Health Care Authority
December 2024

Introduction[1]

Most adult SoonerCare members are limited to 6 prescriptions each month; therefore, prescribing for and dispensing 90-day supplies of chronic maintenance medications will help members who are on multiple medications obtain the maintenance medications necessary. Dispensing 90-day supplies of chronic maintenance medications has been shown to increase medication adherence and persistence, compared to dispensing 30-day supplies. Additionally, 90-day supplies will reduce the SoonerCare member's financial burden as they will pay the same copay for a 90-day supply as they would for a 30-day supply.

In November 2019, the Oklahoma Health Care Authority (OHCA) Board voted to update the current policy and rules regarding dispensing limitations. Previously, medications could only be dispensed and reimbursed by SoonerCare up to a 34-day supply or if the quantity did not exceed 100 units. The updated OHCA policy and rules state the following regarding dispensing limitations and a maintenance drug list (317:30-5-77.1):

> "Prescription quantities shall be limited to a 34-day supply, except in the following situations:
> 1. The Drug Utilization Review (DUR) Board has recommended a different day supply or quantity limit based on published medical data, including the manufacturer's package insert; or
> 2. The product is included on the Maintenance List of medications which are exempted from this limit and may be dispensed up to a 90-day supply; or
> 3. The manufacturer of the drug recommends a dispensing quantity less than a 34-day supply….".
>
> "The DUR Board shall develop a Maintenance List of medications which are used in general practice on a continuing basis. These drugs shall be made available through the Vendor Drug Program in quantities up to a 90-day supply when approved by the prescriber. The DUR Board shall review the Maintenance List at least annually."

The DUR Board recommended and voted on categories of medications for inclusion on the maintenance drug list in December 2019, and the SoonerCare Maintenance Drug List was implemented in January 2020. The

purpose of this report is to provide the DUR Board with the current maintenance drug list for review, which is to be maintained by the DUR Board. Medications included in the maintenance drug list allow a 90-day supply of medications in the claims processing system without the need for an override. Action by the DUR Board is not required unless changes are recommended to the current maintenance drug list.

SoonerCare Maintenance Drug List

The current SoonerCare Maintenance Drug List is available on the OHCA website (https://oklahoma.gov/ohca/rx) and includes the following categories of medications:

- Alzheimer's Medications
- Anticonvulsants
- Antidepressants/Anxiolytics
- Antihypertensive Medications
- Antipsychotic Medications
- Anti-Ulcer Medications
- Bladder Control Medications
- Benign Prostatic Hyperplasia (BPH) Medications
- Cardiovascular Medications
- Chronic Obstructive Pulmonary Disease (COPD) Medications
- Diabetes Medications
- Glaucoma Medications
- Hyperlipidemia Medications
- Non-Controlled Attention-Deficit/Hyperactivity Disorder (ADHD) Medications
- Parkinson's Medications
- Thyroid Medications

Please note that not all medications in each category can be processed for a 90-day supply.

Recommendations

The College of Pharmacy does not recommend any changes to the SoonerCare Maintenance Drug List at this time.

[1] Taitel M, Fensterheim L, Kirkham H, et al. Medication Days' Supply, Adherence, Wastage, and Cost Among Chronic Patients in Medicaid. *MMRR* 2012; 2(3):E1-E13. doi: 10.5600/mmrr.002.03.a04.

Appendix D

Vote to Prior Authorize Ebglyss™ (Lebrikizumab-lbkz) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications

Oklahoma Health Care Authority
December 2024

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

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

- **December 2023:** The FDA approved Adbry® (tralokinumab-ldrm) for an age expansion for the treatment of moderate-to-severe AD in patients 12 years of age or older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Previously, Adbry® was only FDA approved for the treatment of adults with this indication.
- **June 2024:** The FDA approved Adbry® for a new single-dose autoinjector for the treatment of adults with moderate-to-severe AD. The FDA approved dosing of Adbry® for adults is an initial loading dose of 600mg followed by 300mg every other week thereafter. The autoinjector is available as a 300mg/2mL solution which will require half as many injections to achieve the recommended dosing when compared to the other available formulation, the 150mg/mL single-dose syringes, which required 4 separate injections for the 600mg loading dose and 2 separate injections for each 300mg maintenance dose.
- **September 2024:** The FDA approved Ebglyss™ (lebrikizumab-lbkz) for the treatment of adult and pediatric patients 12 years of age and older who weigh at least 40kg with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss™ can be used with or without topical corticosteroids (TCS).

Guideline Update(s):

- **American Academy of Dermatology (AAD):**
  - Updated guidelines were published for the management of AD with phototherapy and systemic therapies in adults. These guidelines update the previous 2014 AAD guidelines, but only provide recommendations for adults. For pediatric patients, the previous 2014 AAD guidelines should continue to be referenced, but the AAD is planning to provide updated pediatric recommendations in a future guideline. Key recommendations made for systemic therapies in adult patients with AD include:

        - Strong recommendations (based on moderate certainty evidence) in favor of abrocitinib, dupilumab, tralokinumab, and upadacitinib in adults with moderate-to-severe AD
- **American Academy of Allergy, Asthma, and Immunology/American College of Allergy, Asthma, and Immunology (AAAAI/ACAAI):**
    - Updated guidelines were published for the management of AD in infants, children, and adults. These guidelines update the previous 2012 AAAAI/ACAAI guidelines. Key recommendations made for the treatment of AD include:
        - Strong recommendations (based on high certainty evidence) in favor of TCS and topical calcineurin inhibitors (TCI) in patients 3 months of age or older
        - Strong recommendations (based on high certainty evidence) in favor of dupilumab and tralokinumab in patients within the FDA approved age range for each product
        - Conditional recommendation (based on moderate certainty evidence) in favor of topical phosphodiesterase-4 (PDE4) inhibitors in patients 3 months of age or older
        - Conditional recommendations (based on low certainty evidence) in favor of abrocitinib and upadacitinib in patients 12 years of age or older
        - Conditional recommendation (based on low certainty evidence) against the use of topical Janus kinase (JAK) inhibitors in patients 12 years of age or older

Ebglyss™ (Lebrikizumab-lbkz) Product Summary[6,7,8]

Therapeutic Class: Interleukin (IL)-13 antagonist

Indication(s): Treatment of adult and pediatric patients 12 years of age and older who weigh at least 40kg with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; Ebglyss™ can be used with or without TCS

How Supplied:
- 250mg/2mL solution in a single-dose prefilled pen
- 250mg/2mL solution in a single-dose prefilled syringe with needle shield

Dosing and Administration:
- Initial Dosing: 500mg [administered as (2) 250mg injections] at week 0 and week 2 followed by 250mg every 2 weeks until week 16 or later, when adequate clinical response is achieved
- Maintenance Dosing: 250mg every 4 weeks

- Administered by subcutaneous (sub-Q) injection into the abdomen, thigh, or back of the upper arm

Efficacy: The efficacy of Ebglyss™ was assessed primarily in 3 Phase 3 studies (ADvocate 1, ADvocate 2, and ADhere) which were randomized, double-blind, placebo-controlled studies. ADvocate 1 and ADvocate 2 were monotherapy trials which compared lebrikizumab monotherapy to placebo. ADhere compared combination therapy with lebrikizumab plus TCS to patients who received placebo plus TCS.

- Key Inclusion Criteria:
  - Chronic AD that has been present for ≥1 year
  - 12 years of age or older and weight ≥40kg
  - Eczema Area and Severity Index (EASI) score ≥16
  - Investigator Global Assessment (IGA) score ≥3
  - Body surface area (BSA) involvement ≥10%
  - History of inadequate response to treatment with topical medications
- Primary Endpoint(s):
  - Proportion of patients achieving an IGA score of 0 ("clear skin") or 1 ("almost clear skin") and at least a 2-point improvement from baseline at week 16
- Results:
  - ADvocate 1: Achieved by 43% of patients who received lebrikizumab vs. 13% of patients who received placebo [treatment difference: 30%; 95% confidence interval (CI): 22%, 38%]
  - ADvocate 2: Achieved by 33% of patients who received lebrikizumab vs. 11% of patients who received placebo (treatment difference: 22%; 95% CI: 14%, 30%)
  - ADhere: Achieved by 41% of patients who received lebrikizumab plus TCS vs. 22% of patients who received placebo plus TCS (treatment difference: 18%; 95% CI: 5%, 32%)

Cost Comparison: AD Injectable Products

Product	Cost Per mL	Cost Per 1st 16 Weeks*	Cost Per Year⁺
Ebglyss™ (lebrikizumab-lbkz) 250mg/2mL	**$1,750.00**	**$35,000.00**	**$66,500.00**
Adbry® (tralokinumab-ldrm) 300mg/2mL	$959.76	$17,275.68	$51,827.04
Dupixent® (dupilumab) 300mg/2mL	$916.54	$16,497.72	$49,493.16

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

Cost Comparison: AD Oral Products

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
Rinvoq® (upadacitinib) 30mg tablet	$207.19	$6,215.70	$74,588.40
Cibinqo® (abrocitinib) 200mg tablet	$185.58	$5,567.40	$66,808.80

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

Recommendations

The College of Pharmacy recommends the prior authorization of Ebglyss™ (lebrikizumab-lbkz) with the following criteria (shown in red):

Ebglyss™ (Lebrikizumab-lbkz) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be 12 years of age or older and weigh ≥40kg; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
5. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) and Dupixent® (dupilumab) must be provided; and
6. Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
7. Requests for concurrent use of Ebglyss™ with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Ebglyss™ has not been studied in combination with other biologic therapies); and

8. Initial approvals will be for a quantity limit override for the initial dosing for the duration of 16 weeks; and
9. Reauthorization may be granted for the maintenance dosing of 250mg every 4 weeks for a duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

The College of Pharmacy also recommends updating the Adbry® (tralokinumab-ldrm), Cibinqo® (abrocitinib), Dupixent® (dupilumab), and Rinvoq® (upadacitinib) approval criteria based on the recent FDA approvals and age expansion for Adbry®, as well as net costs and to be consistent with clinical practice (changes shown in red):

Adbry® (Tralokinumab-ldrm Injection) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be:
   a. 12 ~~18~~ years of age or older for use of the prefilled syringe; ~~and~~ or
   b. 18 years of age or older for use of the autoinjector; and
3. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
2. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
4. Adbry® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
5. Requests for concurrent use of Adbry® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Adbry® has not been studied in combination with other biologic therapies); and
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted for the duration of 1 year if the prescriber documents

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

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

1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
2. For Cibinqo®, member must be 12 years of age or older; and
3. For Rinvoq®, member must be 12 years of age or older; and
4. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Member must have a documented 16-week trial with Adbry® (tralokinumab-ldrm), ~~or~~ Dupixent® (dupilumab), or Ebglyss™ (lebrikizumab-lbkz) that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
7. Requested medication must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
8. For Cibinqo®, prescriber must verify the member will not use antiplatelet therapies (e.g., clopidogrel, prasugrel, ticagrelor) concurrently with Cibinqo®, except for low-dose aspirin, during the first 3 months of treatment; and
9. Cibinqo® and Rinvoq® will not be approved for use in combination with other Janus kinas (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
10. For Rinvoq®, a patient-specific, clinically significant reason why the member cannot use Cibinqo® must be provided; and
11. Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and

12. For Rinvoq®, the maximum approvable dose for AD is 30mg once daily.

Dupixent® (Dupilumab Injection) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies; and
2. Member must be 6 months of age or older; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
5. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and
6. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
7. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
8. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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[7] Silverberg JI, Guttman-Yassky E, Thaci D, et al. Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis. *N Engl J Med* 2023; 388(12):1080-1091. doi: 10.1056/NEJMoa2206714.
[8] Simpson EL, Gooderham M, Wollenberg A, et al. Efficacy and Safety of Lebrikizumab in Combination with Topical Corticosteroids in Adolescents and Adults with Moderate-to-Severe Atopic Dermatitis: A Randomized Clinical Trial (ADhere). *JAMA Dermatol* 2023; 159(2):182-191. doi: 10.1001/jamadermatol.2022.5534.

Appendix E

Vote to Prior Authorize Ohtuvayre™ (Ensifentrine) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications

Oklahoma Health Care Authority
December 2024

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

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

- **January 2024:** Dupixent® (dupilumab) was FDA approved for an age expansion for patients 1 to 11 years of age who weigh at least 15kg with a diagnosis of eosinophilic esophagitis (EoE). Dupixent® was originally approved for EoE in patients 12 years of age and older in May 2022.
- **February 2024:** The FDA approved Xolair® (omalizumab) for the treatment of immunoglobulin E (IgE)-mediated food allergy for the reduction of allergic reactions in patients 1 year of age or older. Xolair® was studied in a Phase 3 trial that included 168 patients who were allergic to peanuts and at least 2 additional foods. Patients were randomized to Xolair® or placebo for 16-20 weeks and the primary endpoint was the percentage of patients who were able to eat ≥600mg of peanut protein without moderate to severe allergic symptoms. The Xolair® group had 68% of patients meet the primary endpoint versus 6% in the placebo patients [difference: 63%; 95% confidence interval (CI): 50%, 73%].
- **April 2024:** Fasenra® (benralizumab) received an age expansion to include patients 6 years of age or older with severe eosinophilic asthma. Additionally, a new 10mg dose will be available for patients weighing <35kg. Fasenra® was originally approved for patients 12 years of age or older with severe eosinophilic asthma in November 2017.
- **June 2024:** The FDA approved Ohtuvayre™ (ensifentrine) for the maintenance treatment of COPD in adults.
- **September 2024:** Dupixent® (dupilumab) was approved for an age expansion as add-on maintenance for chronic rhinosinusitis with nasal polyps (CRSwNP) in patients who are 12 years of age or older. Dupixent® was previously approved for adults with CRSwNP in June 2019.
- **September 2024:** An Abbreviated New Drug Application (ANDA) was approved for formoterol fumarate inhalation solution that includes a LC PLUS nebulizer co-packaged in a kit.

- **September 2024:** Fasenra® (benralizumab) received a new indication for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in patients 18 years of age or older. The safety and efficacy of Fasenra® for EGPA were studied in the MANDARA Phase 3 non-inferiority trial where patients were randomized to Fasenra® 30mg or mepolizumab 100mg. Fasenra® was found to be non-inferior to mepolizumab, and 41% of patients in the Fasenra® arm were tapered off oral corticosteroids versus 26% in the mepolizumab arm (difference: 16%; 95% CI: 1%, 31%).
- **September 2024:** Dupixent® (dupilumab) was approved for a new indication as add-on maintenance treatment of adults with inadequately controlled COPD and an eosinophilic phenotype. The safety and efficacy of Dupixent® were studied in 2 Phase 3 trials, BOREAS and NOTUS, in patients currently on maximal standard of care inhaled therapy [long-acting $beta_2$ agonist/long-acting muscarinic agonist/inhaled corticosteroid (LABA/LAMA/ICS)] and blood eosinophil count ≥300 cells/mcL. The primary endpoint for both trials was the annualized rate of acute moderate or severe COPD exacerbations. Dupixent® showed a 30% reduction in the BOREAS trial and a 34% reduction in the NOTUS trial when compared to placebo. Additionally, improvements in post-bronchodilator forced expiratory volume in 1 second (FEV_1) were assessed, and Dupixent® showed significant improvements in each trial, 74mL in BOREAS and 68mL in NOTUS.

News:

- **April 2024:** In April 2024, it was announced that Teva will be discontinuing the Digihaler® products, including AirDuo® Digihaler®, ArmonAir® Digihaler®, and Proair® Digihaler®, on June 1, 2024. Currently these products are still available until the last lot expiration date; however, the software component of these products was officially discontinued on June 1. The Asthma and Allergy Foundation of America recommended that anyone currently using the Digihaler® products reach out to their provider to determine the best alternative treatment options.

Ohtuvayre™ (Ensifentrine) Product Summary[11]

Therapeutic Class: Phosphodiesterase (PDE) 3 and PDE4 inhibitor

Indication(s): Maintenance treatment of COPD in adults

How Supplied: 3mg/2.5mL inhalation suspension in unit-dose ampules

Dosing and Administration:

- 3mg (1 ampule) twice daily via oral inhalation with a standard jet nebulizer with a mouthpiece

- Ohtuvayre™ should not be physically mixed with other drugs or added to solutions containing other drugs

Efficacy: The efficacy of Ohtuvayre™ was studied in 2 randomized, double-blind, Phase 3 trials, ENHANCE-1 and ENHANCE-2. The 2 trials enrolled a total of 1,553 patients with moderate to severe COPD.

- Key Inclusion Criteria:
  - Clinical diagnosis of COPD
  - Pre- and post-albuterol FEV_1/forced vital capacity (FVC) ratio <0.70
  - Post-albuterol FEV_1 ≥30% and ≤70% of predicted normal (GOLD 2 and GOLD 3 ranges)
  - Grade ≥2 on the Modified Medical Research Council (mMRC) dyspnea scale
  - No maintenance therapy or stable maintenance therapy with either a LABA or LAMA +/- ICS
- Key Exclusion Criteria:
  - Asthma diagnosis
  - LAMA/LABA dual therapy regimen
  - LAMA/LABA/ICS triple therapy regimen
- Intervention(s):
  - Randomized 5:3 to Ohtuvayre™ 3mg twice daily or placebo
- Primary Endpoint(s):
  - Change from baseline in FEV_1 area under the curve (AUC_{0-12h}) post dose at week 12
- Results:
  - ENHANCE-1: 87mL increase in FEV_1 AUC_{0-12h} compared to placebo (95% CI: 55, 118)
  - ENHANCE-2: 94mL increase in FEV_1 AUC_{0-12h} compared to placebo (95% CI: 65, 124)

Cost: The Wholesale Acquisition Cost (WAC) of Ohtuvayre™ is $19.67 per mL or $49.18 per 2.5mL ampule. This results in an estimated cost of $2,950.50 per 30 days and $35,406.00 per year based on recommended dosing.

Recommendations

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

Ohtuvayre™ (Ensifentrine) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and
3. Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second

(FEV_1) ≥30% and <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and
4. Member is inadequately controlled on dual or triple combination long-acting bronchodilator therapy (must have ≥3 claims for long-acting bronchodilators in the previous 6 months); and
5. Member must not be taking Daliresp® (roflumilast) concurrently with Ohtuvayre™; and
6. A quantity limit of 60 ampules (150mL) per 30 days will apply.

Next, the College of Pharmacy recommends the following changes to the Dupixent® (dupilumab) criteria based on the new FDA approval, age expansion, and to be consistent with clinical practice (changes shown in red):

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

1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and
4. Member must have a blood eosinophil count of ≥300 cells/mcL; and
5. Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and
6. Member is inadequately controlled on triple therapy combination [long-acting $beta_2$ agonist/long-acting muscarinic agonist/inhaled corticosteroid (LABA/LAMA/ICS)] used compliantly within the last 3-6 consecutive months, unless contraindicated; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
8. Dupixent® must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma or Oral Corticosteroid-Dependent Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with moderate-to-severe eosinophilic phenotype asthma or oral corticosteroid-dependent asthma; and
2. Member must be 6 years of age or older; and
3. Member must meet 1 of the following:
    a. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); ~~and~~ or
    b. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
4. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
7. Dupixent® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
9. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled CRSwNP; and
2. Member must be 12 ~~18~~ years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or

b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and

5. Dupixent® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
10. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
11. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 2 syringes every 28 days will apply.

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

1. An FDA approved diagnosis of eosinophilic esophagitis (EoE) defined as:
   a. The presence of clinical symptoms of EoE ~~2 or more episodes of dysphagia~~ ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
   b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf) in the esophagus] ~~Member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf)~~; and
2. Member must be 1 ~~12~~ years of age or older and weigh ≥15 ~~40~~kg; and
3. Dupixent® must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a gastroenterologist, allergist, or immunologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and

4. ~~Member must have 2 or more episodes of dysphagia per week; and~~
5. ~~Member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf); and~~
6. Member must have documented trials for a minimum of 8 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. One high-dose proton pump inhibitor; and
   b. One swallowed respiratory corticosteroid (e.g., budesonide); and
7. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
9. A quantity limit of 8mL (4 syringes) every 28 days will apply.

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

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have a Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist for PN within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritus have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding

well to treatment. Additionally, compliance will be evaluated for continued approval.

Next, the College of Pharmacy recommends the following changes to the Fasenra® (benralizumab) criteria based on the new FDA approval, age expansion, and to be consistent with the FDA approved label and clinical practice and recommends the following changes to the approval criteria for Nucala (mepolizumab) based on net costs and to be consistent with clinical practice (changes shown in red):

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved indication for the treatment of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
    a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] with in the past 12 months; or
    b. Member must have refractory disease within the last 6 months following induction of standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent equal to or greater than 7.5mg/day) for a minimum of 4 weeks duration; and
6. Fasenra® must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist for EGPA within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Fasenra® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra®; and
9. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 28 days will apply.

10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant, and prescriber must verify the member is responding to Fasenra® as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dose regimen from baseline.

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

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

authorization request in order to authorize the appropriate dose according to package labeling; and

11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
12. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved diagnosis of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
    a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months; or
    b. Member must have refractory disease within the last 6 months following induction of a standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥7.5mg/day) for a minimum of 4 weeks duration; and
6. Nucala must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist for EGPA within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. A patient-specific, clinically significant reason why the member cannot use Fasenra® (benralizumab injection) must be provided; and
10. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued

approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dosing from baseline.

Nucala (Mepolizumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled CRSwNP; and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
    a. Member has required prior sino-nasal surgery; or
    b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Nucala must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/ pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
11. Requests for concurrent use of Nucala with other biologic medications will be reviewed on a case-by-case basis and will require patient specific information to support the concurrent use; and

12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

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

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Hypereosinophilic Syndrome (HES) Diagnosis]:

1. An FDA approved diagnosis of HES for ≥6 months without an identifiable non-hematologic secondary cause; and
2. Member must be 12 years of age or older; and
3. Member must have a past history of at least 2 confirmed HES flares [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of cytotoxic or immunosuppressive therapy, or hospitalization] within the past 12 months; and
4. Member must have a baseline blood eosinophil count of ≥1,000 cells/mcL in the last 4 weeks prior to initiating Nucala; and
5. Diagnosis of FIP1L1-PDGFRα kinase-positive HES will not be approved; and
6. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥10mg/day) for a minimum of 4 weeks duration or member is unable to tolerate corticosteroid therapy due to significant side effects from corticosteroid therapy; and
7. Nucala must be prescribed by a hematologist or a specialist with expertise in treatment of HES (or an advanced care practitioner with a supervising physician who is a hematologist or a specialist with expertise in treatment of HES); and
8. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
9. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
10. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by fewer HES flares from baseline or a decrease in daily OCS dosing from baseline.

Additionally, the College of Pharmacy recommends the following changes to the Xolair® (omalizumab) criteria based on the new FDA approval and to be consistent with clinical practice and recommends the following changes to the Tezspire® (tezepelumab-ekko) approval criteria to be consistent with clinical practice (changes shown in red):

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

1. An FDA approved diagnosis of IgE-mediated food allergy for the reduction of allergic reactions; and
2. Member must be 1 year of age or older; and
3. Member must have a diagnosis of peanut, milk, egg, wheat, cashew, hazelnut, or walnut allergy confirmed by a positive skin test, positive in vitro test for food-specific IgE, or positive clinician-supervised oral food challenge (documentation of allergy testing results must be submitted); and
4. Prescriber must confirm member will use Xolair® with an allergen-avoidant diet; and
5. Member must have a pretreatment serum IgE level between 30 and 1,850 IU/mL; and
6. Member's weight must be between 10kg and 150kg; and
7. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
9. For authorization of Xolair® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
11. Xolair® must be prescribed by an allergist or immunologist or the member must have been evaluated by an allergist or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to therapy. Additionally, compliance will be evaluated for continued approval.

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

1. Diagnosis of severe persistent asthma [as per National Asthma Education and Prevention Program (NAEPP) guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least 1 perennial aeroallergen (positive perennial aeroallergens must be listed on the prior authorization request); and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and
5. Member's weight must be between 20kg and 150kg; and
6. Member must have failed a medium-to-high-dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
7. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
8. For authorization of Xolair® ~~vial~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or ~~and~~
9. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
10. Xolair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
11. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
12. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval.

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

1. An FDA approved diagnosis of CIU; and

2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. For authorization of Xolair® ~~vial~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or ~~and~~
7. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
8. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
9. A trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
10. Initial dosing will only be approved for 150mg every 4 weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every 4 weeks; and
11. Initial approvals will be for the duration of 3 months at which time compliance will be evaluated for continued approval.

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

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/ pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
6. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and

7. Member must have a pretreatment serum IgE level between 30 and 1,500 IU/mL; and
8. Member's weight must be between 31kg and 150kg; and
9. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
10. For authorization of Xolair® ~~vial~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or ~~and~~
11. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
12. Xolair® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
13. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Tezspire® (Tezepelumab-ekko) Approval Criteria:

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and

6. For authorization of Tezspire® in a health care facility ~~vial or pre-filled syringe~~, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or ~~and~~
7. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and
8. Tezspire® must be prescribed by a pulmonologist or pulmonary specialist, or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

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

1. Creation of Tier-1 approval criteria based on the member's age; and
2. Removing the prior authorization of Wixela Inhub® (fluticasone/ salmeterol inhalation powder) based on net costs; and
3. Moving Alvesco® (ciclesonide) and fluticasone propionate (generic Flovent®) from Tier-1 to Tier-2 based on net costs; and
4. Moving QVAR® RediHaler® (beclomethasone dipropionate) from Tier-2 to Tier-1 based on net costs; and
5. Removal of ArmonAir® Digihaler® (fluticasone propionate) and AirDuo® Digihaler® (fluticasone propionate/salmeterol) due to product discontinuations; and
6. The prior authorization of formoterol fumarate nebulizer solution kit and placement into Tier-2 of the long-acting beta$_2$ agonists (LABA) and long-acting muscarinic antagonists (LAMA) category.

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (QVAR® RediHaler®)	~~**beclomethasone dipropionate (QVAR® RediHaler®)**~~
budesonide (Pulmicort Flexhaler®)	budesonide/formoterol (Symbicort Aerosphere®)
budesonide/formoterol (Symbicort®)β – **Brand Preferred**	**ciclesonide (Alvesco®)**

~~**ciclesonide (Alvesco®)**~~	**fluticasone propionate (Flovent®)**
fluticasone furoate (Arnuity® Ellipta®)	fluticasone furoate/vilanterol (Breo® Ellipta®) – **Brand Preferred**
~~**fluticasone propionate (Flovent®)**~~	~~**fluticasone propionate (ArmonAir® Digihaler®)**~~
fluticasone propionate/salmeterol (Advair®)α	~~**fluticasone propionate/salmeterol (AirDuo® Digihaler®)**~~
mometasone furoate (Asmanex®)	fluticasone propionate/salmeterol (AirDuo RespiClick®)
mometasone furoate/formoterol (Dulera®)◊	mometasone furoate/formoterol 50mcg/5mcg (Dulera®)

~~Tier-1 products indicated for the member's age are covered with no prior authorization required.~~
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria apply to each Tier-2 product.
β Does not include Breyna®; authorization of Breyna® requires a reason why the member cannot use the brand formulation (Symbicort®).
~~α Does not include Wixela Inhub®; authorization of Wixela Inhub® requires a reason why the member cannot use the brand formulation (Advair®) or other generic formulations of fluticasone propionate/salmeterol.~~
◊ Includes all strengths other than Dulera® 50mcg/5mcg.

Inhaled Corticosteroids (ICS) and Combination Products Tier-1 Approval Criteria:

1. Tier-1 products indicated for the member's age are covered with no prior authorization required; or
2. Tier-1 products will be approved for members younger than the FDA approved age range if prescribed by a pulmonologist, immunologist, or an allergist (or a mid-level practitioner supervised by a pulmonologist, immunologist, or an allergist).

~~AirDuo® Digihaler® (Fluticasone Propionate/Salmeterol Inhalation Powder) Approval Criteria:~~

~~1. An FDA approved diagnosis of asthma; and~~
~~2. Member must be 12 years of age or older; and~~
~~3. A patient-specific, clinically significant reason why the member requires AirDuo® Digihaler® over AirDuo RespiClick® and all preferred Tier-1 inhaled corticosteroid (ICS) and long-acting beta$_2$-agonist (ICS/LABA) products (Advair®, Dulera®, and Symbicort®) must be provided; and~~
~~4. Failure of Advair®, Dulera®, and Symbicort® or a reason why Advair®, Dulera®, and Symbicort® are not appropriate for the member must be provided; and~~
~~5. Member must have used an ICS for at least 1 month immediately prior; and~~

6. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or
7. A clinical situation warranting initiation with combination therapy due to severity of asthma; and
8. Prescriber agrees to closely monitor member adherence; and
9. Member should be capable and willing to use the Companion Mobile App and to follow the Instructions for Use, and member must ensure the Digihaler® Companion Mobile App is compatible with their specific smartphone; and
10. Member's phone camera must be functional and able to scan the inhaler QR code and register the AirDuo® Digihaler® inhaler; and
11. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and member compliance >80% with prescribed maintenance therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier 1 medications must be provided. Tier structure rules continue to apply.

ArmonAir® Digihaler® (Fluticasone Propionate Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 12 years of age or older; and
3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) and other preferred monotherapy inhaled corticosteroids (ICS) are not appropriate for the member must be provided; and
4. The prescriber agrees to closely monitor member adherence; and
5. The member should be capable and willing to use the Companion Mobile App and to follow the Instructions for Use, and member must ensure the Digihaler® Companion Mobile App is compatible with their specific smartphone; and
6. The member's phone camera must be functional and able to scan the inhaler QR code and register the ArmonAir® Digihaler® inhaler; and
7. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and member compliance >80% with prescribed maintenance therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier 1 medications must be provided. Tier structure rules continue to apply.

Alvesco® (Ciclesonide) and Fluticasone Propionate (Generic Flovent®) QVAR® RediHaler® (Beclomethasone Dipropionate) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at the age indicated for the requested product:

~~a. QVAR® RediHaler®: Member must be 4 years of age or older; and~~

3. A trial of all available Tier-1 inhaled corticosteroids appropriate to the members' age or a patient-specific, clinically significant reason why they are not appropriate for the member must be provided.

~~**Wixela Inhub® (Fluticasone/Salmeterol Inhalation Powder) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason why the member cannot use the brand formulation (Advair® Diskus®), or other generic formulations (fluticasone/salmeterol) must be provided (brand formulation and other generics are preferred and do not require prior authorization).~~

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

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

[1] Sanofi. Dupixent® FDA Approved as First and Only Treatment Indicated for Children Aged 1 year and Older with Eosinophilic Esophagitis (EoE). Available online at: https://www.sanofi.com/en/media-room/press-releases/2024/2024-01-25-19-30-00-2817342. Issued 01/25/2024. Last accessed 11/15/2024.
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[4] Nuance Pharma. US FDA New Drug Application Approval of Ohtuvayre™ (ensifentrine) for the Maintenance Treatment of COPD. *PR Newswire*. Available online at: https://www.prnewswire.com/apac/news-releases/us-fda-new-drug-application-approval-of-ohtuvayre-ensifentrine-for-the-maintenance-treatment-of-copd-302184106.html. Issued 06/27/2024. Last accessed 11/15/2024.
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[6] Genericus. Formoterol. Available online at: https://genericus.com/formoterol-page. Last accessed 11/15/2024.
[7] Regeneron Pharmaceuticals. Dupixent® (Dupilumab) Approved in the U.S. as First and Only Treatment for Adolescents with Chronic Rhinosinusitis with Nasal Polyps (CRSwNP). Available online at: https://www.globenewswire.com/en/news-release/2024/09/13/2946084/0/en/Dupixent-dupilumab-Approved-in-the-U-S-as-First-and-Only-Treatment-for-Adolescents-with-Chronic-Rhinosinusitis-with-Nasal-Polyps-CRSwNP.html. Issued 09/13/2024. Last accessed 11/15/2024.
[8] AstraZeneca. Fasenra® Approved in the US for Eosinophilic Granulomatosis with Polyangiitis. Available online at: https://www.astrazeneca.com/media-centre/press-releases/2024/fasenra-approved-in-the-us-for-eosinophilic-granulomatosis-with-polyangiitis.html. Issued 09/18/2024. Last accessed 11/15/2024.
[9] Sanofi. Dupixent® Approved in the US As the First-Ever Biologic Medicine for Patients with COPD. Available online at: https://www.sanofi.com/en/media-room/press-releases/2024/2024-09-27-13-35-00-2954551. Issued 09/27/2024. Last accessed 11/15/2024.
[10] Asthma and Allergy Foundation of America. Teva's Digihaler Products to Be Discontinued. Available online at: https://community.aafa.org/blog/teva-digihaler-discontinued. Issued 04/15/2024. Last accessed 11/15/2024.
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Appendix F

Vote to Prior Authorize Nemluvio® (Nemolizumab-ilto)

Oklahoma Health Care Authority
December 2024

Market News and Updates[1]

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

- **August 2024:** The FDA approved Nemluvio® (nemolizumab-ilto) for the treatment of adults with prurigo nodularis (PN).

Nemluvio® (Nemolizumab-ilto) Product Summary[2]

Therapeutic Class: Interleukin-31 (IL-31) receptor antagonist

Indication(s): Treatment of adults with PN

How Supplied: Single-dose prefilled dual chamber pen containing 30mg nemolizumab-ilto lyophilized powder and diluent, water for injection

Dosing and Administration: Administered by subcutaneous (sub-Q) injection based on weight:

- <90kg: 60mg [administered as (2) 30mg injections] once followed by 30mg every 4 weeks
- ≥90kg: 60mg every 4 weeks

Efficacy: The efficacy of Nemluvio® was based primarily on 2 Phase 3, randomized, double-blind, placebo-controlled studies (OLYMPIA 1 and OLYMPIA 2).

- Key Inclusion Criteria:
  - Clinical diagnosis of PN for at least 6 months
  - 18 years of age or older
  - Presence of ≥20 nodular lesions
  - Moderate or severe disease based on an Investigator Global Assessment (IGA) score ≥3 on a scale from 0 to 4
  - Severe pruritus based on a Peak Pruritus Numeric Rating Scale (PP-NRS) score ≥7 on a scale from 0 to 10
- Efficacy Endpoint(s) Assessed by the FDA at Week 16:
  - Proportion of patients achieving both an improvement (reduction) of ≥4 in PP-NRS and IGA of 0 (“clear skin”) or 1 (“almost clear skin”)
  - Proportion of patients achieving IGA of 0 or 1
  - Proportion of patients achieving improvement (reduction) of ≥4 in PP-NRS
  - Proportion of patients achieving PP-NRS <2

- Results:
  - IGA of 0 or 1 and ≥4-point improvement in PP-NRS:
    - OLYMPIA 1: Achieved by 22% of patients who received nemolizumab vs. 2% of patients who received placebo [treatment difference: 15%; 95% confidence interval (CI): 8%, 21%)
    - OLYMPIA 2: Achieved by 25% of patients who received nemolizumab vs. 4% of patients who received placebo (treatment difference: 22%; 95% CI: 14%, 30%)
  - IGA of 0 or 1:
    - OLYMPIA 1: Achieved by 26% of patients who received nemolizumab vs. 7% of patients who received placebo (treatment difference: 15%; 95% CI: 7%, 23%)
    - OLYMPIA 2: Achieved by 38% of patients who received nemolizumab vs. 11% of patients who received placebo (treatment difference: 29%; 95% CI: 19%, 38%)
  - ≥4-point improvement in PP-NRS:
    - OLYMPIA 1: Achieved by 56% of patients who received nemolizumab vs. 16% of patients who received placebo (treatment difference: 38%; 95% CI: 27%, 48%)
    - OLYMPIA 2: Achieved by 49% of patients who received nemolizumab vs. 16% of patients who received placebo (treatment difference: 34%; 95% CI: 23%, 45%)
  - PP-NRS <2:
    - OLYMPIA 1: Achieved by 32% of patients who received nemolizumab vs. 4% of patients who received placebo (treatment difference: 28%; 95% CI: 20%, 36%)
    - OLYMPIA 2: Achieved by 31% of patients who received nemolizumab vs. 7% of patients who received placebo (treatment difference: 26%; 95% CI: 18%, 34%)

Cost Comparison:

Product	Cost Per Pen	Cost Per 28 Days	Cost Per Year
Nemluvio® (nemolizumab-ilto) 30mg pen	**$4,240.00**	**$8,480.00***	**$110,240.00***
Dupixent® (dupilumab) 300mg/2mL pen	$1,833.09	$3,666.18⁺	$47,660.34⁺

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 is based on the FDA approved maximum dose of 60mg every 4 weeks.
⁺Cost is based on the FDA approved maintenance dose of 300mg every 2 weeks.

Recommendations

The College of Pharmacy recommends the prior authorization of Nemluvio® (nemolizumab-ilto) with the following criteria (shown in red):

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

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have severe pruritus as defined by a Peak Pruritus Numeric Rating Scale (PP-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist for PN within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritus have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. A patient-specific, clinically significant reason why the member cannot use Dupixent® (dupilumab) must be provided; and
9. Requests for concurrent use of Nemluvio® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Nemluvio® has not been studied in combination with other biologic therapies); and
10. The member's recent weight must be provided, and approval quantities will be based on the FDA approved dosing regimen; and
11. Initial approvals will be for the duration of 16 weeks. Reauthorization (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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[1] Galderma. Galderma Receives U.S. FDA Approval for Nemluvio® (Nemolizumab) for Adult Patients Living with Prurigo Nodularis. Available online at: https://www.galderma.com/news/galderma-receives-us-fda-approval-nemluvior-nemolizumab-adult-patients-living-prurigo. Issued 08/13/2024. Last accessed 11/14/2024.

[2] Nemluvio® (Nemolizumab-ilto) Prescribing Information. Galderma Laboratories. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761390s000lbl.pdf. Last revised 08/2024. Last accessed 11/14/2024.

Appendix G

Fiscal Year 2024 Annual Review of Skin Cancer Medications

Oklahoma Health Care Authority
December 2024

Current Prior Authorization Criteria

Utilization data for Tecentriq® (atezolizumab) and approval criteria for indications other than skin cancer can be found in the April 2024 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the lung cancer medications.

Bavencio® (Avelumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic MCC; and
2. Member must be 12 years of age or older.

Bavencio® (Avelumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Used as first-line treatment; and
3. Used in combination with axitinib.

Bavencio® (Avelumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Disease has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; or
3. Used as maintenance therapy for members not progressing on a first-line platinum-containing regimen.

Braftovi® (Encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic CRC; and
2. *BRAF* V600E mutation positive; and
3. Used in combination with cetuximab or panitumumab; and
4. Disease must have progressed following adjuvant therapy within 12 months; or
5. Used following progression of any line of metastatic therapy.

Braftovi® (Encorafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and

3. Used in combination with binimetinib.

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.

Cotellic® (Cobimetinib) Approval Criteria [Histiocytic Neoplasm Diagnosis]:
1. Diagnosis of a histiocytic neoplasm; and
2. Member must be 18 years of age or older; and
3. Used as a single agent.

Cotellic® (Cobimetinib) Approval Criteria [Melanoma Diagnosis]:
1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Cobimetinib is not indicated for wild-type *BRAF* melanoma; and
3. Member meets 1 of the following:
    a. Used as first-line therapy in combination with vemurafenib; or
    b. Used as second-line therapy or subsequent therapy with vemurafenib.

Erivedge® (Vismodegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:
1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated; or
2. Diagnosis of metastatic BCC.

Hepzato Kit™ (Melphalan) Approval Criteria [Uveal Melanoma Diagnosis]:
1. Diagnosis of metastatic uveal melanoma; and
2. Presence of hepatic metastases affecting <50% of the liver; and
3. No other extrahepatic metastases; or
4. Presence of extrahepatic metastases limited to the bone, lymph nodes, subcutaneous tissue, and/or lung that is amenable to resection or radiation.

Imlygic® (Talimogene Laherparepvec) Approval Criteria [Melanoma Diagnosis]:
1. Diagnosis of unresectable cutaneous, subcutaneous, or nodal lesions that are recurrent after initial surgery; and
    a. Not indicated in members with visceral metastases; and
2. Member is not immunocompromised or pregnant.

Keytruda® (Pembrolizumab) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic BTC; and
2. Used in combination with gemcitabine and cisplatin.

Keytruda® (Pembrolizumab) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer; and
    a. Tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥10; and
    b. Used in combination with chemotherapy; or
2. Diagnosis of early stage triple-negative breast cancer; and
    a. Disease is considered high-risk; and
    b. Used in combination with chemotherapy as neoadjuvant therapy.

Keytruda® (Pembrolizumab) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
    a. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
    b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
        i. Disease progression on or after chemotherapy; or
        ii. As first-line therapy in combination with chemotherapy, with or without bevacizumab; or
2. Diagnosis of FIGO Stage III-IV cervical cancer; and
    a. Used in combination with concomitant chemotherapy and radiation.

Keytruda® (Pembrolizumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Keytruda® (Pembrolizumab) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of recurrent or metastatic disease; and
2. Not curable by radiation or surgery.

Keytruda® (Pembrolizumab) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
3. Member is not a candidate for curative surgery or radiation; and

4. Used in 1 of the following settings:
    a. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
    b. As a single agent for advanced endometrial cancer that is MSI-H or dMMR.

Keytruda® (Pembrolizumab) Approval Criteria [Esophageal or Gastroesophageal Junction (GEJ) Carcinoma Diagnosis]:

1. Diagnosis of locally advanced, recurrent, or metastatic esophageal or GEJ carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. In combination with platinum- and fluoropyrimidine-based chemotherapy; or
4. For second-line or greater therapy:
    a. Following disease progression after 1 or more prior lines of systemic therapy; and
    b. Tumor must be squamous cell histology; and
    c. Used as a single agent; and
    d. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS ≥10).

Keytruda® (Pembrolizumab) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced, unresectable, or metastatic gastric or GEJ adenocarcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. Human epidermal receptor 2 (HER2)-positive disease; and
        i. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and
        ii. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1; or
    b. HER2-negative disease; and
        i. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Keytruda® (Pembrolizumab) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Used in first-line or recurrent setting; and
2. Squamous cell histology; and

3. If used in the recurrent setting, member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of relapsed or progressive HCC; and
2. Member must have been previously treated with sorafenib; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. For adult members:
    a. Diagnosis of relapsed or refractory cHL; and
        i. Used as a single agent; or
        ii. Exception: lymphocyte-predominant Hodgkin lymphoma; or
        iii. Used in Second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin; or
3. For pediatric members:
    a. Used as a single agent; and
    b. Diagnosis of refractory cHL; or
    c. Relapsed disease after ≥2 therapies.

Keytruda® (Pembrolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Member meets 1 of the following:
    a. Adjuvant treatment of adult and pediatric members 12 years of age or older with stage 2B, 2C, or 3 melanoma following complete resection; or
    b. Diagnosis of unresectable or metastatic melanoma; and
2. Used as a single agent; and
3. Member meets 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line therapy or subsequent therapy for disease progression if not previously used; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
5. For adjuvant treatment of melanoma, approvals will be for a maximum duration of 1 year.

Keytruda® (Pembrolizumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of recurrent, locally advanced, or metastatic MCC; and

2. No history of prior systemic chemotherapy; and
3. Used as a single agent; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

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. Used as a single agent for disease progression on or after platinum-containing chemotherapy (i.e., cisplatin, carboplatin):
        i. Members with EGFR-mutation-positive tumors should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations* (*examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib);* and
        ii. Members with ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations (examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib).*

Keytruda® (Pembrolizumab) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumor (Tissue/Site-Agnostic) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. MSI-H or dMMR solid tumors that have progressed following prior treatment with no satisfactory alternative treatment options.

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 [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of high-risk, NMIBC; and
2. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
3. Member must be ineligible for or has elected not to undergo cystectomy.

Keytruda® (Pembrolizumab) Approval Criteria [Primary Mediastinal Large B-cell Lymphoma (PMBCL) Diagnosis]:

1. Diagnosis of PMBCL; and
2. Member must have refractory disease or relapsed after 2 or more prior lines of therapy; and
3. Authorizations will not be granted for members who require urgent cytoreduction; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of new or recurrent stage 4 clear-cell RCC; and

a. Member has not received previous systemic therapy for advanced disease; and
b. Must be used in combination with axitinib or lenvatinib; and
c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or

2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

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)].

Keytruda® (Pembrolizumab) Approval Criteria [Tumor Mutational Burden-High (TMB-H) Solid Tumors Diagnosis]:

1. Diagnosis of unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors; and
2. Used following disease progression after prior treatment; and
3. No satisfactory alternative treatment options.

Keytruda® (Pembrolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Member must have 1 of the following:
   a. As a single agent for locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
   b. As a single agent within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
   c. As a single agent frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy; and
      i. Cisplatin ineligibility is defined as:
         1. Baseline creatinine clearance of <60mL/min; or
         2. ECOG performance status of 2; or
         3. Class III heart failure; or
         4. Grade 2 or greater peripheral neuropathy; or
         5. Grade 2 or greater hearing loss; or
   d. In combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Kimmtrak® (Tebentafusp-tebn) Approval Criteria [Uveal Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic uveal melanoma; and
2. Positive expression of HLA-A*02:01 genotype.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic BCC; and
2. Member has previously been treated with a hedgehog pathway inhibitor (HHI); or
3. Treatment with a HHI is not appropriate for the member.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of metastatic or locally advanced cSCC; and
2. Member is ineligible for curative surgery or radiation; and
3. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab), Yervoy® (ipilimumab)].

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.

Mekinist® (Trametinib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
2. *BRAF* V600E mutation; and
3. No satisfactory locoregional treatment options.

Mekinist® (Trametinib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and

4. Used in combination with dabrafenib.

Mekinist® (Trametinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
    a. Used as first-line therapy in combination with dabrafenib; or
    b. Used as second-line or subsequent therapy with dabrafenib; or
    c. Used as second-line therapy or subsequent therapy as a single agent if:
        i. Member was intolerant to prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib); and
        ii. No evidence of disease progression on prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib).

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

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

Mekinist® (Trametinib) Approval Criteria [Serous Ovarian Cancer Diagnosis]:

1. Diagnosis of persistent disease or recurrent low-grade serous carcinoma; and
2. Meets 1 of the following:
    a. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
    b. Progression on primary, maintenance, or recurrence therapy; or
    c. Stable or persistent disease (if not on maintenance therapy); or
    d. Complete remission and relapse after completing chemotherapy.

Mekinist® (Trametinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with dabrafenib.

Mektovi® (Binimetinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and

3. Used in combination with encorafenib.

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.

Odomzo® (Sonidegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated; or
2. Diagnosis of metastatic BCC.

Opdivo® (Nivolumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:

1. Member has had complete resection of melanoma; and
2. Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and
3. Member is 12 years of age or older; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Used as a single agent; and
6. Dose as follows:
    a. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; and
    c. Maximum duration of 1 year.

Opdivo® (Nivolumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR).

Opdivo® (Nivolumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with 1 of the following:
        i. Fluoropyrimidine- and platinum-based chemotherapy; or
        ii. Ipilimumab; or

2. Diagnosis of esophageal or GEJ cancer; and
    a. Member has received preoperative chemoradiation; and
    b. Member underwent R0 (complete) resection and has residual disease; and
    c. As a single agent; or
3. Palliative therapy for members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; and
    a. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in first-line setting; and
            1. Used in combination with oxaliplatin and fluorouracil or capecitabine; and
            2. Adenocarcinoma pathology; or
        ii. Used in the second-line or greater setting; and
            1. As a single agent; and
            2. Squamous cell pathology.

Opdivo® (Nivolumab) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic disease; and
2. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Opdivo® (Nivolumab) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic head and neck cancer; and
2. Squamous cell histology; and
3. Member has received prior platinum-containing regimen (i.e., cisplatin, carboplatin); and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Must meet 1 of the following:
    a. If used as first-line therapy, must be used as single agent; and
        i. Ineligible for tyrosine kinase inhibitors or anti-angiogenic agents; or
    b. If used as second-line or greater therapy, may be used as single agent or in combination with ipilimumab; and
        i. Must not have failed other checkpoint inhibitors.

Opdivo® (Nivolumab) Approval Criteria [Hodgkin Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma; and

    a. Exception: lymphocyte-predominant HL
2. Nivolumab must be used in 1 of the following settings:
    a. As a single-agent; or
    b. In combination with brentuximab vedotin as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

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 Yervoy® (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 [Renal Cell Carcinoma (RCC) Diagnosis]:

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

2. Used in 1 of the following settings:
    a. For nivolumab monotherapy:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease; and
        ii. Failed prior therapy with 1 of the following medications:
            1. Sunitinib; or
            2. Sorafenib; or
            3. Pazopanib; or
            4. Axitinib; or
    b. For nivolumab use in combination with ipilimumab:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or
    c. For nivolumab use in combination with cabozantinib:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
        ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and
3. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks thereafter; or
    c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks; nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

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

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

Opdivo® (Nivolumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member is 12 years of age or older; and
3. Used as a single agent or in combination with ipilimumab:

a. As first-line therapy for untreated melanoma; or
b. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
    i. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and

4. Dose as follows:
    a. Single agent:
        i. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or
        ii. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; or
    b. In combination with ipilimumab:
        i. Adult and pediatric patients ≥40kg: Nivolumab 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240mg every 2 weeks or 480mg every 4 weeks; or
        ii. Pediatric patients <40kg: 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3mg/kg every 2 weeks or 6mg/kg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and
    a. Member has undergone radical resection; and
    b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
    a. Used as second-line or greater therapy; and
    b. Previous failure of a platinum-containing regimen; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdualag™ (Nivolumab/Relatlimab-rmbw) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member must be 12 years of age or older; and
3. As first-line therapy; and
4. Member has not previously failed programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab)].

Tafinlar® (Dabrafenib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
3. *BRAF* V600E mutation; and
4. No satisfactory locoregional treatment options.

Tafinlar® (Dabrafenib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and
4. Used in combination with trametinib.

Tafinlar® (Dabrafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Dabrafenib is not indicated for wild-type *BRAF* melanoma; and
3. Used as a single agent or in combination with trametinib; and
4. Must meet 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line or subsequent therapy.

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

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
    a. Not indicated for wild-type BRAF NSCLC; and
3. Used as a single agent or in combination with trametinib.

Tafinlar® (Dabrafenib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with trametinib.

Tecentriq® (Atezolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600 mutation-positive; and
3. Used in combination with cobimetinib and vemurafenib.

Yervoy® (Ipilimumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:

1. Member has had complete resection of melanoma with lymphadenectomy; and
2. Member has stage 3 disease with regional nodes of >1mm and no in-transit metastasis; and
3. Used as a single agent; and
4. Maximum dose of 10mg/kg will apply.

Yervoy® (Ipilimumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and
3. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Used as second-line or greater therapy; and
4. Used in combination with nivolumab; and
5. Must not have failed other checkpoint inhibitors.

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

Yervoy® (Ipilimumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; and
2. Used in combination with nivolumab; and

3. Member has not failed previous programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks.

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

1. Diagnosis of SCLC; and
2. Must meet 1 of the following criteria:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease is progressive on initial chemotherapy; and
3. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Used in combination with nivolumab as:
    a. First-line therapy; or
    b. Second-line or subsequent therapy for disease progression if nivolumab was not previously used; or
3. Used as a single agent for 1 of the following:
    a. First-line therapy as a single course of 4 treatments; or
    b. Second-line or subsequent lines of therapy as a single course of 4 treatments; or
    c. Retreatment, consisting of a 4-dose limit, for a member who had:
        i. No significant systemic toxicity during prior ipilimumab therapy; and
        ii. Whose disease progressed after being stable >6 months following completion of a prior course of ipilimumab; and
        iii. For whom no intervening therapy has been administered; and
4. Maximum dose of 3mg/kg will apply.

Zelboraf® (Vemurafenib) Approval Criteria [Erdheim-Chester Disease (ECD) Diagnosis]:

1. Diagnosis of ECD; and
2. *BRAF* V600E or V600K mutation; and
3. Used as a single agent.

Zelboraf® (Vemurafenib) Approval Criteria [Hairy-Cell Leukemia Diagnosis]:

1. Diagnosis of hairy-cell leukemia; and
2. Used as a single agent; and

3. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine).

Zelboraf® (Vemurafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Vemurafenib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line or subsequent therapy; and
4. Used as a single agent or in combination with cobimetinib.

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

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
    a. Vemurafenib is not indicated for wild-type *BRAF* NSCLC; and
3. Used as a single agent.

Zynyz® (Retifanlimab-dlwr) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic or recurrent locally advanced MCC; and
2. Member must be 18 years of age or older; and
3. A maximum treatment duration of 24 months will apply.

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 Skin Cancer Medications: Fiscal Year 2024

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

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	39	330	$3,244,376.20	$9,831.44	$338.45	24,874	9,586
2023 Total	**39**	**330**	**$3,244,376.20**	**$9,831.44**	**$338.45**	**24,874**	**9,586**
Fiscal Year 2024							
FFS	49	326	$3,468,711.61	$10,640.22	$345.21	25,652	10,048
Aetna	5	12	$93,817.85	$7,818.15	$260.61	645	360
Humana	4	8	$108,202.13	$13,525.27	$458.48	401	236
OCH	7	29	$282,203.35	$9,731.15	$311.14	2,484	907
2024 Total	**53**	**375**	**$3,952,934.94**	**$10,541.16**	**$342.22**	**29,182**	**11,551**
% Change	**35.90%**	**13.60%**	**21.80%**	**7.20%**	**1.10%**	**17.30%**	**20.50%**
Change	**14**	**45**	**$708,558.74**	**$709.72**	**$3.77**	**4,308**	**1,965**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

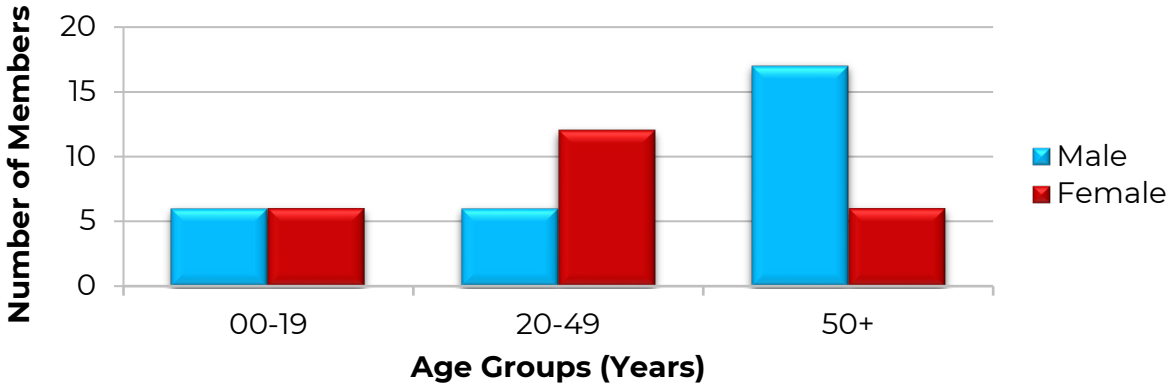
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	431	2,511	$28,312,651.99	$11,275.45	5.83
2023 Total	**431**	**2,511**	**$28,312,651.99**	**$11,275.45**	**5.83**
Fiscal Year 2024					
FFS	379	2,229	$25,841,917.21	$11,593.50	5.88
Aetna	7	13	$126,152.20	$9,704.02	1.86
Humana	6	7	$113,007.20	$16,143.89	1.17
OCH	22	36	$388,384.20	$10,788.45	1.64
2024 Total	**385**	**2,285**	**$26,469,460.81**	**$11,584.01**	**5.94**
% Change	**-10.67%**	**-9.00%**	**-6.51%**	**2.74%**	**1.89%**
Change	**-46**	**-226**	**-$1,843,191.18**	**$308.56**	**0.11**

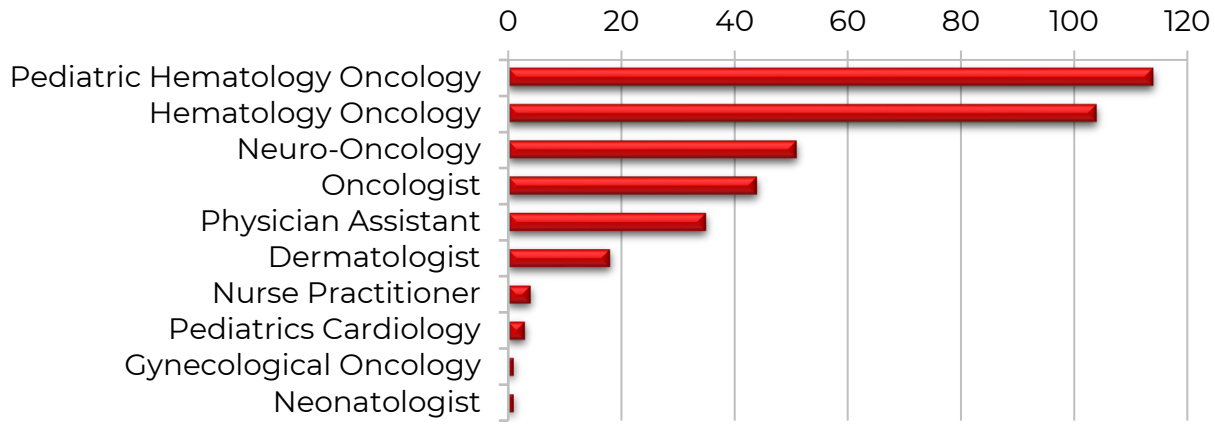
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for skin cancer medications totaled $11,352,899.26.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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



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

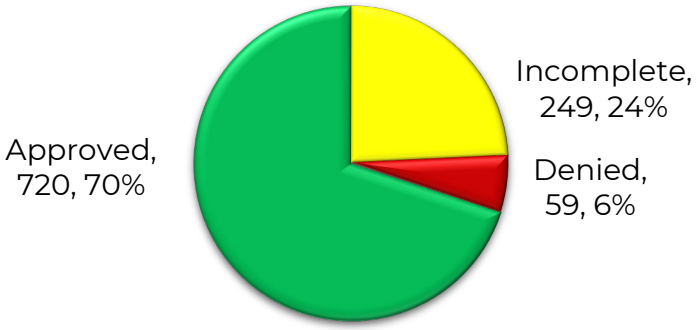


Prior Authorization of Skin Cancer Medications

There were 1,028 prior authorization requests submitted for skin cancer medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

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

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	672	70%	241	25%	52	5%	**965**
Aetna	3	25%	8	67%	1	8%	**12**
Humana	36	86%	0	0%	6	14%	**42**
OCH	9	100%	0	0%	0	0%	**9**
Total	**720**	**70%**	**249**	**24%**	**59**	**6%**	**1,028**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Erivedge® (vismodegib): December 2028
- Zelboraf® (vemurafenib): June 2032
- Braftovi® (encorafenib): August 2033
- Mektovi® (binimetinib): October 2033
- Mekinist® (trametinib dimethyl sulfoxide): February 2034
- Odomzo® (sonidegib phosphate): March 2036
- Cotellic® (cobimetinib fumarate): December 2036
- Tafinlar® (dabrafenib mesylate): December 2038

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

- **March 2024:** The FDA approved Opdivo® (nivolumab) for a new indication, in combination with cisplatin and gemcitabine, for first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.
- **June 2024:** The FDA approved Keytruda® (pembrolizumab) for a new indication, in combination with carboplatin and paclitaxel, followed by single-agent pembrolizumab, for adult patients with primary advanced or recurrent endometrial carcinoma.
- **September 2024:** The FDA approved Keytruda® for a new indication, in combination with pemetrexed and platinum chemotherapy, for the

first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma.

- **October 2024:** The FDA approved Opdivo® for a new indication for the treatment of adult patients with resectable (tumors ≥4cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, for neoadjuvant treatment, in combination with platinum-doublet chemotherapy, followed by single-agent nivolumab as adjuvant treatment after surgery.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for Hodgkin lymphoma allow for the use of Keytruda® for adults with relapsed or refractory classical Hodgkin Lymphoma (cHL) as second line or subsequent systemic therapy in combination with ifosfamide, carboplatin, and etoposide (ICE). Additionally, the guidelines allow for the use of Opdivo® in combination with doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease in patients with relapsed or refractory cHL.
- The NCCN guidelines for pediatric Hodgkin lymphoma allow the use of Keytruda® as a single agent for patients with refractory cHL when a decrease in cardiac function is observed.
- The NCCN guidelines for breast cancer allow the use of Keytruda® as a single agent for adjuvant treatment after surgery in patients with early stage triple-negative breast cancer.
- The NCCN guidelines for cervical cancer allow the use of Keytruda® as second line or subsequent therapy as a single agent in patients with recurrent or metastatic disease.
- The NCCN guidelines for bladder cancer allow the use of Keytruda® as a single agent in patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy or any platinum-containing chemotherapy.
- The NCCN guidelines for small cell lung cancer (SCLC) have removed the recommendation for utilizing Opdivo® in combination with Yervoy® (ipilimumab) for relapsed or progressive disease. Opdivo® may still be used as a single agent in this setting.
- The NCCN guidelines for hairy-cell leukemia recommend the use of Zelboraf® (vemurafenib) in combination with rituximab or obinutuzumab for patients who are not candidates for the use of purine analogs.
- The NCCN guidelines for cervical, vaginal, and vulvar cancer allow the use of Libtayo® (cemiplimab-rwlc) as a single agent in patients with recurrent or metastatic cervical, vaginal, or vulvar cancer as a second-line or subsequent therapy.

Recommendations

The College of Pharmacy also recommends updating the approval criteria for Keytruda® (pembrolizumab) and Opdivo® (nivolumab) based on recent FDA approvals (new criteria and changes shown in red):

Keytruda® (Pembrolizumab) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
    a. Member is not a candidate for curative surgery or radiation; and
    b. Used in 1 of the following settings:
        i. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
        ii. As a single agent for advanced endometrial cancer that is MSI-H or dMMR; or
3. Primary advanced (newly diagnosed stage III/IVA or stage IVB) or recurrent endometrial cancer; and
    a. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance pembrolizumab.

Keytruda® (Pembrolizumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma; and
2. Used as first-line therapy in adult members; and
3. Used in combination with pemetrexed and platinum chemotherapy.

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 Yervoy® (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 resectable disease (tumors ≥4cm or node positive), meeting the following:

a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy, followed by single-agent nivolumab as adjuvant treatment after surgery; and
b. No known EGFR mutations or ALK rearrangements; or

5. For second-line therapy for metastatic disease, meeting the following:
   a. Tumor histology is 1 of the following:
      i. Adenocarcinoma; or
      ii. Squamous cell; or
      iii. Large cell; and
   b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
   d. Used as a single agent; and
   e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and
   a. Member has undergone radical resection; and
   b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
   a. Used as second-line or greater therapy; and
   b. Previous failure of a platinum-containing regimen; and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; or
3. Diagnosis of metastatic or unresectable urothelial carcinoma; and
   a. Used as first-line therapy; and
   b. In combination with cisplatin and gemcitabine.

Lastly, the College of Pharmacy recommends updating the Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Opdivo® (nivolumab), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) approval criteria based on NCCN recommendations (changes and new criteria shown in red):

Keytruda® (Pembrolizumab) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer; and
   a. Tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥10; and
   b. Used in combination with chemotherapy; or
2. Diagnosis of early stage triple-negative breast cancer; and
   a. Disease is considered high-risk; and

b. Used in combination with chemotherapy as neoadjuvant therapy and may be continued as a single agent as adjuvant treatment after surgery.

Keytruda® (Pembrolizumab) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
   a. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
   b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
      i. Disease progression on or after chemotherapy; or
      ii. As first-line therapy in combination with chemotherapy, with or without bevacizumab; or
      iii. As second line or subsequent therapy as a single agent; or
2. Diagnosis of FIGO Stage III-IV cervical cancer; and
   a. Used in combination with concomitant chemotherapy and radiation.

Keytruda® (Pembrolizumab) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. For adult members:
   a. Diagnosis of relapsed or refractory cHL; and
      i. Used as a single agent; or
      ii. Exception: lymphocyte-predominant Hodgkin lymphoma; or
      iii. Used in Second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin (GVD) or ifosfamide, carboplatin, and etoposide (ICE); or
3. For pediatric members:
   a. Used as a single agent; and
   b. Diagnosis of refractory cHL; or
   c. Relapsed disease after ≥2 therapies; or
   d. Decrease in cardiac function is observed.

Keytruda® (Pembrolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Member must have 1 of the following:
   a. As a single agent for locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
   b. As a single agent within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or

c. As a single agent frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy or any platinum-containing chemotherapy; and
    i. Cisplatin ineligibility is defined as:
        1. Baseline creatinine clearance of <60mL/min; or
        2. ECOG performance status of 2; or
        3. Class III heart failure; or
        4. Grade 2 or greater peripheral neuropathy; or
        5. Grade 2 or greater hearing loss; or
d. In combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma; and

2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cervical, Vaginal, or Vulvar Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical, vaginal, or vulvar cancer; and
2. Used as second-line or subsequent therapy; and
3. Used as a single agent; and
4. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab), Yervoy® (ipilimumab)].

Opdivo® (Nivolumab) Approval Criteria [Hodgkin Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma; and
    a. Exception: lymphocyte-predominant HL
2. Nivolumab must be used in 1 of the following settings:
    a. As a single-agent; or
    b. In combination with doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease; or
    c. In combination with brentuximab vedotin as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

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

1. Must meet 1 of the following criteria:
    a. Disease relapsed within 6 months of initial chemotherapy; or
    b. Disease is progressive on initial chemotherapy; and
2. Used as a single agent ~~or in combination with ipilimumab~~; and

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

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

~~1. Diagnosis of SCLC; and~~
~~2. Must meet 1 of the following criteria:~~
~~a. Disease relapsed within 6 months of initial chemotherapy; or~~
~~b. Disease is progressive on initial chemotherapy; and~~
~~3. Used in combination with nivolumab.~~

Zelboraf® (Vemurafenib) Approval Criteria [Hairy-Cell Leukemia Diagnosis]:

1. Diagnosis of hairy-cell leukemia; and
   a. Used as a single agent; and
      i. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine); or
   b. Used in combination with rituximab or obinutuzumab for patients who are not candidates for purine analogs.

Utilization Details of Skin Cancer Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DABRAFENIB PRODUCTS						
TAFINLAR CAP 75MG	60	17	$746,535.67	$12,442.26	3.53	21.52%
TAFINLAR CAP 50MG	44	9	$381,988.11	$8,681.55	4.89	11.01%
SUBTOTAL	**104**	**26**	**$1,128,523.78**	**$10,851.19**	**4**	**32.53%**
TRAMETINIB PRODUCTS						
MEKINIST TAB 0.5MG	44	8	$489,592.31	$11,127.10	5.5	14.11%
MEKINIST TAB 2MG	36	10	$538,253.95	$14,951.50	3.6	15.52%
MEKINIST SOL 0.05MG/ML	4	2	$6,737.24	$1,684.31	2	0.19%
SUBTOTAL	**84**	**20**	**$1,034,583.50**	**$12,316.47**	**4.2**	**29.83%**
COBIMETINIB PRODUCTS						
COTELLIC TAB 20MG	45	8	$284,846.52	$6,329.92	5.63	8.21%
SUBTOTAL	**45**	**8**	**$284,846.52**	**$6,329.92**	**5.63**	**8.21%**
VISMODEGIB PRODUCTS						
ERIVEDGE CAP 150MG	40	13	$518,344.92	$12,958.62	3.08	14.94%
SUBTOTAL	**40**	**13**	**$518,344.92**	**$12,958.62**	**3.08**	**14.94%**
VEMURAFENIB PRODUCTS						
ZELBORAF TAB 240MG	30	5	$215,396.25	$7,179.88	6	6.21%
SUBTOTAL	**30**	**5**	**$215,396.25**	**$7,179.88**	**6**	**6.21%**
ENCORAFENIB PRODUCTS						
BRAFTOVI CAP 75MG	10	2	$155,571.20	$15,557.12	5	4.48%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**10**	**2**	**$155,571.20**	**$15,557.12**	**5**	**4.48%**
SONIDEGIB PRODUCTS						
ODOMZO CAP 200MG	8	3	$53,366.59	$6,670.82	2.67	1.54%
SUBTOTAL	**8**	**3**	**$53,366.59**	**$6,670.82**	**2.67**	**1.54%**
BINIMETINIB PRODUCTS						
MEKTOVI TAB 15MG	5	1	$78,078.85	$15,615.77	5	2.25%
SUBTOTAL	**5**	**1**	**$78,078.85**	**$15,615.77**	**5**	**2.25%**
TOTAL	**326**	**49***	**$3,468,711.61**	**$10,640.22**	**6.65**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DABRAFENIB PRODUCTS						
TAFINLAR CAP 75MG	3	2	$29,168.77	$9,722.92	1.5	31.09%
TAFINLAR CAP 50MG	2	1	$11,326.22	$5,663.11	2	12.07%
SUBTOTAL	**5**	**3**	**$40,494.99**	**$8,099.00**	**1.67**	**43.16%**
SONIDEGIB PRODUCTS						
ODOMZO CAP 200MG	4	2	$34,126.78	$8,531.70	2	36.38%
SUBTOTAL	**4**	**2**	**$34,126.78**	**$8,531.70**	**2**	**36.38%**
TRAMETINIB PRODUCTS						
MEKINIST SOL 0.05MG/ML	2	1	$3,368.62	$1,684.31	2	3.59%
MEKINIST TAB 2MG	1	1	$15,827.46	$15,827.46	1	16.87%
SUBTOTAL	**3**	**2**	**$19,196.08**	**$6,398.69**	**1.5**	**20.46%**
TOTAL	**12**	**5***	**$93,817.85**	**$7,818.15**	**2.4**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRAMETINIB PRODUCTS						
MEKINIST TAB 2MG	2	1	$31,654.92	$15,827.46	2	29.26%
SUBTOTAL	**2**	**1**	**$31,654.92**	**$15,827.46**	**2**	**29.26%**
DABRAFENIB PRODUCTS						
TAFINLAR CAP 75MG	2	1	$29,157.36	$14,578.68	2	26.95%
SUBTOTAL	**2**	**1**	**$29,157.36**	**$14,578.68**	**2**	**26.95%**
VISMODEGIB PRODUCTS						
ERIVEDGE CAP 150MG	2	1	$26,759.84	$13,379.92	2	24.73%
SUBTOTAL	**2**	**1**	**$26,759.84**	**$13,379.92**	**2**	**24.73%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SONIDEGIB PRODUCTS						
ODOMZO CAP 200MG	2	2	$20,630.01	$10,315.01	1	19.07%
SUBTOTAL	**2**	**2**	**$20,630.01**	**$10,315.01**	**1**	**19.07%**
TOTAL	**8**	**4***	**$108,202.13**	**$13,525.27**	**2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DABRAFENIB PRODUCTS						
TAFINLAR CAP 75MG	7	3	$51,065.34	$7,295.05	2.33	18.10%
TAFINLAR CAP 50MG	7	3	$50,945.20	$7,277.89	2.33	18.05%
SUBTOTAL	**14**	**6**	**$102,010.54**	**$7,286.47**	**2.33**	**36.15%**
TRAMETINIB PRODUCTS						
MEKINIST TAB 0.5MG	6	3	$83,714.10	$13,952.35	2	29.66%
MEKINIST SOL 0.05MG/ML	3	1	$15,090.33	$5,030.11	3	5.35%
SUBTOTAL	**9**	**4**	**$98,804.43**	**$10,978.27**	**2.25**	**35.01%**
SONIDEGIB PRODUCTS						
ODOMZO CAP 200MG	3	1	$41,248.62	$13,749.54	3	14.62%
SUBTOTAL	**3**	**1**	**$41,248.62**	**$13,749.54**	**3**	**14.62%**
VISMODEGIB PRODUCTS						
ERIVEDGE CAP 150MG	3	1	$40,139.76	$13,379.92	3	14.22%
SUBTOTAL	**3**	**1**	**$40,139.76**	**$13,379.92**	**3**	**14.22%**
TOTAL	**29**	**7***	**$282,203.35**	**$9,731.15**	**4.14**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9271 PEMBROLIZUMAB INJ	1,566	271	$18,794,921.03	$12,001.87	5.78
J9299 NIVOLUMAB INJ	486	92	$4,723,195.88	$9,718.51	5.28
J9119 CEMIPLIMAB-RWLC INJ	87	13	$827,715.00	$9,513.97	6.69
J9228 IPILIMUMAB INJ	72	26	$1,029,273.30	$14,295.46	2.77
J9298 NIVOL/RELATLIMAB-RMBW INJ	15	5	$444,643.20	$29,642.88	3
J9023 AVELUMAB INJ	3	1	$22,168.80	$7,389.60	3
TOTAL	**2,229**	**379**	**$25,841,917.21**	**$11,593.50**	**5.88**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; NIVOL = nivolumab
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9271 PEMBROLIZUMAB INJ	9	5	$101,250.00	$11,250.00	1.8
J9119 CEMIPLIMAB-RWLC INJ	2	1	$19,306.00	$9,653.00	2
J9299 NIVOLUMAB INJ	2	1	$5,596.20	$2,798.10	2
TOTAL	**13**	**7**	**$126,152.20**	**$9,704.02**	**1.86**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Humana Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9271 PEMBROLIZUMAB INJ	5	4	$68,140.00	$13,628.00	1.25
J9298 NIVOL/RELATLIMAB-RMBW INJ	1	1	$29,944.00	$29,944.00	1
J9299 NIVOLUMAB INJ	1	1	$14,923.20	$14,923.20	1
TOTAL	**7**	**6**	**$113,007.20**	**$16,143.89**	**1.17**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; NIVOL = nivolumab
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Health Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9271 PEMBROLIZUMAB INJ	22	14	$251,216.00	$11,418.91	1.57
J9299 NIVOLUMAB INJ	10	7	$107,571.40	$10,757.14	1.43
J9023 AVELUMAB INJ	4	1	$29,596.80	$7,399.20	4
TOTAL	**36**	**22**	**$388,384.20**	**$10,788.45**	**1.64**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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Appendix H

Fiscal Year 2024 Annual Review of Antidepressants

Oklahoma Health Care Authority
December 2024

Current Prior Authorization Criteria

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps*
escitalopram tabs & soln (Lexapro®)			fluoxetine tabs*
fluoxetine caps & soln (Prozac®)			fluoxetine DR (Prozac® Weekly™)*
fluvoxamine (Luvox®)			fluvoxamine CR (Luvox CR®)
paroxetine (Paxil®)			paroxetine CR (Paxil CR®)
sertraline tabs & soln (Zoloft®)			sertraline 150mg & 200mg caps*
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)*
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)*
venlafaxine tabs & ER caps (Effexor®, Effexor XR®)			trazodone 300mg tabs (Desyrel®)*
venlafaxine 37.5mg, 75mg & 150mg ER tabs (Effexor XR®)			venlafaxine besylate ER 112.5mg tablets*
			venlafaxine ER 225mg tabs (Effexor XR®)

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)*
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity®)*
			esketamine nasal spray (Spravato®)*
			gepirone (Exxua™)*
			zuranolone (Zurzuvae®)*

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.
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets

Antidepressants Tier-2 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial of 2 Tier-1 medications at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response. Tier-1 selection must include at least 1 medication from the SSRI category; or
2. Prior stabilization on the Tier-2 medication documented within the last 100 days. A past history of success on the Tier-2 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by Tier-1 medications or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Tier-3 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier 1 selection must include at least 1 medication from the SSRI category) and a trial of a Tier-2 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or
2. Prior stabilization on the Tier-3 medication documented within the last 100 days. A past history of success on the Tier-3 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by a lowered tiered medication or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Special Prior Authorization (PA) Approval Criteria:

1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or
2. A petition may be submitted for consideration whenever a unique patient-specific situation exists; and
3. Tier structure rules still apply.

Auvelity® (Dextromethorphan/Bupropion) Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD); and
2. Member must be 18 years of age or older; and
3. Prescriber must agree that member's blood pressure will be assessed prior to treatment initiation and monitored periodically during treatment; and
4. Prescriber must agree to screen members for history of bipolar disorder, mania, or hypomania; and
5. Member must not be taking any other medications containing bupropion or dextromethorphan; and
6. Member must not have any contraindications to therapy (i.e., seizure disorder; current or prior diagnosis of bulimia or anorexia nervosa; abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs; concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; known hypersensitivity to bupropion, dextromethorphan, or other components of Auvelity®); and
7. Member must not have severe hepatic or renal impairment; and
8. The maximum approvable dose is 1 tablet once daily if the member has moderate renal impairment, is taking a strong CYP2D6 inhibitor (e.g., paroxetine, fluoxetine, quinidine), or is a known poor CYP2D6 metabolizer; and
9. Prescriber must verify that female members are not currently pregnant and will use effective contraception while receiving treatment with Auvelity®; and
10. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier 1 selection must include bupropion as 1 of the 2 trials), 1 Tier-2 medication, and 1 Tier-3 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or
11. Prior stabilization on the requested medication documented within the last 100 days. A history of success on the requested medication will also be considered with adequate documentation; and
12. A quantity limit of 60 tablets per 30 days will apply.

Citalopram Capsule Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD) in adults; and
2. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without prior authorization, in place of the capsule formulation must be provided; and
4. Citalopram capsules will not be approved for members 60 years of age or older; and
5. A quantity limit of 30 capsules per 30 days will apply.

Desyrel® (Trazodone 300mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products including 2 trazodone 150mg tablets or 3 trazodone 100mg tablets to achieve a 300mg dose must be provided.

Drizalma Sprinkle™ (Duloxetine Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:

1. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
2. A patient-specific, clinically significant reason why the member cannot use generic duloxetine 20mg, 30mg, or 60mg capsules, which are available without prior authorization, in place of Drizalma Sprinkle™ must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply.

Exxua™ (Gepirone) Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD); and
2. Member must be 18 years of age or older; and
3. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier-1 selection must include at least 1 medication from the SSRI category), 1 Tier-2 medication, and 1 Tier-3 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; and
4. Member must not have any contraindications to Exxua™, including:
    a. Prolonged QTc interval >450msec; and
    b. Congenital long QT syndrome; and
    c. Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin); and
    d. Severe hepatic impairment; and
    e. Concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; and
5. A quantity limit of 30 tablets per 30 days will apply.

Fluoxetine Tablet Approval Criteria:

1. Fluoxetine capsules are available without prior authorization. The tablet formulation will require prior authorization and a patient-specific, clinically significant reason why the tablet formulation is required in place of the capsule formulation.

Irenka™ (Duloxetine 40mg Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:

1. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
2. A patient-specific, clinically significant reason why the member cannot use 2 duloxetine 20mg capsules in place of Irenka™ 40mg capsules must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply; and

Marplan® (Isocarboxazid) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use any of the Tier-3 monoamine oxidase inhibitors (MAOIs) or other cost-effective, lower tiered alternatives in place of Marplan® must be provided.

Sertraline Capsule Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD) in adults or obsessive-compulsive disorder (OCD) in adults and pediatric members 6 years of age and older; and
2. Member must have initiated treatment with sertraline tablets for dose titration up to the 150mg or 200mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use sertraline tablets, which are available without prior authorization, in place of the capsule formulation must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Depressive Symptoms in Adults with Major Depressive Disorder (MDD) with Acute Suicidal Ideation or Behavior Diagnosis]:

1. An FDA approved indication of depressive symptoms in adults with MDD with acute suicidal ideation or behavior; and
2. Member must be 18 years of age or older; and
3. Spravato® must be used in conjunction with an oral antidepressant; and
4. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
5. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with package labeling; and

6. Member must not have any contraindications to therapy [i.e., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
7. Member must not have severe hepatic impairment (Child Pugh C); and
8. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
9. Prescriber must verify female member is not breastfeeding; and
10. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
11. Member must be enrolled in the Spravato® REMS program; and
12. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
13. For initial approval, the number of doses the member received while hospitalized, if applicable, and the dates of these doses must be provided to allow authorization of the appropriate quantity for the initial 4 weeks of treatment; and
14. For continued authorization, prescriber must verify member demonstrated an adequate response during the initial 4 weeks of treatment, verify member is using Spravato® in combination with an oral antidepressant, and provide patient-specific, clinically significant information to support continued use of Spravato®; and
15. A quantity limit of 8 kits per 28 days will apply.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Treatment-Resistant Depression Diagnosis]:

1. An FDA approved diagnosis of treatment-resistant depression in adults; and
2. Member must be 18 years of age or older; and
3. Spravato® must be used in conjunction with an oral antidepressant; and
4. Member must have had an inadequate response to at least 2 different antidepressants from different classes at least 4 weeks in duration each and titrated to recommended dosing during the current depressive episode, unless contraindicated or clinically significant adverse effects; and
5. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
6. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with package labeling; and
7. Member must not have any contraindications to therapy [e.g., aneurysmal vascular disease (including thoracic and abdominal aorta,

intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
8. Member must not have severe hepatic impairment (Child Pugh C); and
9. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
10. Prescriber must verify female member is not breastfeeding; and
11. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
12. Member must be enrolled in the Spravato® REMS program; and
13. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
14. Initial approvals will be for the duration of the induction phase. For continued authorization, prescriber must verify member demonstrated an adequate response during the induction phase and verify member is using Spravato® in combination with an oral antidepressant; and
15. A quantity limit of 4 kits per 28 days will apply for maintenance dosing.

Venlafaxine Besylate Extended-Release (ER) Tablets Approval Criteria:

1. An FDA approved indication for the treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD); and
2. Member must be 18 years of age or older; and
3. Member must have received at least 75mg of venlafaxine ER capsules for at least 4 days; and
4. A patient-specific, clinically significant reason why the member cannot use venlafaxine ER capsules must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Zurzuvae® (Zuranolone) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe postpartum depression (PPD); and
2. Member must be ≤12 months postpartum and the date of delivery must be provided; and
3. Member must be a female 18 years of age or older; and
4. Prescriber must verify the following:
    a. Member has been counseled on the proper administration of Zurzuvae® including taking with a fat-containing meal; and
    b. Member has been counseled on the central nervous system (CNS) depression effects of Zurzuvae® and the member agrees not to drive or engage in other potentially hazardous activities until at least 12 hours after administration; and

c. Member is not currently pregnant and will use effective contraception while receiving treatment and for 7 days after the last dose of Zurzuvae®; and
d. Member is not breastfeeding or has agreed to temporarily hold breastfeeding during Zurzuvae® therapy and for 7 days after the last dose; or
e. If the member does not agree to cease breastfeeding, the following must be provided:
    i. Prescriber attests that the benefits of Zurzuvae® therapy while breastfeeding outweigh the risks to the infant due to studies showing that Zurzuvae® is present in breastmilk; and
    ii. Member has been counseled on the potential risks of CNS depression effects that may occur in the infant; and

5. Dosing and approval duration will be limited to the following:
    a. 50mg once daily for 14 days; or
    b. For members with severe hepatic impairment, moderate to severe renal impairment, or concomitant use with CYP3A4 inhibitors:
        i. 30mg once daily for 14 days; and
    c. If a dose reduction to 40mg once daily is required due to CNS depression effects, the prescriber should contact the specialty pharmacy that filled the member's initial Zurzuvae® prescription to obtain the 20mg capsules from the manufacturer for the remainder of the member's treatment course; and
6. Approvals will be for 1 treatment course.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment of Major Depressive Disorder (MDD):*

1. For Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), or Vraylar® (cariprazine), a diagnosis of MDD requires current use of an antidepressant and requires previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting antidepressant) and a trial of aripiprazole tablets that did not yield adequate response; and
2. Tier structure rules still apply.

*Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), and Vraylar® (cariprazine) are reviewed annually with the atypical antipsychotic medications. A full review of these medications, including utilization data, can be found in the June 2024 Drug Utilization Review (DUR) Board packet.

Utilization of Antidepressants: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	142,925	718,951	$12,853,852.27	$17.88	$0.43	34,355,671	29,839,100
2023 Total	**142,925**	**718,951**	**$12,853,852.27**	**$17.88**	**$0.43**	**34,355,671**	**29,839,100**
Fiscal Year 2024							
FFS	128,322	557,716	$12,443,903.38	$22.31	$0.53	27,249,556	23,646,319
Aetna	13,821	26,972	$745,835.73	$27.65	$0.64	1,332,123	1,164,703
Humana	16,320	34,863	$969,995.35	$27.82	$0.70	1,628,900	1,395,615
OCH	15,651	31,000	$649,378.62	$20.95	$0.53	1,379,250	1,217,042
2024 Total	**137,264**	**650,551**	**$14,809,113.08**	**$22.76**	**$0.54**	**31,589,828**	**27,423,679**
% Change	**-4.00%**	**-9.50%**	**15.20%**	**27.30%**	**25.60%**	**-8.10%**	**-8.10%**
Change	**-5,661**	**-68,400**	**$1,955,260.81**	**$4.88**	**$0.11**	**-2,765,843**	**-2,415,421**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for the antidepressant medications totaled $2,876,831.35.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

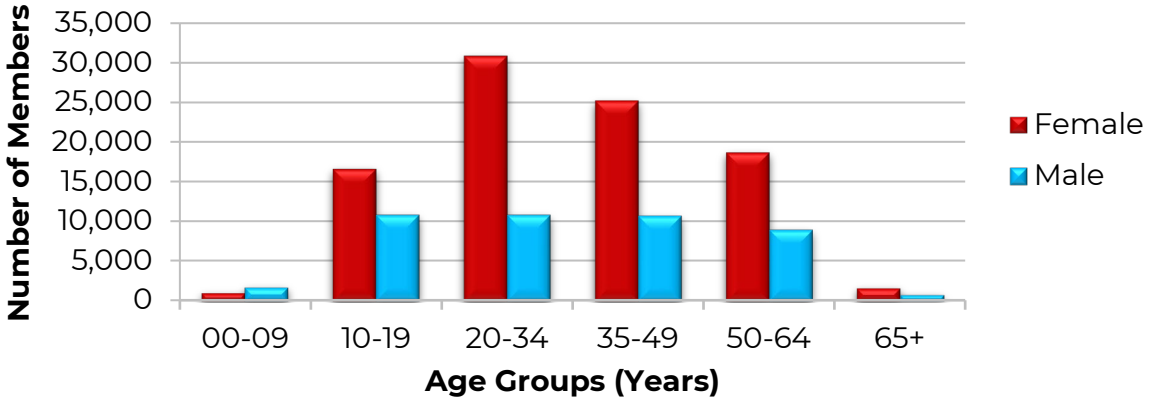
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	2	35	$34,371.05	$982.03	17.5
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**2**	**35**	**$34,371.05**	**$982.03**	**17.5**

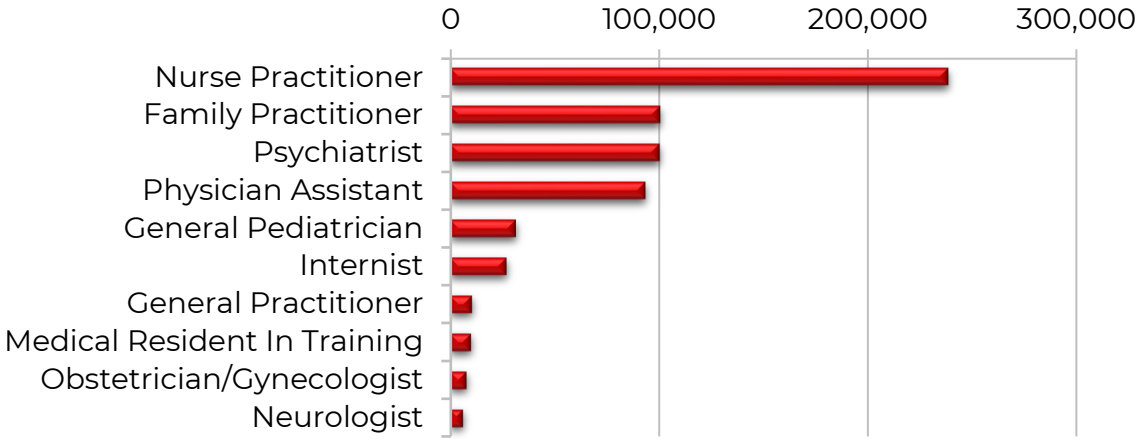
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: There were no paid medical claims for antidepressants during fiscal year 2023 to allow for a fiscal year comparison.

[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 Antidepressants: Pharmacy Claims (All Plans)



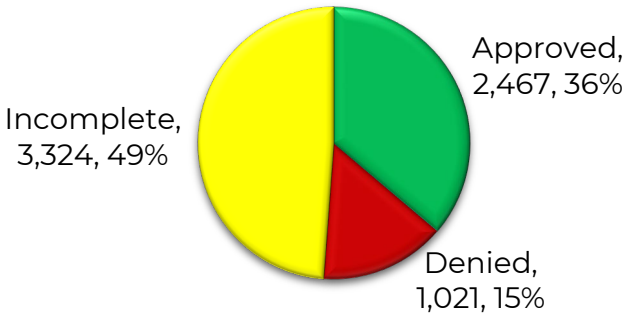
Top Prescriber Specialties of Antidepressants by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Antidepressants

There were 6,812 prior authorization requests submitted for antidepressants during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	2,307	37%	3,150	51%	775	12%	**6,232**
Aetna	109	24%	174	39%	168	37%	**451**
Humana	6	19%	0	0%	25	81%	**31**
OCH	45	46%	0	0%	53	54%	**98**
Total	**2,467**	**36%**	**3,324**	**49%**	**1,021**	**15%**	**6,812**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Exxua™ [gepirone extended-release (ER) tablets]: September 2025
- Aplenzin® (bupropion ER tablets): June 2026
- Forfivo XL® (bupropion ER tablets): June 2027
- Trintellix® (vortioxetine tablets): September 2032
- Fetzima® (levomilnacipran ER capsules): May 2032
- Spravato® (esketamine nasal spray): February 2040
- Drizalma Sprinkle™ [duloxetine delayed-release (DR) capsules]: April 2037
- Zurzuvae® (zuranolone capsules): December 2037
- Auvelity® (dextromethorphan/bupropion ER tablets): April 2043

News:

- **October 2024:** Sage Therapeutics announced that they will not be pursuing further development of Zurzuvae® (zuranolone) for the diagnosis of major depressive disorder (MDD) at this time. In August 2023, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) for Zurzuvae® as a treatment for MDD, requiring that additional studies be completed to support approval. Sage is instead planning to prioritize its resources to the postpartum depression (PPD) community. They also announced that they plan to stop the commercialization of Zulresso® (brexanolone), which was FDA approved in 2019 for PPD but is administered as a continuous intravenous infusion over 60 hours, in favor of shifting their focus on the commercialization of Zurzuvae®, which is dosed orally once daily for 14 days. Zulresso® will be available until December 31, 2024.

Pipeline:

- **Spravato® (Esketamine):** A supplemental New Drug Application (sNDA) was submitted to the FDA for approval of Spravato® as monotherapy for adults with treatment-resistant depression. Phase 4 results that evaluated the safety and efficacy of Spravato® as

monotherapy showed a rapid change in Montgomery-Asberg Depression Rating Scale (MADRS) total score as early as 24 hours after the first Spravato® dose and sustained through at least 4 weeks of treatment. There were no new safety concerns identified and safety was consistent with existing data for Spravato® used in combination with an oral antidepressant. At this time a Prescription Drug User Fee Act (PDUFA) date has not been announced.

- **CYB003:** CYB003 is an investigational deuterated psilocin molecule that is being studied as adjunctive treatment for MDD in adults. Phase 2 data showed 50% of patients were in remission after (2) 12mg doses and had a mean change from baseline in MADRS score by 18 points. For the 16mg dose, 71% of patients were in remission after 2 doses of 16mg and had a mean change from baseline in MADRS score of 23 points. Results have shown a sustained benefit of CYB003 for 4 months after the second dose with 60% on 12mg and 75% on 16mg. CYB003 has been granted FDA Breakthrough Therapy Designation and a Phase 3 trial has been initiated.

Recommendations

The College of Pharmacy recommends the following changes to the Antidepressants Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier charts and criteria):

1. Moving Aplenzin® (bupropion ER) from Special PA Tier to Tier-1 based on net costs; and
2. Removal of the general Special PA approval criteria and updating with specific criteria for each product for clarity.

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps
escitalopram tabs & soln (Lexapro®)			fluoxetine tabs
fluoxetine caps & soln (Prozac®)			fluoxetine DR (Prozac® Weekly™)
fluvoxamine (Luvox®)			fluvoxamine CR (Luvox CR®)
paroxetine (Paxil®)			paroxetine CR (Paxil CR®)
sertraline tabs & soln (Zoloft®)			sertraline 150mg & 200mg caps

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	~~**bupropion ER (Aplenzin®)**~~
bupropion ER (Aplenzin®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
duloxetine (Cymbalta®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)
mirtazapine (Remeron®, Remeron SolTab®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)			trazodone 300mg tabs (Desyrel®)
venlafaxine tabs & ER caps (Effexor®, Effexor XR®)			venlafaxine besylate ER 112.5mg tablets
venlafaxine 75mg & 150mg ER tabs (Effexor XR®)			venlafaxine ER 225mg tabs (Effexor XR®)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity®)
			esketamine nasal spray (Spravato®)
			gepirone (Exxua™)
			zuranolone (Zurzuvae™)

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.
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets

~~**Antidepressants Special Prior Authorization (PA) Approval Criteria:**~~

~~1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or~~

2. ~~A petition may be submitted for consideration whenever a unique patient-specific situation exists; and~~
3. ~~Tier structure rules still apply.~~

Forfivo XL® [Bupropion Extended-Release (ER)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products, including using 3 bupropion 150mg XL tablets to achieve the 450mg dose, must be provided.

Luvox CR® (Fluvoxamine CR) and Paxil CR® (Paroxetine CR) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Tier-1 immediate-release products that are available without prior authorization must be provided.

Venlafaxine Extended-Release (ER) 225mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products, including using 3 venlafaxine ER 75mg capsules or tablets to achieve the 225mg dose, must be provided.

Utilization Details of Antidepressants: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
SERTRALINE PRODUCTS						
SERTRALINE TAB 50MG	37,600	15,226	$466,211.90	$12.40	2.47	3.75%
SERTRALINE TAB 100MG	37,251	11,557	$498,897.16	$13.39	3.22	4.01%
SERTRALINE TAB 25MG	19,081	8,548	$221,103.90	$11.59	2.23	1.78%
SERTRALINE CON 20MG/ML	726	196	$39,401.36	$54.27	3.7	0.32%
ZOLOFT TAB 50MG	9	1	$3,698.44	$410.94	9	0.03%
SUBTOTAL	**94,667**	**35,528**	**$1,229,312.76**	**$12.99**	**2.66**	**9.88%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	40,884	14,979	$430,247.97	$10.52	2.73	3.46%
TRAZODONE TAB 100MG	31,256	9,672	$360,858.90	$11.55	3.23	2.90%
TRAZODONE TAB 150MG	16,169	4,507	$222,067.32	$13.73	3.59	1.78%
SUBTOTAL	**88,309**	**29,158**	**$1,013,174.19**	**$11.47**	**3.03**	**8.14%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	36,351	13,694	$398,902.75	$10.97	2.65	3.21%
FLUOXETINE CAP 40MG	21,184	6,950	$251,575.90	$11.88	3.05	2.02%
FLUOXETINE CAP 10MG	17,475	7,310	$213,672.48	$12.23	2.39	1.72%
FLUOXETINE SOL 20MG/5ML	1,661	404	$69,184.15	$41.65	4.11	0.56%
PROZAC CAP 40MG	4	1	$10,593.86	$2,648.47	4	0.09%
PROZAC CAP 20MG	1	1	$2,521.41	$2,521.41	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**76,676**	**28,360**	**$946,450.55**	**$12.34**	**2.7**	**7.61%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	33,785	14,106	$415,279.48	$12.29	2.4	3.34%
ESCITALOPRAM TAB 20MG	29,892	9,469	$411,476.35	$13.77	3.16	3.31%
ESCITALOPRAM TAB 5MG	7,532	3,512	$92,963.80	$12.34	2.14	0.75%
ESCITALOPRAM SOL 5MG/5ML	337	83	$24,841.33	$73.71	4.06	0.20%
LEXAPRO TAB 20MG	6	3	$7,768.85	$1,294.81	2	0.06%
LEXAPRO TAB 10MG	4	2	$2,842.42	$710.61	2	0.02%
SUBTOTAL	**71,556**	**27,175**	**$955,172.23**	**$13.35**	**2.63**	**7.68%**
BUPROPION PRODUCTS						
BUPROPION XL HCL TAB 150MG	24,964	10,589	$397,046.11	$15.90	2.36	3.19%
BUPROPION XL HCL TAB 300MG	17,757	6,105	$298,441.35	$16.81	2.91	2.40%
BUPROPION SR TAB 150MG	8,038	3,407	$139,114.58	$17.31	2.36	1.12%
BUPROPION SR TAB 100MG	3,483	1,466	$54,639.05	$15.69	2.38	0.44%
BUPROPION TAB 75MG	2,388	1,032	$35,113.10	$14.70	2.31	0.28%
BUPROPION SR TAB 200MG	1,942	672	$33,070.59	$17.03	2.89	0.27%
BUPROPION TAB 100MG	1,542	611	$25,166.68	$16.32	2.52	0.20%
WELLBUTRIN XL TAB 150MG	9	3	$43,747.02	$4,860.78	3	0.35%
SUBTOTAL	**60,123**	**23,885**	**$1,026,338.48**	**$17.07**	**2.52**	**8.25%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	25,369	7,984	$422,006.56	$16.63	3.18	3.39%
DULOXETINE CAP 30MG	18,447	7,826	$273,381.43	$14.82	2.36	2.20%
DULOXETINE CAP 20MG	5,199	2,281	$78,868.02	$15.17	2.28	0.63%
CYMBALTA CAP 60MG	6	2	$6,227.23	$1,037.87	3	0.05%
SUBTOTAL	**49,021**	**18,093**	**$780,483.24**	**$15.92**	**2.71**	**6.27%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER CAP 150MG	11,331	3,468	$191,978.09	$16.94	3.27	1.54%
VENLAFAXINE ER CAP 75MG	10,092	3,951	$150,137.42	$14.88	2.55	1.21%
VENLAFAXINE ER CAP 37.5MG	5,193	2,624	$71,431.83	$13.76	1.98	0.57%
VENLAFAXINE TAB 75MG	1,757	607	$24,570.09	$13.98	2.89	0.20%
VENLAFAXINE TAB 37.5MG	922	460	$11,615.79	$12.60	2	0.09%
VENLAFAXINE TAB 100MG	528	144	$8,199.11	$15.53	3.67	0.07%
VENLAFAXINE TAB 50MG	318	122	$4,461.22	$14.03	2.61	0.04%
VENLAFAXINE TAB 25MG	188	91	$2,396.86	$12.75	2.07	0.02%
VENLAFAXINE ER TAB 75MG	32	22	$783.30	$24.48	1.45	0.01%
VENLAFAXINE ER TAB 150MG	32	21	$520.02	$16.25	1.52	0.00%
EFFEXOR XR CAP 150MG	24	3	$24,574.92	$1,023.96	8	0.20%
VENLAFAXINE ER TAB 37.5MG	10	10	$255.90	$25.59	1	0.00%
SUBTOTAL	**30,427**	**11,523**	**$490,924.55**	**$16.13**	**2.64**	**3.95%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	14,309	5,102	$174,201.30	$12.17	2.8	1.40%
MIRTAZAPINE TAB 30MG	8,366	2,834	$106,965.09	$12.79	2.95	0.86%
MIRTAZAPINE TAB 7.5MG	3,296	1,224	$95,638.39	$29.02	2.69	0.77%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MIRTAZAPINE TAB 45MG	2,858	762	$40,431.79	$14.15	3.75	0.32%
MIRTAZAPINE ODT 15MG	444	154	$10,024.08	$22.58	2.88	0.08%
MIRTAZAPINE ODT 30MG	174	47	$4,338.70	$24.94	3.7	0.03%
MIRTAZAPINE ODT 45MG	144	45	$4,133.97	$28.71	3.2	0.03%
SUBTOTAL	**29,591**	**10,168**	**$435,733.32**	**$14.73**	**2.91**	**3.50%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	12,119	4,933	$119,487.37	$9.86	2.46	0.96%
CITALOPRAM TAB 40MG	8,416	2,794	$86,436.73	$10.27	3.01	0.69%
CITALOPRAM TAB 10MG	6,495	2,678	$66,568.39	$10.25	2.43	0.53%
CITALOPRAM SOL 10MG/5ML	126	32	$6,253.25	$49.63	3.94	0.05%
SUBTOTAL	**27,156**	**10,437**	**$278,745.74**	**$10.26**	**2.6**	**2.24%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	5,225	2,213	$58,294.90	$11.16	2.36	0.47%
PAROXETINE TAB 40MG	3,686	1,153	$54,165.41	$14.69	3.2	0.44%
PAROXETINE TAB 10MG	3,008	1,372	$38,208.44	$12.70	2.19	0.31%
PAROXETINE TAB 30MG	2,109	741	$28,361.71	$13.45	2.85	0.23%
PAROXETINE SUS 10MG/5ML	128	24	$50,752.92	$396.51	5.33	0.41%
PAXIL SUS 10MG/5ML	1	1	$131.30	$131.30	1	0.00%
SUBTOTAL	**14,157**	**5,504**	**$229,914.68**	**$16.24**	**2.57**	**1.85%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	1,925	390	$46,954.99	$24.39	4.94	0.38%
FLUVOXAMINE TAB 50MG	1,645	431	$34,023.00	$20.68	3.82	0.27%
FLUVOXAMINE TAB 25MG	527	181	$9,529.30	$18.08	2.91	0.08%
SUBTOTAL	**4,097**	**1,002**	**$90,507.29**	**$22.09**	**4.09**	**0.73%**
TIER-1 SUBTOTAL	**545,780**	**200,833**	**$7,476,757.033**	**$13.70**	**2.72**	**60.08%**
TIER-2 UTILIZATION						
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 50MG	2,396	830	$70,144.49	$29.28	2.89	0.56%
DESVENLAFAXINE ER TAB 100MG	2,232	614	$70,284.64	$31.49	3.64	0.56%
DESVENLAFAXINE ER TAB 25MG	624	298	$17,383.52	$27.86	2.09	0.14%
PRISTIQ TAB 100MG	3	1	$3,793.14	$1,264.38	3	0.03%
TIER-2 SUBTOTAL	**5,255**	**1,743**	**$161,605.79**	**$30.75**	**3.01**	**1.30%**
TIER-3 UTILIZATION						
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	1,718	315	$762,911.22	$444.07	5.45	6.13%
TRINTELLIX TAB 10MG	1,190	302	$523,273.60	$439.73	3.94	4.21%
TRINTELLIX TAB 5MG	314	103	$145,981.25	$464.91	3.05	1.17%
SUBTOTAL	**3,222**	**720**	**$1,432,166.07**	**$444.50**	**4.48**	**11.51%**
VILAZODONE PRODUCTS						
VILAZODONE TAB 40MG	884	158	$44,760.64	$50.63	5.59	0.36%
VILAZODONE TAB 20MG	358	101	$16,172.72	$45.18	3.54	0.13%
VILAZODONE TAB 10MG	104	45	$5,672.65	$54.54	2.31	0.05%
VIIBRYD TAB 40MG	89	22	$29,297.82	$329.19	4.05	0.24%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VIIBRYD TAB 20MG	43	10	$21,392.94	$497.51	4.3	0.17%
VIIBRYD TAB 10MG	1	1	$324.62	$324.62	1	0.00%
SUBTOTAL	**1,479**	**337**	**$117,621.39**	**$79.53**	**4.39**	**0.95%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 80MG	50	7	$23,696.89	$473.94	7.14	0.19%
FETZIMA CAP 40MG	34	10	$13,612.61	$400.37	3.4	0.11%
FETZIMA CAP 20MG	33	12	$14,525.59	$440.17	2.75	0.12%
FETZIMA CAP 120MG	22	3	$10,445.58	$474.80	7.33	0.08%
SUBTOTAL	**139**	**32**	**$62,280.67**	**$448.06**	**4.34**	**0.50%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 100MG	32	19	$5,837.03	$182.41	1.68	0.05%
DESVENLAFAXINE ER TAB 50MG	14	9	$1,974.45	$141.03	1.56	0.02%
SUBTOTAL	**46**	**28**	**$7,811.48**	**$169.81**	**1.64**	**0.06%**
TRANYLCYPROMINE PRODUCTS						
TRANYLCYPROMINE TAB 10MG	17	3	$2,692.96	$158.41	5.67	0.02%
SUBTOTAL	**17**	**3**	**$2,692.96**	**$158.41**	**5.67**	**0.02%**
NEFAZODONE PRODUCTS						
NEFAZODONE TAB 150MG	4	2	$286.78	$71.70	2	0.00%
NEFAZODONE TAB 100MG	3	1	$166.96	$55.65	3	0.00%
NEFAZODONE TAB 250MG	1	1	$55.43	$55.43	1	0.00%
SUBTOTAL	**8**	**4**	**$509.17**	**$63.65**	**2**	**0.00%**
SELEGILINE PRODUCTS						
EMSAM PATCH 12MG/24H⁺	4	1	$0.00	$0.00	4	0.00%
EMSAM PATCH 9MG/24HR⁺	2	1	$0.00	$0.00	2	0.00%
EMSAM PATCH 6MG/24HR	1	1	$2,057.21	$2,057.21	1	0.02%
SUBTOTAL	**7**	**3**	**$2,057.21**	**$293.89**	**2.33**	**0.02%**
TIER-3 SUBTOTAL	**4,918**	**1,127**	**$1,625,138.95**	**$330.45**	**4.36**	**13.06%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
ESKETAMINE PRODUCTS						
SPRAVATO SOL 84MG DOSE	851	165	$2,780,336.62	$3,267.14	5.16	22.73%
SPRAVATO SOL 56MG DOSE	105	89	$129,031.25	$1,228.87	1.18	1.05%
SUBTOTAL	**956**	**254**	**$2,909,367.87**	**$3,043.27**	**3.76**	**23.78%**
FLUOXETINE PRODUCTS						
FLUOXETINE TAB 10MG	229	73	$2,895.17	$12.64	3.14	0.02%
FLUOXETINE TAB 20MG	93	23	$1,663.46	$17.89	4.04	0.01%
FLUOXETINE CAP 90MG DR	23	2	$2,576.64	$112.03	11.5	0.02%
FLUOXETINE TAB 60MG	3	2	$83.51	$27.84	1.5	0.00%
SUBTOTAL	**348**	**100**	**$7,218.78**	**$20.74**	**3.48**	**0.06%**
PAROXETINE PRODUCTS						
PAROXETINE ER TAB 25MG	94	12	$2,969.10	$31.59	7.83	0.02%
PAROXETINE ER TAB 37.5MG	67	11	$2,021.32	$30.17	6.09	0.02%
PAROXETINE ER TAB 12.5MG	13	2	$351.84	$27.06	6.5	0.00%
SUBTOTAL	**174**	**25**	**$5,342.26**	**$30.70**	**6.96**	**0.04%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEXTROMETHORPHAN/BUPROPION PRODUCTS						
AUVELITY TAB 45-105MG	123	38	$124,080.69	$1,008.79	3.24	1.00%
SUBTOTAL	**123**	**38**	**$124,080.69**	**$1,008.79**	**3.24**	**1.00%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE ER CAP 150MG	85	11	$22,314.37	$262.52	7.73	0.18%
FLUVOXAMINE ER CAP 100MG	13	3	$3,949.33	$303.79	4.33	0.03%
SUBTOTAL	**98**	**14**	**$26,263.70**	**$268.00**	**7**	**0.21%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 40MG	31	6	$2,867.22	$92.49	5.17	0.02%
SUBTOTAL	**31**	**6**	**$2,867.22**	**$92.49**	**5.17**	**0.02%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER TAB 225MG	11	1	$623.14	$56.65	11	0.01%
SUBTOTAL	**11**	**1**	**$623.14**	**$56.65**	**11**	**0.01%**
ZURANOLONE PRODUCTS						
ZURZUVAE CAP 25MG	8	8	$85,767.05	$10,720.88	1	0.69%
SUBTOTAL	**8**	**8**	**$85,767.05**	**$10,720.88**	**1**	**0.69%**
BUPROPION PRODUCTS						
APLENZIN TAB 348MG	5	1	$12,122.61	$2,424.52	5	0.10%
APLENZIN TAB 522MG	1	1	$5,823.14	$5,823.14	1	0.05%
SUBTOTAL	**6**	**2**	**$17,945.75**	**$2,990.96**	**3**	**0.14%**
SERTRALINE PRODUCTS						
SERTRALINE CAP 150MG	5	2	$794.82	$158.96	2.5	0.01%
SUBTOTAL	**5**	**2**	**$794.82**	**$158.96**	**2.5**	**0.01%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 300MG	3	1	$130.33	$43.44	3	0.00%
SUBTOTAL	**3**	**1**	**$130.33**	**$43.44**	**3**	**0.00%**
SPECIAL PA SUBTOTAL	**1,763**	**451**	**$3,180,401.61**	**$1,803.97**	**3.91**	**25.56%**
TOTAL	**557,716**	**128,322***	**$12,443,903.38**	**$22.31**	**4.35**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CON = concentrate; DR = delayed-release; ER = extended-release; HCL = hydrochloride; ODT = orally disintegrating tablet; SOL = solution; SR = sustained-release; SUS = suspension; TAB = tablet; XL = extended-release
[+]The claims for Emsam® patch 12MG/24HR and 9MG/24HR in FY24 were for 1 member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
SERTRALINE PRODUCTS						
SERTRALINE TAB 100MG	1,805	1,197	$25,500.60	$14.13	1.51	3.42%
SERTRALINE TAB 50MG	1,737	1,230	$22,778.91	$13.11	1.41	3.05%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SERTRALINE TAB 25MG	1,066	744	$12,854.38	$12.06	1.43	1.72%
SERTRALINE CON 20MG/ML	20	12	$639.06	$31.95	1.67	0.09%
SUBTOTAL	**4,628**	**3,183**	**$61,772.95**	**$13.35**	**1.45**	**8.28%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	1,823	1,226	$20,731.22	$11.37	1.49	2.78%
FLUOXETINE CAP 40MG	1,065	709	$13,804.29	$12.96	1.5	1.85%
FLUOXETINE CAP 10MG	894	604	$11,391.21	$12.74	1.48	1.53%
FLUOXETINE SOL 20MG/5ML	58	30	$2,045.02	$35.26	1.93	0.27%
SUBTOTAL	**3,840**	**2,569**	**$47,971.74**	**$12.49**	**1.49**	**6.43%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	1,709	1,065	$17,710.58	$10.36	1.6	2.37%
TRAZODONE TAB 100MG	1,400	830	$16,024.53	$11.45	1.69	2.15%
TRAZODONE TAB 150MG	575	342	$7,519.51	$13.08	1.68	1.01%
SUBTOTAL	**3,684**	**2,237**	**$41,254.62**	**$11.20**	**1.65**	**5.53%**
BUPROPION PRODUCTS						
BUPROPION XL HCL TAB 150MG	1,451	1,005	$23,161.46	$15.96	1.44	3.11%
BUPROPION XL HCL TAB 300MG	1,060	705	$19,210.63	$18.12	1.5	2.58%
BUPROPION SR TAB 150MG	408	292	$6,883.64	$16.87	1.4	0.92%
BUPROPION SR TAB 100MG	171	119	$2,632.15	$15.39	1.44	0.35%
BUPROPION TAB 75MG	115	79	$1,767.77	$15.37	1.46	0.24%
BUPROPION SR TAB 200MG	108	71	$2,091.89	$19.37	1.52	0.28%
BUPROPION TAB 100MG	98	57	$1,781.08	$18.17	1.72	0.24%
SUBTOTAL	**3,411**	**2,328**	**$57,528.62**	**$16.87**	**1.47**	**7.71%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	1,549	1,132	$20,832.69	$13.45	1.37	2.79%
ESCITALOPRAM TAB 20MG	1,339	941	$20,112.30	$15.02	1.42	2.70%
ESCITALOPRAM TAB 5MG	384	271	$5,004.59	$13.03	1.42	0.67%
ESCITALOPRAM SOL 5MG/5ML	5	3	$412.30	$82.46	1.67	0.06%
LEXAPRO TAB 20MG	1	1	$1,332.17	$1,332.17	1	0.18%
SUBTOTAL	**3,278**	**2,348**	**$47,694.05**	**$14.55**	**1.4**	**6.39%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	1,218	843	$21,642.19	$17.77	1.44	2.90%
DULOXETINE CAP 30MG	898	630	$13,715.21	$15.27	1.43	1.84%
DULOXETINE CAP 20MG	261	187	$4,371.43	$16.75	1.4	0.59%
SUBTOTAL	**2,377**	**1,660**	**$39,728.83**	**$16.71**	**1.43**	**5.33%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER CAP 75MG	577	398	$9,106.73	$15.78	1.45	1.22%
VENLAFAXINE ER CAP 150MG	568	397	$10,445.79	$18.39	1.43	1.40%
VENLAFAXINE ER CAP 37.5MG	292	214	$4,338.83	$14.86	1.36	0.58%
VENLAFAXINE TAB 75MG	109	60	$1,540.10	$14.13	1.82	0.21%
VENLAFAXINE TAB 37.5MG	60	35	$755.30	$12.59	1.71	0.10%
VENLAFAXINE TAB 100MG	23	15	$343.68	$14.94	1.53	0.05%
VENLAFAXINE ER TAB 150MG	15	9	$262.83	$17.52	1.67	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VENLAFAXINE TAB 50MG	13	7	$187.92	$14.46	1.86	0.03%
VENLAFAXINE TAB 25MG	4	4	$54.03	$13.51	1	0.01%
VENLAFAXINE ER TAB 37.5MG	3	2	$85.71	$28.57	1.5	0.01%
VENLAFAXINE ER TAB 75MG	3	3	$72.40	$24.13	1	0.01%
SUBTOTAL	**1,667**	**1,144**	**$27,193.32**	**$16.31**	**1.46**	**3.65%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	553	403	$6,092.62	$11.02	1.37	0.82%
CITALOPRAM TAB 40MG	412	297	$4,865.35	$11.81	1.39	0.65%
CITALOPRAM TAB 10MG	259	190	$2,819.02	$10.88	1.36	0.38%
CITALOPRAM SOL 10MG/5ML	3	1	$148.42	$49.47	3	0.02%
SUBTOTAL	**1,227**	**891**	**$13,925.41**	**$11.35**	**1.38**	**1.87%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	539	348	$6,856.01	$12.72	1.55	0.92%
MIRTAZAPINE TAB 30MG	338	221	$4,580.97	$13.55	1.53	0.61%
MIRTAZAPINE TAB 7.5MG	115	86	$3,255.88	$28.31	1.34	0.44%
MIRTAZAPINE TAB 45MG	98	54	$1,428.96	$14.58	1.81	0.19%
MIRTAZAPINE ODT 30MG	13	6	$305.36	$23.49	2.17	0.04%
MIRTAZAPINE ODT 15MG	8	7	$202.17	$25.27	1.14	0.03%
MIRTAZAPINE ODT 45MG	5	3	$120.66	$24.13	1.67	0.02%
SUBTOTAL	**1,116**	**725**	**$16,750.01**	**$15.01**	**1.54**	**2.25%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	218	158	$2,721.54	$12.48	1.38	0.36%
PAROXETINE TAB 10MG	178	125	$2,511.47	$14.11	1.42	0.34%
PAROXETINE TAB 40MG	146	103	$2,415.06	$16.54	1.42	0.32%
PAROXETINE TAB 30MG	109	71	$1,628.36	$14.94	1.54	0.22%
PAROXETINE SUS 10MG/5ML	5	2	$960.28	$192.06	2.5	0.13%
SUBTOTAL	**656**	**459**	**$10,236.71**	**$15.60**	**1.43**	**1.37%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	84	39	$1,903.26	$22.66	2.15	0.26%
FLUVOXAMINE TAB 50MG	58	34	$1,082.34	$18.66	1.71	0.15%
FLUVOXAMINE TAB 25MG	22	12	$406.58	$18.48	1.83	0.05%
SUBTOTAL	**164**	**85**	**$3,392.18**	**$20.68**	**1.93**	**0.45%**
TIER-1 SUBTOTAL	**26,048**	**17,629**	**$367,448.44**	**$14.11**	**1.48**	**49.27%**
TIER-2 UTILIZATION						
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 50MG	163	118	$4,612.26	$28.30	1.38	0.62%
DESVENLAFAXINE ER TAB 100MG	141	95	$4,403.04	$31.23	1.48	0.59%
DESVENLAFAXINE ER TAB 25MG	63	42	$1,765.22	$28.02	1.5	0.24%
TIER-2 SUBTOTAL	**367**	**255**	**$10,780.52**	**$29.37**	**1.44**	**1.45%**
TIER-3 UTILIZATION						
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	80	42	$38,043.37	$475.54	1.9	5.10%
TRINTELLIX TAB 10MG	63	37	$30,761.25	$488.27	1.7	4.12%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRINTELLIX TAB 5MG	19	14	$9,136.16	$480.85	1.36	1.22%
SUBTOTAL	**162**	**93**	**$77,940.78**	**$481.12**	**1.74**	**10.45%**
VILAZODONE PRODUCTS						
VILAZODONE TAB 40MG	64	29	$2,770.14	$43.28	2.21	0.37%
VILAZODONE TAB 20MG	39	18	$1,602.16	$41.08	2.17	0.21%
VILAZODONE TAB 10MG	18	12	$782.01	$43.45	1.5	0.10%
SUBTOTAL	**121**	**59**	**$5,154.31**	**$42.60**	**2.05**	**0.69%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 120MG	3	1	$1,474.71	$491.57	3	0.20%
FETZIMA CAP 40MG	2	1	$985.03	$492.52	2	0.13%
SUBTOTAL	**5**	**2**	**$2,459.74**	**$491.95**	**2.5**	**0.33%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 100MG	3	1	$367.86	$122.62	3	0.05%
DESVENLAFAXINE ER TAB 50MG	2	2	$224.66	$112.33	1	0.03%
SUBTOTAL	**5**	**3**	**$592.52**	**$118.50**	**1.67**	**0.08%**
PHENELZINE PRODUCTS						
PHENELZINE TAB 15MG	2	1	$111.87	$55.94	2	0.01%
SUBTOTAL	**2**	**1**	**$111.87**	**$55.94**	**2**	**0.01%**
NEFAZODONE PRODUCTS						
NEFAZODONE TAB 200MG	1	1	$11.96	$11.96	1	0.00%
SUBTOTAL	**1**	**1**	**$11.96**	**$11.96**	**1**	**0.00%**
TIER-3 SUBTOTAL	**296**	**159**	**$86,271.18**	**$291.46**	**1.86**	**11.57%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
ESKETAMINE PRODUCTS						
SPRAVATO SOL 84MG DOSE	81	28	$229,697.04	$2,835.77	2.89	30.80%
SPRAVATO SOL 56MG DOSE	8	8	$13,222.25	$1,652.78	1	1.77%
SUBTOTAL	**89**	**36**	**$242,919.29**	**$2,729.43**	**2.47**	**32.57%**
FLUOXETINE PRODUCTS						
FLUOXETINE TAB 10MG	41	35	$462.27	$11.27	1.17	0.06%
FLUOXETINE TAB 20MG	23	22	$336.84	$14.65	1.05	0.05%
FLUOXETINE TAB 60MG	16	12	$359.40	$22.46	1.33	0.05%
SUBTOTAL	**80**	**69**	**$1,158.51**	**$14.48**	**1.16**	**0.16%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 40MG	20	14	$969.51	$48.48	1.43	0.13%
SUBTOTAL	**20**	**14**	**$969.51**	**$48.48**	**1.43**	**0.13%**
DEXTROMETHORPHAN/BUPROPION PRODUCTS						
AUVELITY TAB 45-105MG	17	10	$16,459.18	$968.19	1.7	2.21%
SUBTOTAL	**17**	**10**	**$16,459.18**	**$968.19**	**1.7**	**2.21%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER TAB 225MG	15	11	$449.37	$29.96	1.36	0.06%
SUBTOTAL	**15**	**11**	**$449.37**	**$29.96**	**1.36**	**0.06%**
PAROXETINE PRODUCTS						
PAROXETINE ER TAB 25MG	9	3	$318.23	$35.36	3	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PAROXETINE ER TAB 37.5MG	3	1	$78.38	$26.13	3	0.01%
SUBTOTAL	**12**	**4**	**$396.61**	**$33.05**	**3**	**0.05%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 300MG	10	9	$409.29	$40.93	1.11	0.05%
SUBTOTAL	**10**	**9**	**$409.29**	**$40.93**	**1.11**	**0.05%**
BUPROPION PRODUCTS						
BUPROPION XL HCL TAB 450MG	6	5	$1,085.02	$180.84	1.2	0.15%
SUBTOTAL	**6**	**5**	**$1,085.02**	**$180.84**	**1.2**	**0.15%**
SERTRALINE PRODUCTS						
SERTRALINE CAP 150MG	4	4	$640.46	$160.12	1	0.09%
SERTRALINE CAP 200MG	2	2	$319.46	$159.73	1	0.04%
SUBTOTAL	**6**	**6**	**$959.92**	**$159.99**	**1**	**0.13%**
CITALOPRAM PRODUCTS						
CITALOPRAM CAP 30MG	4	3	$502.90	$125.73	1.33	0.07%
SUBTOTAL	**4**	**3**	**$502.90**	**$125.73**	**1.33**	**0.07%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE CAP 100MG ER	1	1	$114.58	$114.58	1	0.02%
SUBTOTAL	**1**	**1**	**$114.58**	**$114.58**	**1**	**0.02%**
ZURANOLONE PRODUCTS						
ZURZUVAE CAP 25MG	1	1	$15,911.41	$15,911.41	1	2.13%
SUBTOTAL	**1**	**1**	**$15,911.41**	**$15,911.41**	**1**	**2.13%**
SPECIAL PA SUBTOTAL	**261**	**169**	**$281,335.59**	**$1,077.91**	**1.54**	**37.72%**
TOTAL	**26,972**	**13,821***	**$745,835.73**	**$27.65**	**1.95**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CON = concentrate; DR = delayed-release; ER = extended-release; HCL = hydrochloride; ODT = orally disintegrating tablet; SOL = solution; SR = sustained-release; SUS = suspension; TAB = tablet; XL = extended-release
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
SERTRALINE PRODUCTS						
SERTRALINE TAB 50MG	2,164	1,481	$28,387.86	$13.12	1.46	2.93%
SERTRALINE TAB 100MG	2,106	1,407	$30,225.03	$14.35	1.5	3.12%
SERTRALINE TAB 25MG	1,064	716	$12,774.40	$12.01	1.49	1.32%
SERTRALINE CON 20MG/ML	17	9	$910.20	$53.54	1.89	0.09%
SUBTOTAL	**5,351**	**3,613**	**$72,297.49**	**$13.51**	**1.48**	**7.45%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	2,450	1,447	$25,331.38	$10.34	1.69	2.61%
TRAZODONE TAB 100MG	1,906	1,043	$21,326.63	$11.19	1.83	2.20%
TRAZODONE TAB 150MG	829	441	$11,107.55	$13.40	1.88	1.15%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**5,185**	**2,931**	**$57,765.56**	**$11.14**	**1.77**	**5.96%**
BUPROPION PRODUCTS						
BUPROPION XL HCL TAB 150MG	2,193	1,284	$32,268.43	$14.71	1.71	3.33%
BUPROPION XL HCL TAB 300MG	1,602	890	$25,235.12	$15.75	1.8	2.60%
BUPROPION SR TAB 150MG	504	357	$8,620.59	$17.10	1.41	0.89%
BUPROPION SR TAB 100MG	211	152	$3,323.43	$15.75	1.39	0.34%
BUPROPION TAB 75MG	148	97	$2,234.71	$15.10	1.53	0.23%
BUPROPION SR TAB 200MG	141	94	$2,768.70	$19.64	1.5	0.29%
BUPROPION TAB 100MG	98	56	$1,764.41	$18.00	1.75	0.18%
SUBTOTAL	**4,897**	**2,930**	**$76,215.39**	**$15.56**	**1.67**	**7.86%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	2,069	1,386	$23,582.20	$11.40	1.49	2.43%
FLUOXETINE CAP 40MG	1,352	892	$16,859.63	$12.47	1.52	1.74%
FLUOXETINE CAP 10MG	919	638	$11,646.98	$12.67	1.44	1.20%
FLUOXETINE SOL 20MG/5ML	54	26	$1,967.69	$36.44	2.08	0.20%
SUBTOTAL	**4,394**	**2,942**	**$54,056.50**	**$12.30**	**1.49**	**5.57%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	1,885	1,347	$25,256.34	$13.40	1.4	2.60%
ESCITALOPRAM TAB 20MG	1,680	1,126	$25,230.66	$15.02	1.49	2.60%
ESCITALOPRAM TAB 5MG	391	288	$5,111.33	$13.07	1.36	0.53%
ESCITALOPRAM SOL 5MG/5ML	10	5	$545.90	$54.59	2	0.06%
LEXAPRO TAB 20MG	2	2	$2,444.20	$1,222.10	1	0.25%
LEXAPRO TAB 5MG	1	1	$417.80	$417.80	1	0.04%
SUBTOTAL	**3,969**	**2,769**	**$59,006.23**	**$14.87**	**1.43**	**6.08%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	1,666	1,089	$29,631.41	$17.79	1.53	3.05%
DULOXETINE CAP 30MG	1,225	845	$19,151.79	$15.63	1.45	1.97%
DULOXETINE CAP 20MG	322	223	$5,328.18	$16.55	1.44	0.55%
CYMBALTA CAP 60MG	1	1	$548.71	$548.71	1	0.06%
SUBTOTAL	**3,214**	**2,158**	**$54,660.09**	**$17.01**	**1.49**	**5.64%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER CAP 75MG	841	472	$12,279.03	$14.60	1.78	1.27%
VENLAFAXINE ER CAP 150MG	784	491	$14,140.11	$18.04	1.6	1.46%
VENLAFAXINE ER CAP 37.5MG	424	264	$5,917.59	$13.96	1.61	0.61%
VENLAFAXINE TAB 75MG	124	64	$1,756.53	$14.17	1.94	0.18%
VENLAFAXINE TAB 37.5MG	55	32	$650.81	$11.83	1.72	0.07%
VENLAFAXINE TAB 100MG	40	21	$615.68	$15.39	1.9	0.06%
VENLAFAXINE TAB 25MG	20	15	$278.31	$13.92	1.33	0.03%
VENLAFAXINE ER TAB 37.5MG	14	11	$458.95	$32.78	1.27	0.05%
VENLAFAXINE ER TAB 150MG	11	7	$193.27	$17.57	1.57	0.02%
VENLAFAXINE TAB 50MG	9	5	$134.09	$14.90	1.8	0.01%
VENLAFAXINE ER TAB 75MG	9	5	$203.90	$22.66	1.8	0.02%
EFFEXOR XR CAP 150MG	2	1	$2,427.78	$1,213.89	2	0.25%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**2,333**	**1388**	**$39,056.05**	**$16.74**	**1.68**	**4.03%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	802	474	$9,720.63	$12.12	1.69	1.00%
MIRTAZAPINE TAB 30MG	476	255	$6,113.66	$12.84	1.87	0.63%
MIRTAZAPINE TAB 45MG	201	100	$2,788.41	$13.87	2.01	0.29%
MIRTAZAPINE TAB 7.5MG	173	108	$4,205.51	$24.31	1.6	0.43%
MIRTAZAPINE ODT 15MG	23	15	$481.14	$20.92	1.53	0.05%
MIRTAZAPINE ODT 45MG	6	4	$143.70	$23.95	1.5	0.01%
MIRTAZAPINE ODT 30MG	4	2	$89.62	$22.41	2	0.01%
SUBTOTAL	**1,685**	**958**	**$23,542.67**	**$13.97**	**1.76**	**2.43%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	679	488	$7,460.32	$10.99	1.39	0.77%
CITALOPRAM TAB 40MG	505	340	$5,828.05	$11.54	1.49	0.60%
CITALOPRAM TAB 10MG	329	226	$3,393.42	$10.31	1.46	0.35%
CITALOPRAM SOL 10MG/5ML	4	3	$110.27	$27.57	1.33	0.01%
SUBTOTAL	**1,517**	**1057**	**$16,792.06**	**$11.07**	**1.44**	**1.73%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	290	215	$3,536.74	$12.20	1.35	0.36%
PAROXETINE TAB 40MG	214	143	$3,443.08	$16.09	1.5	0.35%
PAROXETINE TAB 10MG	206	143	$2,882.01	$13.99	1.44	0.30%
PAROXETINE TAB 30MG	133	86	$1,817.35	$13.66	1.55	0.19%
PAROXETINE SUS 10MG/5ML	4	2	$2,325.46	$581.37	2	0.24%
SUBTOTAL	**847**	**589**	**$14,004.64**	**$16.53**	**1.44**	**1.44%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	75	35	$1,806.45	$24.09	2.14	0.19%
FLUVOXAMINE TAB 50MG	47	31	$891.97	$18.98	1.52	0.09%
FLUVOXAMINE TAB 25MG	38	24	$649.79	$17.10	1.58	0.07%
SUBTOTAL	**160**	**90**	**$3,348.21**	**$20.93**	**1.78**	**0.35%**
TIER-1 SUBTOTAL	**33,552**	**21,425**	**$470,744.89**	**$14.03**	**1.57**	**48.53%**
TIER-2 UTILIZATION						
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 50MG	200	127	$4,977.29	$24.89	1.57	0.51%
DESVENLAFAXINE ER TAB 100MG	186	93	$4,715.42	$25.35	2	0.49%
DESVENLAFAXINE ER TAB 25MG	48	39	$1,264.29	$26.34	1.23	0.13%
TIER-2 SUBTOTAL	**434**	**259**	**$10,957.00**	**$25.25**	**1.68**	**1.13%**
TIER-3 UTILIZATION						
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	110	53	$52,871.22	$480.65	2.08	5.45%
TRINTELLIX TAB 10MG	110	63	$52,363.99	$476.04	1.75	5.40%
TRINTELLIX TAB 5MG	30	18	$14,427.73	$480.92	1.67	1.49%
SUBTOTAL	**250**	**134**	**$119,662.94**	**$478.65**	**1.87**	**12.34%**
VILAZODONE PRODUCTS						
VILAZODONE TAB 40MG	68	32	$2,910.56	$42.80	2.13	0.30%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VILAZODONE TAB 20MG	56	30	$2,465.02	$44.02	1.87	0.25%
VILAZODONE TAB 10MG	23	19	$1,023.98	$44.52	1.21	0.11%
VIIBRYD TAB 40MG	3	2	$1,034.00	$344.67	1.5	0.11%
VIIBRYD TAB 20MG	1	1	$344.86	$344.86	1	0.04%
VIIBRYD TAB 10MG	1	1	$344.12	$344.12	1	0.04%
SUBTOTAL	**152**	**85**	**$8,122.54**	**$53.44**	**1.79**	**0.84%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 80MG	7	3	$3,435.85	$490.84	2.33	0.35%
FETZIMA CAP 40MG	6	2	$2,956.54	$492.76	3	0.30%
SUBTOTAL	**13**	**5**	**$6,392.39**	**$491.72**	**2.6**	**0.66%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 100MG	5	3	$615.28	$123.06	1.67	0.06%
DESVENLAFAXINE ER TAB 50MG	4	2	$487.71	$121.93	2	0.05%
SUBTOTAL	**9**	**5**	**$1,102.99**	**$122.55**	**1.8**	**0.11%**
NEFAZODONE PRODUCTS						
NEFAZODONE TAB 150MG	1	1	$91.79	$91.79	1	0.01%
SUBTOTAL	**1**	**1**	**$91.79**	**$91.79**	**1**	**0.01%**
TIER-3 SUBTOTAL	**425**	**230**	**$135,372.65**	**$318.52**	**1.85**	**13.96%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
FLUOXETINE PRODUCTS						
FLUOXETINE TAB 10MG	74	51	$861.13	$11.64	1.45	0.09%
FLUOXETINE TAB 20MG	72	48	$1,120.08	$15.56	1.5	0.12%
FLUOXETINE TAB 60MG	34	25	$811.12	$23.86	1.36	0.08%
SUBTOTAL	**180**	**124**	**$2,792.33**	**$15.51**	**1.45**	**0.29%**
ESKETAMINE PRODUCTS						
SPRAVATO SOL 84MG DOSE	86	24	$249,152.31	$2,897.12	3.58	25.69%
SPRAVATO SOL 56MG DOSE	10	8	$23,286.40	$2,328.64	1.25	2.40%
SUBTOTAL	**96**	**32**	**$272,438.71**	**$2,837.90**	**3**	**28.09%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER TAB 225MG	38	23	$1,187.65	$31.25	1.65	0.12%
VENLAFAXINE TAB 112.5MG	1	1	$205.66	$205.66	1	0.02%
SUBTOTAL	**39**	**24**	**$1,393.31**	**$35.73**	**1.63**	**0.14%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 300MG	30	16	$1,231.97	$41.07	1.88	0.13%
SUBTOTAL	**30**	**16**	**$1,231.97**	**$41.07**	**1.88**	**0.13%**
SERTRALINE PRODUCTS						
SERTRALINE CAP 150MG	19	13	$3,149.44	$165.76	1.46	0.32%
SERTRALINE CAP 200MG	7	4	$1,160.32	$165.76	1.75	0.12%
SUBTOTAL	**26**	**17**	**$4,309.76**	**$165.76**	**1.53**	**0.44%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 40MG	20	15	$965.65	$48.28	1.33	0.10%
SUBTOTAL	**20**	**15**	**$965.65**	**$48.28**	**1.33**	**0.10%**
PAROXETINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PAROXETINE ER TAB 25MG	13	6	$334.30	$25.72	2.17	0.03%
PAROXETINE ER TAB 37.5MG	5	4	$133.70	$26.74	1.25	0.01%
PAROXETINE ER TAB 12.5MG	3	1	$71.55	$23.85	3	0.01%
SUBTOTAL	**21**	**11**	**$539.55**	**$25.69**	**1.91**	**0.06%**
DEXTROMETHORPHAN/BUPROPION PRODUCTS						
AUVELITY TAB 45-105MG	19	13	$18,292.50	$962.76	1.46	1.89%
SUBTOTAL	**19**	**13**	**$18,292.50**	**$962.76**	**1.46**	**1.89%**
BUPROPION PRODUCTS						
BUPROPION XL HCL TAB 450MG	12	7	$2,301.35	$191.78	1.71	0.24%
SUBTOTAL	**12**	**7**	**$2,301.35**	**$191.78**	**1.71**	**0.24%**
CITALOPRAM PRODUCTS						
CITALOPRAM CAP 30MG	4	3	$663.04	$165.76	1.33	0.07%
SUBTOTAL	**4**	**3**	**$663.04**	**$165.76**	**1.33**	**0.07%**
ZURANOLONE PRODUCTS						
ZURZUVAE CAP 25MG	3	3	$47,734.23	$15,911.41	1	4.92%
SUBTOTAL	**3**	**3**	**$47,734.23**	**$15,911.41**	**1**	**4.92%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE ER CAP 150MG	2	1	$258.41	$129.21	2	0.03%
SUBTOTAL	**2**	**1**	**$258.41**	**$129.21**	**2**	**0.03%**
SPECIAL PA SUBTOTAL	**452**	**266**	**$352,920.81**	**$780.80**	**1.7**	**36.38%**
TOTAL	**34,863**	**16,320***	**$969,995.35**	**$27.82**	**2.14**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CON = concentrate; DR = delayed-release; ER = extended-release; HCL = hydrochloride; ODT = orally disintegrating tablet; SOL = solution; SR = sustained-release; SUS = suspension; TAB = tablet; XL = extended-release
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
SERTRALINE PRODUCTS						
SERTRALINE TAB 50MG	2,264	1,547	$29,518.40	$13.04	1.46	4.55%
SERTRALINE TAB 100MG	2,011	1,332	$28,205.45	$14.03	1.51	4.34%
SERTRALINE TAB 25MG	1,264	882	$15,306.54	$12.11	1.43	2.36%
SERTRALINE CON 20MG/ML	30	18	$1,183.71	$39.46	1.67	0.18%
ZOLOFT TAB 50MG	2	1	$857.20	$428.60	2	0.13%
ZOLOFT CON 20MG/ML	1	1	$295.46	$295.46	1	0.05%
SUBTOTAL	**5,572**	**3,781**	**$75,366.76**	**$13.53**	**1.47**	**11.61%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	2,489	1,482	$25,952.32	$10.43	1.68	4.00%
TRAZODONE TAB 100MG	1,769	1,009	$20,161.02	$11.40	1.75	3.10%
TRAZODONE TAB 150MG	801	445	$10,582.43	$13.21	1.8	1.63%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**5,059**	**2,936**	**$56,695.77**	**$11.21**	**1.72**	**8.73%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	2,064	1,390	$23,691.00	$11.48	1.48	3.65%
FLUOXETINE CAP 40MG	1,171	807	$14,646.96	$12.51	1.45	2.26%
FLUOXETINE CAP 10MG	1,127	756	$14,151.40	$12.56	1.49	2.18%
FLUOXETINE SOL 20MG/5ML	81	47	$2,371.19	$29.27	1.72	0.37%
SUBTOTAL	**4,443**	**3,000**	**$54,860.55**	**$12.35**	**1.48**	**8.45%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	1,809	1,270	$24,015.29	$13.28	1.42	3.70%
ESCITALOPRAM TAB 20MG	1,341	943	$19,918.01	$14.85	1.42	3.07%
ESCITALOPRAM TAB 5MG	504	342	$6,551.00	$13.00	1.47	1.01%
ESCITALOPRAM SOL 5MG/5ML	18	9	$810.94	$45.05	2	0.12%
SUBTOTAL	**3,672**	**2,564**	**$51,295.24**	**$13.97**	**1.43**	**7.90%**
BUPROPION PRODUCTS						
BUPROPION XL HCL TAB 150MG	1,511	1,016	$22,465.02	$14.87	1.49	3.46%
BUPROPION XL HCL TAB 300MG	1,237	725	$19,343.96	$15.64	1.71	2.98%
BUPROPION SR TAB 150MG	408	294	$6,739.07	$16.52	1.39	1.04%
BUPROPION SR TAB 100MG	202	135	$3,150.18	$15.59	1.5	0.49%
BUPROPION SR TAB 200MG	115	77	$2,011.87	$17.49	1.49	0.31%
BUPROPION TAB 75MG	111	77	$1,663.74	$14.99	1.44	0.26%
BUPROPION TAB 100MG	70	46	$1,157.86	$16.54	1.52	0.18%
WELLBUTRIN XL TAB 150MG	1	1	$1,924.59	$1,924.59	1	0.30%
SUBTOTAL	**3,655**	**2,371**	**$58,456.29**	**$15.99**	**1.54**	**9.00%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	1,220	877	$21,804.57	$17.87	1.39	3.36%
DULOXETINE CAP 30MG	905	665	$14,054.48	$15.53	1.36	2.16%
DULOXETINE CAP 20MG	269	196	$4,368.33	$16.24	1.37	0.67%
SUBTOTAL	**2,394**	**1738**	**$40,227.38**	**$16.80**	**1.38**	**6.19%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER CAP 75MG	649	401	$9,234.23	$14.23	1.62	1.42%
VENLAFAXINE ER CAP 150MG	542	373	$9,854.62	$18.18	1.45	1.52%
VENLAFAXINE ER CAP 37.5MG	321	223	$4,453.22	$13.87	1.44	0.69%
VENLAFAXINE TAB 75MG	79	49	$1,107.79	$14.02	1.61	0.17%
VENLAFAXINE TAB 37.5MG	61	45	$776.55	$12.73	1.36	0.12%
VENLAFAXINE TAB 100MG	28	15	$454.44	$16.23	1.87	0.07%
VENLAFAXINE ER TAB 150MG	20	13	$352.30	$17.62	1.54	0.05%
VENLAFAXINE ER TAB 75MG	18	10	$415.59	$23.09	1.8	0.06%
VENLAFAXINE TAB 50MG	17	12	$248.05	$14.59	1.42	0.04%
VENLAFAXINE TAB 25MG	13	8	$173.61	$13.35	1.63	0.03%
VENLAFAXINE ER TAB 37.5MG	7	5	$176.03	$25.15	1.4	0.03%
SUBTOTAL	**1,755**	**1154**	**$27,246.43**	**$15.53**	**1.52**	**4.20%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	734	448	$8,826.29	$12.02	1.64	1.36%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MIRTAZAPINE TAB 30MG	365	221	$4,706.11	$12.89	1.65	0.72%
MIRTAZAPINE TAB 7.5MG	160	97	$3,809.22	$23.81	1.65	0.59%
MIRTAZAPINE TAB 45MG	127	71	$1,756.50	$13.83	1.79	0.27%
MIRTAZAPINE ODT 15MG	28	14	$550.33	$19.65	2	0.08%
MIRTAZAPINE ODT 45MG	6	4	$151.14	$25.19	1.5	0.02%
MIRTAZAPINE ODT 30MG	5	3	$104.78	$20.96	1.67	0.02%
SUBTOTAL	**1,425**	**858**	**$19,904.37**	**$13.97**	**1.66**	**3.07%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	567	408	$6,269.49	$11.06	1.39	0.97%
CITALOPRAM TAB 40MG	405	297	$4,818.05	$11.90	1.36	0.74%
CITALOPRAM TAB 10MG	310	216	$3,326.89	$10.73	1.44	0.51%
CITALOPRAM SOL 10MG/5ML	2	2	$46.87	$23.44	1	0.01%
SUBTOTAL	**1,284**	**923**	**$14,461.30**	**$11.26**	**1.39**	**2.23%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	214	159	$2,666.50	$12.46	1.35	0.41%
PAROXETINE TAB 10MG	131	102	$1,825.75	$13.94	1.28	0.28%
PAROXETINE TAB 40MG	127	95	$2,027.68	$15.97	1.34	0.31%
PAROXETINE TAB 30MG	101	72	$1,416.70	$14.03	1.4	0.22%
PAROXETINE SUS 10MG/5ML	6	2	$555.60	$92.60	3	0.09%
SUBTOTAL	**579**	**430**	**$8,492.23**	**$14.67**	**1.35**	**1.31%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	76	38	$1,801.10	$23.70	2	0.28%
FLUVOXAMINE TAB 50MG	57	33	$1,109.32	$19.46	1.73	0.17%
FLUVOXAMINE TAB 25MG	26	13	$431.61	$16.60	2	0.07%
SUBTOTAL	**159**	**84**	**$3,342.03**	**$21.02**	**1.89**	**0.51%**
TIER-1 SUBTOTAL	**29,997**	**19,839**	**$410,348.35**	**$13.68**	**1.51**	**63.19%**
TIER-2 UTILIZATION						
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 50MG	159	105	$3,972.74	$24.99	1.51	0.61%
DESVENLAFAXINE ER TAB 100MG	138	77	$3,429.41	$24.85	1.79	0.53%
DESVENLAFAXINE ER TAB 25MG	55	36	$1,298.92	$23.62	1.53	0.20%
PRISTIQ TAB 100MG	1	1	$430.77	$430.77	1	0.07%
PRISTIQ TAB 25MG	1	1	$429.56	$429.56	1	0.07%
TIER-2 SUBTOTAL	**354**	**220**	**$9,561.40**	**$27.01**	**1.61**	**1.47%**
TIER-3 UTILIZATION						
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	90	45	$43,344.02	$481.60	2	6.67%
TRINTELLIX TAB 10MG	62	41	$29,876.50	$481.88	1.51	4.60%
TRINTELLIX TAB 5MG	40	28	$18,124.58	$453.11	1.43	2.79%
SUBTOTAL	**192**	**114**	**$91,345.10**	**$475.76**	**1.68**	**14.07%**
VILAZODONE PRODUCTS						
VILAZODONE TAB 40MG	51	24	$2,203.75	$43.21	2.13	0.34%
VILAZODONE TAB 10MG	22	12	$967.12	$43.96	1.83	0.15%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VILAZODONE TAB 20MG	18	15	$711.91	$39.55	1.2	0.11%
VIIBRYD TAB 40MG	1	1	$344.65	$344.65	1	0.05%
SUBTOTAL	**92**	**52**	**$4,227.43**	**$45.95**	**1.77**	**0.65%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 40MG	2	1	$985.03	$492.52	2	0.15%
FETZIMA CAP 80MG	2	1	$979.90	$489.95	2	0.15%
SUBTOTAL	**4**	**2**	**$1,964.93**	**$491.23**	**2**	**0.30%**
TRANYLCYPROMINE PRODUCTS						
TRANYLCYPROMINE TAB 10MG	4	2	$498.75	$124.69	2	0.08%
SUBTOTAL	**4**	**2**	**$498.75**	**$124.69**	**2**	**0.08%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE ER TAB 100MG	3	3	$518.67	$172.89	1	0.08%
SUBTOTAL	**3**	**3**	**$518.67**	**$172.89**	**1**	**0.08%**
SELEGILINE PRODUCTS						
EMSAM PATCH 6MG/24HR	2	1	$4,114.42	$2,057.21	2	0.63%
SUBTOTAL	**2**	**1**	**$4,114.42**	**$2,057.21**	**2**	**0.63%**
TIER-3 SUBTOTAL	**297**	**174**	**$102,669.30**	**$345.69**	**1.71**	**15.81%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
FLUOXETINE PRODUCTS						
FLUOXETINE TAB 10MG	84	54	$946.10	$11.26	1.56	0.15%
FLUOXETINE TAB 20MG	76	52	$1,144.15	$15.05	1.46	0.18%
FLUOXETINE TAB 60MG	27	19	$608.91	$22.55	1.42	0.09%
FLUOXETINE DR CAP 90MG	1	1	$131.90	$131.90	1	0.02%
SUBTOTAL	**188**	**126**	**$2,831.06**	**$15.06**	**1.49**	**0.44%**
ESKETAMINE PRODUCTS						
SPRAVATO SOL 84MG DOSE	37	9	$75,732.47	$2,046.82	4.11	11.66%
SPRAVATO SOL 56MG DOSE	5	4	$8,553.56	$1,710.71	1.25	1.32%
SUBTOTAL	**42**	**13**	**$84,286.03**	**$2,006.81**	**3.23**	**12.98%**
SERTRALINE PRODUCTS						
SERTRALINE CAP 150MG	21	13	$3,501.54	$166.74	1.62	0.54%
SERTRALINE CAP 200MG	2	2	$331.52	$165.76	1	0.05%
SUBTOTAL	**23**	**15**	**$3,833.06**	**$166.65**	**1.53**	**0.59%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE ER TAB 225MG	22	16	$677.50	$30.80	1.38	0.10%
SUBTOTAL	**22**	**16**	**$677.50**	**$30.80**	**1.38**	**0.10%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 300MG	20	15	$757.66	$37.88	1.33	0.12%
SUBTOTAL	**20**	**15**	**$757.66**	**$37.88**	**1.33**	**0.12%**
BUPROPION PRODUCTS						
BUPROPION XL HCL TAB 450MG	14	7	$4,252.91	$303.78	2	0.65%
SUBTOTAL	**14**	**7**	**$4,252.91**	**$303.78**	**2**	**0.65%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 40MG	13	11	$574.81	$44.22	1.18	0.09%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**13**	**11**	**$574.81**	**$44.22**	**1.18**	**0.09%**
DEXTROMETHORPHAN/BUPROPION PRODUCTS						
AUVELITY TAB 45-105MG	12	9	$12,311.36	$1,025.95	1.33	1.90%
SUBTOTAL	**12**	**9**	**$12,311.36**	**$1,025.95**	**1.33**	**1.90%**
PAROXETINE PRODUCTS						
PAROXETINE ER TAB 25MG	5	2	$157.66	$31.53	2.5	0.02%
PAROXETINE ER TAB 37.5MG	4	2	$104.47	$26.12	2	0.02%
PAROXETINE ER TAB 12.5MG	1	1	$26.68	$26.68	1	0.00%
SUBTOTAL	**10**	**5**	**$288.81**	**$28.88**	**2**	**0.04%**
CITALOPRAM PRODUCTS						
CITALOPRAM CAP 30MG	5	4	$828.80	$165.76	1.25	0.13%
SUBTOTAL	**5**	**4**	**$828.80**	**$165.76**	**1.25**	**0.13%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE ER CAP 150MG	2	2	$246.16	$123.08	1	0.04%
SUBTOTAL	**2**	**2**	**$246.16**	**$123.08**	**1**	**0.04%**
ZURANOLONE PRODUCTS						
ZURZUVAE CAP 25MG	1	1	$15,911.41	$15,911.41	1	2.45%
SUBTOTAL	**1**	**1**	**$15,911.41**	**$15,911.41**	**1**	**2.45%**
SPECIAL PA SUBTOTAL	**352**	**224**	**$126,799.57**	**$360.23**	**1.57**	**19.53%**
TOTAL	**31,000**	**15,651***	**$649,378.62**	**$20.95**	**1.98**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CON = concentrate; DR = delayed-release; ER = extended-release; HCL = hydrochloride; ODT = orally disintegrating tablet; SOL = solution; SR = sustained-release; SUS = suspension; TAB = tablet; XL = extended-release
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ESKETAMINE >56MG (G2083)	35	2	$34,371.05	$982.03	17.5
TOTAL	**35**	**2**	**$34,371.05**	**$982.03**	**17.5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 11/2024. Last accessed 11/15/2024.
[2] Sage Therapeutics. Sage Therapeutics Announces Third Quarter 2024 Financial Results and Highlights Pipeline and Business Updates. Available online at: https://investor.sagerx.com/news-releases/news-release-details/sage-therapeutics-announces-third-quarter-2024-financial-results. Issued 10/29/2024. Last accessed 11/19/2024.
[3] Cybin. CYB003: Deuterated Psilocin Program with FDA Breakthrough Therapy Designation. Available online at: https://cybin.com/cyb003/. Last accessed 11/19/2024.
[4] Cybin. Cybin Reports Positive Phase 2 Data for CYB003, Demonstrating Breakthrough 12-Month Efficacy in Treating Major Depressive Disorder. *Businesswire*. Available online at: https://www.businesswire.com/news/home/20241118852918/en/Cybin-Reports-Positive-Phase-2-Data-for-CYB003-Demonstrating-Breakthrough-12-Month-Efficacy-in-Treating-Major-Depressive-Disorder/. Issued 11/18/2024. Last accessed 11/19/2024.
[5] Johnson & Johnson. Johnson & Johnson Seeks U.S. FDA approval of Spravato® (Esketamine) As the First and Only Monotherapy for Adults with Treatment-Resistant Depression. Available online at: https://www.investor.jnj.com/news/news-details/2024/Johnson--Johnson-seeks-U.S.-FDA-approval-of-SPRAVATO-esketamine-as-the-first-and-only-monotherapy-for-adults-with-treatment-resistant-depression/default.aspx. Issued 07/22/2024. Last accessed 11/19/2024.

Appendix I

Fiscal Year 2024 Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan)

Oklahoma Health Care Authority
December 2024

Current Prior Authorization Criteria

Empaveli® (Pegcetacoplan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Empaveli® must be prescribed by, or in consultation with, a gastroenterologist, hematologist, geneticist, or a specialist with expertise in the treatment of PNH; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Enspryng® (Satralizumab-mwge) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and

3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and
5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and
13. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
14. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Rystiggo® (Rozanolixizumab-noli) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IVa; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥3 (with at least 3 points from non-ocular symptoms); and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient

specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Rystiggo® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Rystiggo® in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®, Zilbrysq®); and
9. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
3. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:
    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and

6. Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
8. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. Use of Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and
10. Member must not be receiving Soliris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and
11. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Soliris® (Eculizumab) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Soliris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and

3. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Member must be:
   a. 1 month of age or older for the intravenous (IV) formulation; or
   b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
4. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS; and
5. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
6. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and

5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Ultomiris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. The subcutaneous (sub-Q) formulation of Ultomiris® will not be approved for a diagnosis of gMG; and
11. Member must not be receiving Ultomiris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be:
    a. 1 month of age or older for the intravenous (IV) formulation; or
    b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
7. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and
5. Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
15. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
16. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Veopoz® (Pozelimab-bbfg) Approval Criteria [CD55-Deficent Protein-Losing Enteropathy (PLE) Diagnosis]:

1. An FDA approved diagnosis of CD55-deficient PLE confirmed by all of the following:
    a. Genetic testing identifying biallelic pathogenic mutations in the *CD55* gene (results of genetic testing must be submitted); and
    b. A history of PLE; and
2. Member has active disease defined by hypoalbuminemia (serum albumin concentration ≤3.2g/dL) with 1 or more of the following signs or symptoms within the last 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema; and
3. Member must be 1 year of age or older; and
4. Prescriber must verify the member has received the meningococcal vaccine 2 weeks prior to treatment unless urgent treatment is needed; and
5. Veopoz® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or other specialist with expertise in the treatment of CD55-deficient PLE; and
6. Prescriber must verify that Veopoz® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a normalization of serum albumin or documentation of a positive clinical response to therapy.

Vyvgart® (Efgartigimod Alfa-fcab) and Vyvgart® Hytrulo (Efgartigimod alfa/Hyaluronidase-qvfc) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥5; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and

7. Vyvgart® or Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Vyvgart® or Vyvgart® Hytrulo in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®, Zilbrysq®); and
9. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Zilbrysq® (Zilucoplan) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Zilbrysq® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber and pharmacy must be enrolled in the Zilbrysq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Member must not be receiving Zilbrysq® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and
11. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Zilbrysq®; and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Utilization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	7	39	$2,200,272.11	$56,417.23	$1,312.81	3,419	1,676
2023 Total	**7**	**39**	**$2,200,272.11**	**$56,417.23**	**$1,312.81**	**3,419**	**1,676**
Fiscal Year 2024							
FFS	8	42	$2,014,985.01	$47,975.83	$1,239.23	4,760	1,626
Aetna	2	4	$162,049.63	$40,512.41	$1,884.30	507	86
Humana	1	3	$123,934.23	$41,311.41	$1,475.41	68	84
OCH	2	3	$145,593.74	$48,531.25	$1,692.95	353	86
2024 Total	**10**	**52**	**$2,446,562.61**	**$47,049.28**	**$1,299.98**	**5,688**	**1,882**
% Change	**42.90%**	**33.30%**	**11.20%**	**-16.60%**	**-1.00%**	**66.40%**	**12.30%**
Change	**3**	**13**	**$246,290.50**	**-$9,367.95**	**-$12.83**	**2,269**	**206**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Comparison of Fiscal Years: Medical Claims (All Plans)

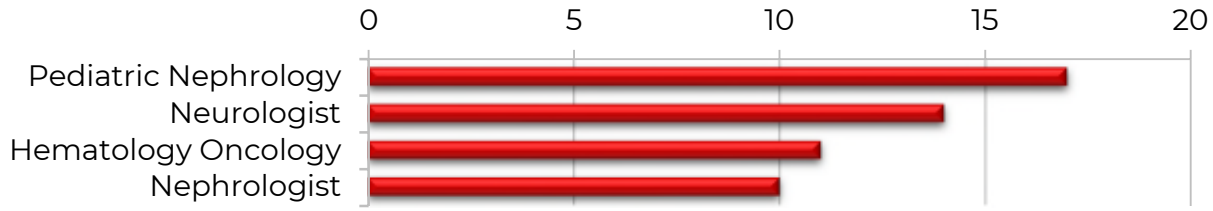
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	15	121	$3,016,651.73	$24,931.01	8.07
2023 Total	**15**	**121**	**$3,016,651.73**	**$24,931.01**	**8.07**
Fiscal Year 2024					
FFS	18	159	$3,653,783.50	$22,979.77	8.83
Aetna	1	1	$16,920.90	$16,920.90	1
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**18**	**160**	**$3,670,704.40**	**$22,941.90**	**8.89**
% Change	**20.00%**	**32.23%**	**21.68%**	**-7.98%**	**10.16%**
Change	**3**	**39**	**$654,052.67**	**-$1,989.11**	**0.82**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Demographics of Members Utilizing Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing complement inhibitors and miscellaneous immunomodulatory agents during fiscal year 2024, detailed demographic information could not be provided.

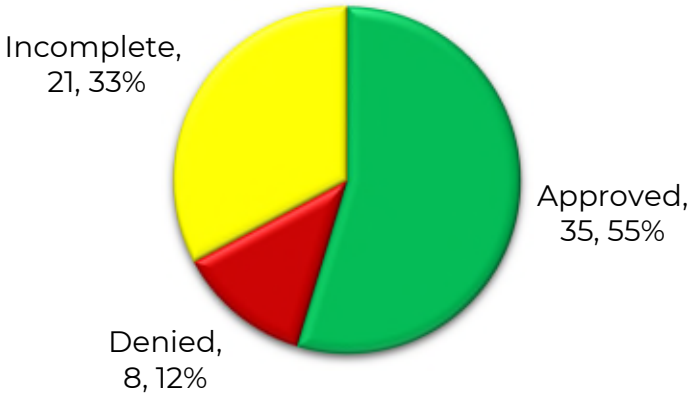
Top Prescriber Specialties of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Pharmacy Claims (All Plans)



Prior Authorization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents

There were 64 prior authorization requests submitted for the complement inhibitors and miscellaneous immunomodulatory agents during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	27	49%	21	38%	7	13%	**55**
Aetna	1	100%	0	0%	0	0%	**1**
Humana	5	100%	0	0%	0	0%	**5**
OCH	2	67%	0	0%	1	33%	**3**
Total	**35**	**55%**	**21**	**33%**	**8**	**12%**	**64**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans

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

Anticipated Patent Expiration(s):

- Voydeya™ (danicopan): February 2035
- Zilbrysq® (zilucoplan): June 2035
- Empaveli® (pegcetacoplan): December 2038
- Fabhalta® (iptacopan): July 2041

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

- **December 2023:** The FDA approved Fabhalta® (iptacopan), a complement factor B inhibitor, as the first oral monotherapy for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
- **March 2024:** The FDA approved Voydeya™ (danicopan), complement factor D inhibitor, as add-on therapy to Soliris® (eculizumab) or Ultomiris® (ravulizumab-cwvz) for the treatment of extravascular hemolysis (EVH) in adults with PNH.
- **March 2024:** The FDA approved Ultomiris® (ravulizumab-cwvz) for a new indication for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive. Soliris® (eculizumab) and Ultomiris® are now FDA approved for the same 4 indications of atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG), PNH, and now NMOSD. Ultomiris® has been modified to provide an extended half-life enabling a longer dosing interval of 8 weeks vs. every 2 weeks with Soliris®. The approval of Ultomiris® for NMOSD was based on the results of the CHAMPION-NMOSD Phase 3 clinical trial which compared Ultomiris® to an external placebo arm from the Soliris® PREVENT clinical trial. The primary endpoint, which was the time to first adjudicated on-trial relapse, was met; no patients had a relapse in the Ultomiris® group over the course of 84 patient-years compared to 20 patients who had an adjudicated relapse in the PREVENT placebo group over the course of 46.9 patient-years.
- **May 2024:** The FDA approved Bkemv™ (eculizumab-aeeb) as an interchangeable biosimilar to Soliris® (eculizumab). Bkemv™ was approved for the treatment of patients with PNH or aHUS, 2 of the 4 currently approved indications for Soliris®.
- **June 2024:** The FDA approved a new indication for Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) to treat chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. The approval was based on the results of the ADHERE trial, which was a 2 stage, multicenter trial that included an open-label period, stage A, to identify Vyvgart® Hytrulo responders who then entered a randomized, double-blind, placebo controlled, withdrawal period, stage B. The results of stage A showed 69% (221/322) of patients treated with Vyvgart® Hytrulo were responders, regardless of prior treatment. Additionally, stage B

met its primary endpoint demonstrating a 61% reduction in the risk of relapse versus placebo [hazard ratio (HR): 0.39; 95% confidence interval (CI): 0.25, 0.61; P<0.0001].

- **June 2024:** The FDA approved Piasky® (crovalimab-akkz), a complement C5 inhibitor, for the treatment of PNH in adult and pediatric patients 13 years of age and older who weigh at least 40kg.
- **July 2024:** The FDA approved Epysqli® (eculizumab-aagh) as a biosimilar to Soliris® for the treatment of PNH and aHUS. This is the second biosimilar to Soliris® approved.
- **August 2024:** The FDA granted accelerated approval for Fabhalta® for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of rapid disease progression. Fabhalta® is the first complement inhibitor approved for this indication.
- **October 2024:** The FDA approved a new indication for Bkemv™ to treat generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Bkemv™ is now approved for 3 of the 4 approved indications for Soliris®.
- **November 2024:** The FDA approved a new indication for Epysqli® to treat gMG in adult patients who are anti-AChR antibody positive. Epysqli® is now approved for 3 of the 4 approved indications for Soliris®.

Guidelines:

- **August 2024:** Updated draft guidelines for the management of Immunoglobin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV) were published by the Kidney Disease Improving Global Outcomes (KDIGO) for public draft review. Some of the key updates included:
    - The definition of a patient at risk of progressive loss of kidney function was changed from the prior definition of proteinuria >0.75-1g/day despite ≥90 days of optimized supportive care. The update defines at risk patients as having proteinuria ≥0.5g/day (or equivalent), while on or off treatment for IgAN, and recommends treatment/additional treatment should be started in all cases.
    - The treatment goal is to reduce the rate of loss of kidney function <1mL/min per year for the rest of a patient's life. Urine protein excretion is the only validated biomarker to help guide clinical decision making and should be maintained <0.5 g/day and multiple therapies may be needed to achieve this goal.
    - The focus of management for most patients should be simultaneous to prevent or reduce IgA immune complex formation and immune complex-mediated glomerular injury [i.e. treatment with Tarpeyo® (budesonide delayed-release capsule)] as well as to manage the consequences of existing IgAN induced nephron loss [i.e., treatment with lifestyle modifications, renin-

angiotensin system inhibitors (RASi), and sodium-glucose cotransporter-2 (SGLT-2) inhibitors].

Pipeline:

- **Batoclimab:** Batoclimab is a fully humanized monoclonal IgG antibody that is a neonatal Fc receptor (FcRn) antagonist. It is currently being studied for gMG and would be the third medication in this class after Vyvgart® and Rystiggo®. The results of a recent Phase 3 trial showed that, after 6 weeks of treatment, the batoclimab-treated group had a greater sustained improvement in the myasthenia gravis activities of daily living (MG-ADL) score compared to the placebo-treated group (58% vs. 31%, respectively; P=0.001).

Fabhalta® (Iptacopan) Product Summary[19]

Therapeutic Class: Complement factor B inhibitor

Indication(s):

- Treatment of adults with PNH
- Reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g
    - This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Fabhalta® slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

How Supplied: 200mg oral capsule

Dosing and Administration:

- 200mg orally twice daily with or without food
- Patients switching from Soliris® (eculizumab) should initiate Fabhalta® no later than 1 week after the last dose of Soliris®.
- Patients switching from Ultomiris® (ravulizumab-cwvz) should initiate Fabhalta® no later than 6 weeks after the last dose of Ultomiris®.

Efficacy:

- The efficacy of Fabhalta® for the treatment of adults with PNH was studied in 2 clinical trials, the Phase 3 APPLY-PNH trial which studied patients with residual anemia already on an anti-C5 treatment and the Phase 3 APPOINT-PNH trial that studied treatment-naïve patients with PNH. The Phase 3 APPLY-PNH trial was a multi-center, randomized, open-label, active comparator-controlled, parallel group study. The

Phase 3 APPOINT-PNH trial was a multi-center, single-arm, open-label trial.

- Key Inclusion Criteria:
    - Both trials:
        - ≥18 years of age
        - Diagnosis of PNH confirmed by high-sensitivity flow cytometry with clone size ≥10%
        - Mean hemoglobin (Hb) level <10g/dL
    - APPLY-PNH required the patient to be on a stable dose of an anti-C5 treatment (eculizumab or ravulizumab) for at least 6 months prior to randomization.
    - APPOINT-PNH required lactate dehydrogenase (LDH) to be >1.5 x upper limit of normal (ULN).
- Intervention:
    - APPLY-PNH:
        - Patients were randomized (8:5) to 1 of the following regimens for 24 weeks:
            - Fabhalta® 200mg orally twice daily
            - Continue anti-C5 treatment
    - APPOINT-PNH:
        - All patients received Fabhalta® 200mg orally twice daily for 24 weeks
- Primary Outcomes and Results:
    - APPLY-PNH:
        - Proportion of patients demonstrating:
            - Sustained increase in ≥2g/dL in Hb levels from baseline in the absence of transfusions
                - 82.3% in the Fabhalta® treated group vs. 0% anti-C5 treatment group (difference: 81.5%; 95% CI: 71.6, 91.4; P<0.0001)
            - Sustained Hb levels ≥12g/dL in the absence of transfusions
                - 67.7% in the Fabhalta® treated group vs. 0% anti-C5 treatment group (difference: 66.6%; 95% CI: 54.6, 78.6; P<0.0001)
    - APPOINT-PNH:
        - Proportion of patients achieving an increase in Hb levels from baseline ≥2g/dL in the absence of transfusions
            - 77.5% of patients treated with Fabhalta® achieved this outcome (95% CI: 61.5%, 89.2%)

- The efficacy of Fabhalta® for the treatment of IgAN was studied in a multi-center, randomized, double-blind trial, called APPLAUSE-IgAN.
  - Key Inclusion Criteria:
    - ≥18 years of age
    - Biopsy-proven IgAN
    - eGFR ≥20mL/min/1.73m^2
    - UPCR ≥1g/g
    - Stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy with or without a stable dose of a sodium-glucose cotransporter-2 (SGLT-2) inhibitor
  - Intervention:
    - Randomized 1:1 to either Fabhalta® 200mg or placebo twice daily
  - Primary Outcomes and Results:
    - Percent reduction in UPCR at 9 months relative to baseline
      - 44% in the Fabhalta® group vs. 9% in the placebo group (difference: 38%; 95% CI: 26%, 49%; P<0.0001)

Piasky® (Crovalimab-akkz) Product Summary[20]

Therapeutic Class: Complement C5 inhibitor

Indication(s): Treatment of PNH in adult and pediatric patients 13 years of age and older who weigh ≥40kg

How Supplied: 340mg/2mL in a single-dose vial for injection

Dosing and Administration:

- One loading dose administered by intravenous (IV) infusion on day 1, followed by 4 additional weekly loading doses administered by subcutaneous (sub-Q) injections on day 2, 8, 15, and 22.
- The maintenance dose should start on day 29 and is administered every 4 weeks by sub-Q injection.
- The recommended dosing is based on actual body weight (see Figure 1 below).

Figure 1: Piasky® Dosage Regimen Based on Body Weight

Body Weight	≥40kg to <100kg	≥100kg
Loading Dose		
Day 1	1,000mg (IV)	1,500 mg (IV)
Day 2, 8, 15, 22	340mg (sub-Q)	340mg (sub-Q)
Maintenance Dose		
Day 29 & every 4 weeks after	680mg (sub-Q)	1,020mg (sub-Q)

IV = intravenous; sub-Q = subcutaneous

Efficacy: The efficacy of Piasky® in patients with PNH was studied in COMMODORE 2, a Phase 3, randomized, active-controlled, open-label, non-inferiority trial.

- Key Inclusion Criteria:
  - Actual body weight ≥40kg at screening
  - LDH level ≥2 x ULN at screening
  - ≥1 or more PNH-related signs or symptoms in the past 3 months
  - Not previously treated with a complement inhibitor
- Intervention:
  - 204 patients were randomized in a 2:1 ratio to receive either Piasky® or Soliris® (eculizumab)
  - Additionally, 6 pediatric patients (aged >12 years and body weight ≥40kg) received Piasky® as a separate non-randomized cohort.
- Primary Outcomes and Results:
  - Percentage of patients who achieved transfusion avoidance from baseline through week 25
    - 65.7% in the Piasky® group vs. 68.1% in the Soliris® group (difference: -2.8%; 95% CI: -15.7, 11.1)
  - Percentage of patients with hemolysis control (as measured by the mean proportion of patients with LDH ≤1.5 x ULN) from week 5 through week 25
    - 79.3% in the Piasky® group vs. 79.0% in the Soliris® group (odds ratio: 1.02; 95% CI: 0.57, 1.82)

Voydeya™ (Danicopan) Product Summary[21]

Therapeutic Class: Complement factor D inhibitor

Indication(s): Add-on therapy to ravulizumab or eculizumab for the treatment of EVH in adults with PNH

- **Limitation(s) of Use**: Voydeya™ has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab.

How Supplied: 50mg and 100mg tablets

Dosing and Administration:

- 150mg 3 times a day orally, with or without food.
- Based on clinical response, may increase to 200mg 3 times daily.

Efficacy: The efficacy of Voydeya™ as add-on therapy to ravulizumab or eculizumab was studied in a multiple-region, randomized, double-blind Phase 3 trial, ALXN2040-PNH-301.

- Key Inclusion Criteria:
  - ≥18 years of age

- Diagnosis of PNH with clinically significant EVH defined as anemia (Hb ≤9.5g/dL) with absolute reticulocyte count ≥120 x 10^9/L with or without transfusion support
- On a stable dose of ravulizumab or eculizumab for at least the previous 6 months

- Intervention:
  - 63 patients were randomized in a 2:1 ratio for 12 weeks to receive Voydeya™ or placebo in addition to background ravulizumab or eculizumab treatment.
- Primary Outcome and Results:
  - Mean change from baseline to week 12 in Hb level
    - 2.9g/dL in Voydeya™ group vs. 0.5g/dL in the placebo group (difference: 2.4; 95% CI: 1.7, 3.2; P<0.0007)

Cost Comparison: PNH Therapies

Medication	Cost Per Unit	Cost Per Year
Fabhalta® (Iptacopan) 200mg capsule	**$753.42**	**$542,462.40α**
Voydeya™ (danicopan) 100mg tablet	**$30.60**	**$66,096.00β**
Piasky® (crovalimab-akkz) 340mg/2mL	**$8,845.00**	**$459,940.00+**
Empaveli® (pegcetacoplan) 1080mg/20mL	$234.74	$488,259.20*
Soliris® (eculizumab) 300mg/30mL	$217.43	$508,786.20±
Ultomiris® (ravulizumab-cwvz) 1,100mg/11mL	$2,134.67	$493,108.77∞

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Unit = capsule, mL, or tablet
αCost based on the FDA approved dose of 200mg twice daily.
βCost based on the FDA approved maximum dose of 200mg 3 times daily.
+Cost based on the FDA approved maintenance dose of 680mg sub-Q every 4 weeks for patients weighing ≥40kg to <100kg.
*Cost based on the FDA approved dose of 1,080mg twice weekly.
±Cost based on the FDA approved maintenance dose of 900mg every 2 weeks.
∞Cost based on the FDA approved maintenance dose of 3,300mg every 8 weeks for patients weighing >60kg to <100kg.

Cost Comparison: IgAN Therapies

Medication	Cost Per Unit	Cost Per Year
Fabhalta® (Iptacopan) 200mg capsule	**$753.42**	**$542,462.40α**
Tarpeyo® (budesonide delayed-release) 4mg capsule	$135.35	$146,178.00 β

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Unit = capsule or tablet
αCost based on the FDA approved dose of 200mg twice daily.
βCost based on the FDA approved dose of 16mg orally once daily for a duration of 9 months.

Recommendations

The College of Pharmacy recommends the prior authorization of Fabhalta® (iptacopan), Piasky® (crovalimab-akkz), and Voydeya™ (danicopan) with the following criteria (shown in red):

Fabhalta® (Iptacopan) Approval Criteria [Immunoglobulin A Nephropathy (IgAN) Diagnosis]:

1. An FDA approved indication to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy; and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria >0.5g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. Member must have previously tried Tarpeyo® [budesonide delayed-release (DR) capsule] or a patient-specific, clinically significant reason why the member cannot use Tarpeyo® must be provided; and
8. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Fabhalta® (Iptacopan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Fabhalta® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and

5. For members switching from Soliris® (eculizumab) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 1 week after the last dose of Soliris®; and
6. For members switching from Ultomiris® (ravulizumab-cwvz) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 6 weeks after the last dose of Ultomiris®; and
7. Member must not be receiving Fabhalta® in combination with another complement inhibitor used to treat PNH (i.e., Empaveli®, Piasky®, Soliris®, Ultomiris®, Voydeya®); and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Piasky® (Crovalimab-akkz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 13 years of age or older and must weigh ≥40kg; and
3. Piasky® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Piasky® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from another C5 inhibitor (i.e., Soliris® or Ultomiris®), the prescriber must verify the first intravenous (IV) loading dose of Piasky® will be administered no sooner than the time of the next scheduled C5 inhibitor dose and member will be monitored for Type III hypersensitivity reactions; and
7. Member must not be receiving Piasky® in combination with another complement inhibitor used to treat PNH (i.e., Empaveli®, Fabhalta®, Soliris®, Ultomiris®, Voydeya®); and
8. A quantity limit override for the loading dose will be approved upon meeting Piasky® approval criteria. A quantity limit of 6mL per 28 days will apply for the maintenance dose; and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Voydeya™ (Danicopan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and

3. Voydeya™ must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Member must have been treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab-cwvz) for at least the previous 6 months; and
5. Prescriber must verify member is experiencing clinically significant extravascular hemolysis (EVH) while on Soliris® or Ultomiris®; and
6. Member must remain on treatment with Soliris® or Ultomiris® while on Voydeya™; and
7. Member must not be receiving Voydeya® in combination with another complement protein C3 inhibitor (i.e., Empaveli®) or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Voydeya™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment through therapy; and
10. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy recommends the addition of prior authorization criteria for Ultomiris® (ravulizumab) for a diagnosis of NMOSD and for Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) for a diagnosis of CIPD based on the new FDA approved indications with the following criteria (shown in red):

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 1 relapse in the last 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Ultomiris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and

8. Member must not be receiving Ultomiris® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Soliris®, Uplizna®); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Approval Criteria [Chronic Inflammatory Demyelinating Polyneuropathy (CIPD) Diagnosis]:

1. An FDA approved diagnosis of CIPD; and
2. Member must be 18 years of age or older; and
3. Vyvgart® Hytrulo 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 previously failed treatment with intravenous immunoglobulin (IVIG) or a patient specific, clinically significant reason why the member cannot use intravenous immunoglobulin (IVIG) must be provided; and
5. Initial approvals will be for 12 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy also recommends the prior authorization of Bkemv™ (eculizumab-aeeb) and Epysqli® (eculizumab-aagh) with criteria similar to the Soliris® (eculizumab) approval criteria for aHUS, gMG, and PNH with the following additional criteria (changes shown in red):

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS;
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® 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
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement inhibitor used to treat aHUS (i.e., Ultomiris®); and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:
   a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
   b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and
6. Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
8. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. For use of Bkemv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
10. Use of Bkemv™, Epysqli®, or Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and
11. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®,

Vyvgart®, Vyvgart® Hytrulo) or another complement inhibitor used to treat gMG (i.e., Ultomiris®, Zilbrysq®); and

12. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a ~~gastroenterologist, geneticist,~~ hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® 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
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement protein C5 inhibitor (i.e., Piasky®, Ultomiris®), complement protein C3 inhibitor (i.e., Empaveli®), or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy recommends the following change to the Empaveli® (pegcetacoplan) and Ultomiris® (ravulizumab-cwvz) PNH approval criteria based on the new FDA approvals and to be consistent with clinical practice (changes shown in red):

Empaveli® (Pegcetacoplan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and

3. Empaveli® must be prescribed by, or in consultation with, a ~~gastroenterologist,~~ hematologist, oncologist, ~~geneticist,~~ or a specialist with expertise in the treatment of PNH; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®; and
8. Member must not be receiving Empaveli® in combination with another complement inhibitor used to treat PNH (i.e., Fabhalta®, Piasky®, Soliris®, Ultomiris®, Voydeya®); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be:
   a. 1 month of age or older for the intravenous (IV) formulation; or
   b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Ultomiris® must be prescribed by, or in consultation with, a ~~gastroenterologist,~~ ~~geneticist~~, hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
7. Member must not be receiving Ultomiris® in combination with another complement protein C5 inhibitor (i.e., Piasky®, Soliris®), complement

protein C3 inhibitor (i.e., Empaveli®), or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and

8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends the following changes to the Enspryng® (satralizumab-mwge), Rystiggo® (rozanolixizumab-noli), Soliris® (eculizumab), Ultomiris® (ravulizumab-cwvz), Uplizna® (inebilizumab-cdon), Veopoz® (pozelimab-bbfg), Vyvgart® (efgartigimod Alfa-fcab), Vyvgart® Hytrulo (efgartigimod alfa/Hyaluronidase-qvfc), and Zilbrysq® (zilucoplan) approval criteria to be consistent with clinical practice (changes shown in red):

Enspryng® (Satralizumab-mwge) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and
5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and

13. Member must not be receiving Enpsryng® in combination with other immunomodulators to treat NMOSD (i.e., Soliris®, Ultomiris®, Uplizna®); and
14. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
15. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Rystiggo® (Rozanolixizumab-noli) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IVa; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥3 (with at least 3 points from non-ocular symptoms); and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Rystiggo® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Rystiggo® in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®, Zilbrysq®) or with another neonatal Fc receptor blocker used to treat gMG (i.e., Vyvgart®, Vyvgart® Hytrulo); and
9. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Soliris® (Eculizumab) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and

3. Member must have a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Soliris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Soliris® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Ultomiris®, Uplizna®); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Member must be:
   a. 1 month of age or older for the intravenous (IV) formulation; or
   b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
4. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS; and
5. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
6. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
8. Member must not be receiving Ultomiris® in combination with another complement inhibitor used to treat aHUS (i.e., Soliris®); and

9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Ultomiris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. The subcutaneous (sub-Q) formulation of Ultomiris® will not be approved for a diagnosis of gMG; and
11. Member must not be receiving Ultomiris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo) or another complement inhibitor used to treat gMG (i.e., Soliris®, Zilbrysq®); and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and

4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and
5. Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
15. Member must not be receiving Uplizna® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Soliris®, Ultomiris®); and
16. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Veopoz® (Pozelimab-bbfg) Approval Criteria [CD55-Deficient Protein-Losing Enteropathy (PLE) Diagnosis]:

1. An FDA approved diagnosis of CD55-deficient PLE confirmed by all of the following:

   a. Genetic testing identifying biallelic pathogenic mutations in the *CD55* gene (results of genetic testing must be submitted); and
   b. A history of PLE; and
2. Member has active disease defined by hypoalbuminemia (serum albumin concentration ≤3.2g/dL) with 1 or more of the following signs or symptoms within the last 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema; and
3. Member must be 1 year of age or older; and
4. Prescriber must verify the member has received the meningococcal vaccine 2 weeks prior to treatment unless urgent treatment is needed; and
5. Veopoz® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or other specialist with expertise in the treatment of CD55-deficient PLE; and
6. The prescriber must verify that Veopoz® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a normalization of serum albumin or documentation of a positive clinical response to therapy. Subsequent approvals will be for 1 year.

Vyvgart® (Efgartigimod Alfa-fcab) and Vyvgart® Hytrulo (Efgartigimod alfa/Hyaluronidase-qvfc) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥5; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Vyvgart® or Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Vyvgart® or Vyvgart® Hytrulo in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®,

Zilbrysq®) or with another neonatal Fc receptor blocker used to treat gMG (i.e., Rystiggo®); and
9. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Zilbrysq® (Zilucoplan) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Zilbrysq® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber and pharmacy must be enrolled in the Zilbrysq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Member must not be receiving Zilbrysq® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo) or another complement inhibitor used to treat gMG (i.e., Soliris®, Ultomiris®); and
11. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Zilbrysq®; and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Utilization Details of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ULTOMIRIS INJ 300MG/3ML	17	5	$986,394.95	$58,023.23	3.4	48.95%
SOLIRIS INJ 10MG/ML	13	2	$574,165.78	$44,166.60	6.5	28.49%
EMPAVELI INJ 54MG/ML	9	1	$330,502.05	$36,722.45	9	16.40%
ZILBRYSQ INJ 32.4MG/0.81ML	3	1	$123,922.23	$41,307.41	3	6.15%
TOTAL	**42**	**8***	**$2,014,985.01**	**$47,975.83**	**5.25**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SOLIRIS INJ 10MG/ML	3	1	$104,402.22	$34,800.74	3	64.43%
ULTOMIRIS INJ 300MG/3ML	1	1	$57,647.41	$57,647.41	1	35.57%
TOTAL	**4**	**2***	**$162,049.63**	**$40,512.41**	**2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ZILBRYSQ INJ 32.4MG/0.81ML	3	1	$123,934.23	$41,311.41	3	100%
TOTAL	**3**	**1***	**$123,934.23**	**$41,311.41**	**3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
EMPAVELI INJ 54MG/ML	2	1	$75,138.34	$37,569.17	2	51.61%
ULTOMIRIS INJ 1,100MG/11ML	1	1	$70,455.40	$70,455.40	1	48.39%
TOTAL	**3**	**2***	**$145,593.74**	**$48,531.25**	**1.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VYVGART INJ 400MG/20ML (J9332)	97	7	$1,085,664.00	$11,192.41	13.86
ULTOMIRIS INJ 300MG/30ML (J1303)	33	7	$1,876,089.40	$56,851.19	4.71
SOLIRIS INJ 10MG/ML (J1300)	29	5	$692,030.10	$23,863.11	5.8
TOTAL	**159**	**18***	**$3,653,783.50**	**$22,979.77**	**8.83**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SOLIRIS INJ 10MG/ML (J1300)	1	1	$16,920.90	$16,920.90	1
TOTAL	**1**	**1**	**$16,920.90**	**$16,920.90**	**1**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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Appendix J

Fiscal Year 2024 Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol)

Oklahoma Health Care Authority
December 2024

Current Prior Authorization Criteria

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS I) confirmed by:
   a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing to confirm biallelic pathogenic mutations in the *IDUA* gene (results of genetic testing must be submitted); and
2. For Scheie syndrome, the prescriber must document that the member has moderate-to-severe symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS I; and
4. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency confirmed by:
   a. Enzyme assay demonstrating a deficiency of TPP-1 enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *TPP1* gene (results of genetic testing must be submitted); and

2. Member must be 3 years of age or older; and
3. Brineura® must be prescribed by a specialist with expertise in the treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
4. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration; and
5. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
6. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
7. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
8. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and
9. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
10. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by ≤2 point decline in Motor plus Language CLN2 score from baseline. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Cerdelga® (Eliglustat) Approval Criteria:

1. An FDA approved diagnosis of type 1 Gaucher disease (GD1) confirmed by:
    a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. Member is classified as 1 of the following as detected by an FDA-cleared test:
    a. CYP2D6 extensive metabolizers (EMs); or
    b. CYP2D6 intermediate metabolizers (IMs); or
    c. CYP2D6 poor metabolizers (PMs); and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and

4. Prescriber must verify the member will not take Cerdelga® concurrently with another therapy for GD1; and
5. For CYP2D6 EMs and IMs, a quantity limit of 56 capsules per 28 days will apply. For CYP2D6 PMs, a quantity limit of 28 capsules per 28 days will apply; and
6. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Cerezyme® (Imiglucerase), Elelyso® (Taliglucerase Alfa), and Vpriv® (Velaglucerase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Gaucher disease (GD) confirmed by:
    a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. Prescriber must confirm member has symptomatic (e.g., anemia, thrombocytopenia, bone disease, splenomegaly, hepatomegaly) type 1 or type 3 GD; and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD; and
4. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
5. Prescriber must verify the member will not take the requested therapy concurrently with another therapy for GD; and
6. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of corneal cystine crystal accumulation in members with cystinosis confirmed by 1 of the following:
    a. Identification of cystine crystals in the cornea on slit lamp examination; or
    b. Identification of elevated cystine concentration in polymorphonuclear leukocytes; or

c. Molecular genetic testing confirming biallelic pathogenic variants in the *CTNS* gene (results of genetic testing must be submitted); and
2. The requested medication must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has been counseled on the proper storage of the requested medication; and
4. For Cystadrops®, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Cystaran® must be provided; and
5. A quantity limit of 4 bottles per month will apply.

Elaprase® (Idursulfase) Approval Criteria:

1. An FDA approved diagnosis of Hunter syndrome (mucopolysaccharidosis type II; MPS II) confirmed by:
   a. Enzyme assay demonstrating a deficiency of iduronate-2-sulfatase enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming a hemizygous pathogenic variant in the *IDS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS II; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Elfabrio® (Pegunigalsidase Alfa-iwxj) and Fabrazyme® (Agalsidase Beta) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease confirmed by 1 of the following:
   a. Molecular genetic testing confirming a pathogenic variant in the galactosidase alpha (*GLA*) gene (results of genetic testing must be submitted); or
   b. Enzyme assay demonstrating a deficiency of alpha-galactosidase A enzyme activity (<5% of normal) (results of assay must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Fabry disease; and
3. Requests for Elfabrio® will require a patient-specific, clinically significant reason why the member cannot use Fabrazyme®; and

4. Member will not be approved for concomitant use with Galafold® (migalastat); and
5. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Initial approvals will be for the duration of 6 months. After that time, compliance will be required for continued authorization and prescriber must verify the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Galafold® (Migalastat) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease with a confirmed amenable galactosidase alpha (*GLA*) gene variant based on *in vitro* assay data (results of genetic testing must be submitted); and
2. Galafold® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Fabry disease (or an advanced care practitioner with a supervising physician who is a geneticist or other specialist with expertise in the treatment of Fabry disease); and
3. Member must have an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2; and
4. Galafold® will not be approved for concomitant use with enzyme replacement therapy (ERT); and
5. Galafold® will initially be approved for 6 months. After that time, compliance will be required for continued approval and prescriber must verify the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
6. A quantity limit of 14 capsules per 28 days will apply.

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of lysosomal acid lipase (LAL) deficiency confirmed by:
    a. Enzyme assay demonstrating a deficiency of LAL enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *LIPA* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of LAL deficiency; and
3. Kanuma® (sebelipase alfa) must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and

4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Lamzede® (Velmanase Alfa-tycv) Approval Criteria:

1. An FDA approved diagnosis of alpha-mannosidosis confirmed by:
   a. Enzyme assay verifying alpha-mannosidase enzyme activity <11% of normal (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *MAN2B1* gene (results of genetic testing must be submitted); and
2. Member's recent weight (kg) taken within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
3. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Lamzede®; and
4. Lamzede® must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
   a. Lamzede® must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
5. Lamzede® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; and
6. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Infantile-Onset Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
   a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and

2. Lumizyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
3. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Late-Onset (Non-Infantile) Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
    a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. Provider must document presence of symptoms of Pompe disease; and
3. Lumizyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
5. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Mepsevii® (Vestronidase Alfa-vjbk) Approval Criteria:

1. An FDA approved diagnosis of Sly syndrome (mucopolysaccharidosis VII; MPS VII) confirmed by:
    a. Enzyme assay demonstrating a deficiency of beta-glucuronidase enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing to confirm biallelic pathogenic variants in the *GUSB* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS VII; and
3. Mepsevii® must be administered by a health care professional prepared to manage anaphylaxis; and
4. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
    a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing to confirm biallelic pathogenic variants in the *ARSB* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS VI; and
3. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Nexviazyme® (Avalglucosidase Alfa-ngpt) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
    a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. Prescriber must document presence of symptoms of Pompe disease; and
3. Nexviazyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
5. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Opfolda® (Miglustat) and Pombiliti® (Cipaglucosidase Alfa-atga) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:

   a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. Member must be 18 years of age or older and weigh ≥40kg; and
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Member must be receiving a different enzyme replacement therapy (ERT) for Pompe disease and not experiencing improvement on the current ERT product; and
5. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for at least 60 days after the final dose; and
6. Pombiliti® must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
   a. Must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
7. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease; and
8. Opfolda® must be used in combination with Pombiliti®; and
   a. A separate, completed prior authorization request must be received for both medications; and
9. Member will not be approved for concomitant use with other ERT products for Pompe disease; and
10. Member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
11. For Opfolda®, the following quantity limits will apply:
   a. Weight ≥50kg: 8 capsules per 28 days; or
   b. Weight 40kg to <50kg: 6 capsules per 28 days; and
12. Initial approvals will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Procysbi® (Cysteamine Bitartrate) Delayed-Release Capsule and Granule Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis confirmed by 1 of the following:

    a. Identification of elevated cystine concentration in polymorphonuclear leukocytes; or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *CTNS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a nephrologist or other specialist with expertise in the treatment of cystinosis; and
3. A patient specific, clinically significant reason why the member cannot use the short-acting formulation, Cystagon® (cysteamine bitartrate), must be provided; and
4. Use of Procysbi® granules will also require a patient specific, clinically significant reason why the member cannot use the capsule formulation of Procysbi®.

Vimizim® (Elosulfase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Morquio A syndrome (mucopolysaccharidosis type IVA; MPS IVA) confirmed by:
    a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing to confirm biallelic pathogenic variants in the *GALNS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS IVA; and
3. Vimizim® must be administered by a health care professional prepared to manage anaphylaxis; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Xenpozyme® (Olipudase Alfa-rpcp) Approval Criteria:

1. An FDA approved diagnosis of acid sphingomyelinase deficiency (ASMD) type B or A/B confirmed by:
    a. Documented lab results verifying <10% of acid sphingomyelinase (ASM) activity from control (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *SMPD1* gene (results of genetic testing must be submitted); and

2. Documentation of baseline AST and ALT within 1 month prior to treatment initiation or within 72 hours prior to treatment escalation; and
3. Member's weight (kg) and body mass index (BMI) within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
    a. BMI ≤30: The dosage is based on actual body weight (kg); or
    b. BMI >30: The dosage is based on adjusted body weight; and
4. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Xenpozyme®; and
5. Prescriber must verify ALT and AST will be assessed to manage the risk of elevated transaminases as directed by package labeling; and
6. Xenpozyme® must be administered by a health care provider prepared to manage anaphylaxis. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Xenpozyme® will be administered; and
    a. Xenpozyme® must be shipped via cold chain supply to the health care facility where the member is scheduled to receive treatment; or
    b. Xenpozyme® must be shipped via cold chain supply to the member's home and administered by a home health care provider prepared to manage anaphylaxis, and the member or member's caregiver must be trained on the proper storage of Xenpozyme®; and
        i. For consideration of home administration by a home health care provider, prescriber must verify member is receiving the maintenance dose and is tolerating the Xenpozyme® infusion well; and
7. Xenpozyme® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Zavesca® (Miglustat) Approval Criteria:

1. An FDA approved diagnosis of mild/moderate type 1 Gaucher disease (GD1) confirmed by:
    a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or

   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
   a. Cerezyme® (imiglucerase); or
   b. Elelyso® (taliglucerase alfa); or
   c. Vpriv® (velaglucerase alfa); and
3. Zavesca® is brand preferred. Requests for generic miglustat will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and
5. Prescriber must verify the member will not take Zavesca® concurrently with another therapy for GD1; and
6. A quantity limit of 90 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Utilization of Lysosomal Storage Disease Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	12	134	$3,628,997.28	$27,082.07	$1,137.26	5,428	3,191
2023 Total	**12**	**134**	**$3,628,997.28**	**$27,082.07**	**$1,137.26**	**5,428**	**3,191**
Fiscal Year 2024							
FFS	14	144	$3,836,319.08	$26,641.10	$1,253.70	5,022	3,060
Aetna	1	1	$29,901.41	$29,901.41	$1,067.91	14	28
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	2	4	$95,769.84	$23,942.46	$977.24	65	98
2024 Total	**14**	**149**	**$3,961,990.33**	**$26,590.54**	**$1,243.56**	**5,101**	**3,186**
% Change	**16.70%**	**11.20%**	**9.20%**	**-1.80%**	**9.30%**	**-6.00%**	**-0.20%**
Change	**2**	**15**	**$332,993.05**	**-$491.53**	**$106.30**	**-327**	**-5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	6	124	$1,829,954.57	$14,757.70	20.67
2023 Total	**6**	**124**	**$1,829,954.57**	**$14,757.70**	**20.67**
Fiscal Year 2024					
FFS	7	169	$1,856,581.08	$10,985.69	24.14
Aetna	0	0	$0.00	$0.00	0
Humana	1	2	$6,514.68	$3,257.34	2
OCH	2	4	$65,031.20	$16,257.80	2
2024 Total	**9**	**175**	**$1,928,126.96**	**$11,017.87**	**19.44**
% Change	**50.00%**	**41.13%**	**5.36%**	**-25.34%**	**-5.95%**
Change	**3**	**51**	**$98,172.39**	**-$3,739.83**	**-1.23**

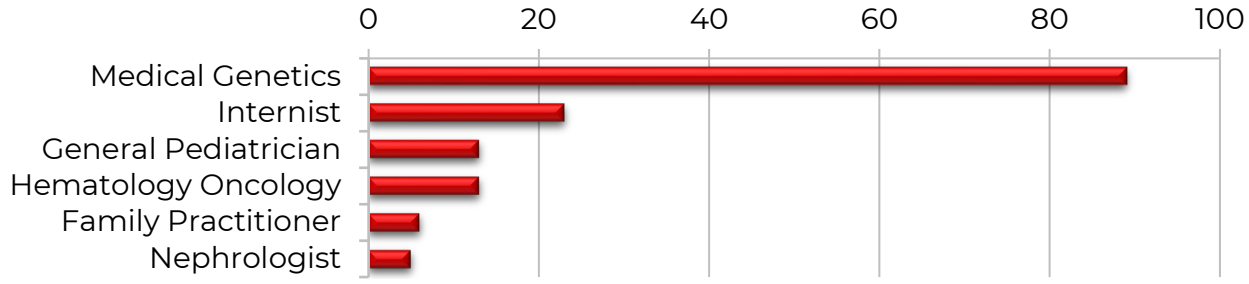
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for lysosomal storage disease medications totaled $1,142,550.65.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Lysosomal Storage Disease Medications: Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing lysosomal storage disease medications during fiscal year 2024, detailed demographic information could not be provided.

Top Prescriber Specialties of Lysosomal Storage Disease Medications: Pharmacy Claims (All Plans)

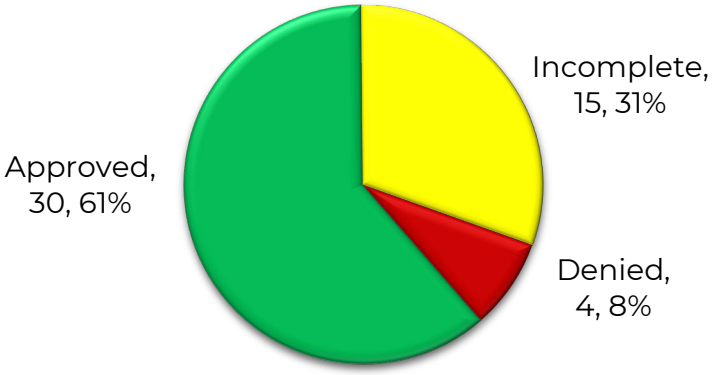


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Prior Authorization of Lysosomal Storage Disease Medications

There were 49 prior authorization requests submitted for lysosomal storage disease medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	28	64%	15	34%	1	2%	**44**
Aetna	0	N/A	0	N/A	0	N/A	**0**
Humana	0	0%	0	0%	2	100%	**2**
OCH	2	67%	0	0%	1	33%	**3**
Total	**30**	**61%**	**15**	**31%**	**4**	**8%**	**49**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Miplyffa™ (arimoclomol): August 2029
- Procysbi® (cysteamine bitartrate): February 2037
- Opfolda® (miglustat): August 2037
- Cerdelga® (eliglustat): December 2038
- Galafold® (migalastat): January 2042

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

- **March 2024:** The FDA approved Lenmeldy™ (atidarsagene autotemcel), an autologous hematopoietic stem cell (HSC)-based gene therapy, for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). Lenmeldy™ is the first FDA approved treatment for MLD.

- **July 2024:** The FDA approved Brineura® (cerliponase alfa) for an age expansion to include patients with neuronal ceroid lipofuscinosis type 2 (CLN2) from the time of birth. Brineura® is not recommended in patients younger than 37 weeks post-menstrual age (gestational age at birth plus post-natal age) or those weighing <2.5kg. Previously, Brineura® was only FDA approved for patients 3 years of age or older with late infantile CLN2. Additionally, a *Boxed Warning* has been added for Brineura® regarding the risk of hypersensitivity reactions, including anaphylaxis.
- **September 2024:** The FDA approved Miplyffa™ (arimoclomol), in combination with miglustat, for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.
- **September 2024:** The FDA approved Aqneursa™ (levacetylleucine) for the treatment of neurological manifestations of NPC in adults and pediatric patients weighing ≥15 kg.

Lenmeldy™ (Atidarsagene Autotemcel) Product Summary[7]

Therapeutic Class: Autologous HSC-based gene therapy

Indication(s): Treatment of children with PSLI, PSEJ, or ESEJ MLD

How Supplied: Single-dose cell suspension for intravenous (IV) infusion contained in 1 to 8 infusion bags which contain 2-11.8 x 10^6 cells/mL (1.8-11.8 x 10^6 CD34+ cells/mL) suspended in cryopreservation solution

Dosing and Administration:

- The dose of Lenmeldy™ is calculated based on body weight and the MLD subtype, with a minimum and maximum recommended dose. The maximum recommended dose is 30 x 10^6 CD34+ cells/kg for all subtypes. The minimum recommended doses are as follows:
  - PSLI: 4.2 x 10^6 CD34+ cells/kg
  - PSEJ: 9 x 10^6 CD34+ cells/kg
  - ESEJ: 6.6 x 10^6 CD34+ cells/kg
- Patients must undergo HSC mobilization followed by apheresis to obtain the CD34+ cells for manufacturing.
- Myeloablative conditioning must be administered before the infusion of Lenmeldy™.
- Lenmeldy™ is administered as an IV infusion via central venous catheter. Up to 8 bags of Lenmeldy™ may be needed to administer the full dose. Each bag should be infused within 30 minutes via gravity or infusion pump. If more than 1 bag is required for the dose, do not administer more than 1 bag per hour.

Efficacy: The efficacy of Lenmeldy™ was assessed in 2 single-arm, open-label studies and a European expanded access program (EAP). In total, efficacy was assessed for 37 patients who received Lenmeldy™, including 20 PSLI patients, 7 PSEJ patients, and 10 ESEJ patients. Efficacy was compared to an external untreated natural history cohort of children with MLD, including 28 patients with late infantile MLD and 21 patients with early juvenile MLD.

- Key Inclusion Criteria:
  - Biochemical and molecular diagnosis of MLD based on:
    - Arylsulfatase A (ARSA) activity below the normal range; and
    - Presence of 2 disease-causing mutations in the *ARSA* gene or, in the case of a novel *ARSA* variant, a 24-hour urine collection was required to show elevated sulfatide levels
- Key Exclusion Criteria:
  - Underwent allogeneic hematopoietic stem cell transplant (HSCT) within the past 6 months
  - Underwent allogeneic HSCT with evidence of residual cells of donor origin
- Intervention(s):
  - Hematopoietic stem cells were collected by bone marrow collection in 29 patients, by apheresis following administration of granulocyte-colony stimulating factor (G-CSF) and plerixafor in 8 patients, or by both methods in 2 patients
  - All patients received busulfan conditioning prior to Lenmeldy™ administration
  - 39 patients received Lenmeldy™, but 2 children with advanced disease were excluded from the efficacy analysis
- Primary Endpoint(s):
  - 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 PSLI MLD patients
- Results:
  - PSLI Patients:
    - 17 PSLI patients treated with Lenmeldy™ have been followed until at least 5 years of age, at which time 100% of the Lenmeldy™-treated patients remained event-free compared to 0% of the untreated late infantile children from the natural history cohort
    - 14 patients treated with Lenmeldy™ had sufficient follow-up to determine survival at 6 years of age, at which time 100% of the Lenmeldy™-treated patients were alive compared to only 58% of the untreated patients
  - For results for the 7 PSEJ and 10 ESEJ patients, please refer to the Lenmeldy™ package labeling.

Cost: The Wholesale Acquisition Cost (WAC) for Lenmeldy™ is $4.25 million per 1-time treatment.

Aqneursa™ (Levacetylleucine) Product Summary[8,9]

Therapeutic Class: Modified amino acid

Indication(s): Treatment of neurological manifestations of NPC in adults and pediatric patients weighing ≥15kg

How Supplied: Unit-dose packets containing 1g levacetylleucine strawberry flavored granules

Dosing and Administration:

- Administered orally up to 3 times daily based on actual body weight:

Body Weight	Morning Dose	Afternoon Dose	Evening Dose
15kg to <25kg	1g	No dose	1g
25kg to <35kg	1g	1g	1g
35kg or more	2g	1g	1g

- If the 2g dose is needed, 2 packets must be prepared individually.
- The contents of 1 packet should be emptied into a container with 40mL of water, orange juice, or almond milk. Hot liquid should not be used. The medication should be stirred to form a suspension.
- The suspension should be swallowed immediately (within 30 minutes).
- The above steps should be repeated with a second packet if a dose of 2g is needed.
- See the full *Prescribing Information* for additional instructions if administration through a gastrostomy tube (G-tube) is needed.

Efficacy: The efficacy of Aqneursa™ was assessed primarily in a Phase 3, randomized, double-blind, placebo-controlled, 2-period crossover study that enrolled a total of 60 patients with NPC.

- Key Inclusion Criteria:
  - Confirmed genetic diagnosis of NPC
  - Must be 4 years of age or older and weigh ≥15kg
  - Presence of at least mild disease-related neurological symptoms
  - If utilizing miglustat, patient must have been on a stable dose for at least 42 days prior to study entry and had to agree to continue it at a stable dose throughout the duration of the study
- Intervention(s): Patients were randomized 1:1 to 1 of 2 treatment sequences:
  - Sequence 1: Levacetylleucine for 12 weeks followed by immediate crossover to placebo for 12 weeks; or
  - Sequence 2: Placebo for 12 weeks followed by immediate crossover to levacetylleucine for 12 weeks

- Primary Endpoint(s):
  - Estimated mean functional scale for assessment and rating of ataxia (fSARA) score assessed at the end of each 12-week treatment period (on a scale from 0-16 with lower scores indicating better neurological status)
- Results:
  - Estimated mean fSARA score was 5.1 while receiving levacetylleucine and 5.6 while receiving placebo [treatment difference: -0.4; 95% confidence interval (CI): -0.7, -0.2; P<0.001]

Miplyffa™ (Arimoclomol) Product Summary[10,11]

Therapeutic Class: Heat shock protein inducer

Indication(s): Treatment, in combination with miglustat, of neurological manifestations of NPC in adult and pediatric patients 2 years of age and older

How Supplied: 47mg, 62mg, 93mg, and 124mg oral capsules

Dosing and Administration: Miplyffa™ should be administered orally, in combination with miglustat, with the following recommended doses based on actual body weight:
- 8 to 15kg: 47mg 3 times a day
- >15kg to 30kg: 62mg 3 times a day
- >30kg to 55kg: 93mg 3 times a day
- >55kg: 124mg 3 times a day
- See the full *Prescribing Information* for additional administration instructions for patients who have difficulty swallowing capsules or when the use of a feeding tube (nasogastric or gastric tube) is needed.

Efficacy: The efficacy of Miplyffa™ was assessed primarily in a Phase 2/3 randomized, double-blind, placebo-controlled study that enrolled a total of 50 patients with NPC.
- Key Inclusion Criteria:
  - Confirmed diagnosis of NPC
  - Must be 2 to 19 years of age
  - Presence of at least 1 neurological sign of disease
  - If utilizing miglustat, patient must have been on a stable dose for at least 6 months prior to study entry
- Intervention(s): Patients were randomized 2:1 to receive weight-adjusted arimoclomol (31mg to 124mg) or placebo orally 3 times per day
- Primary Endpoint Evaluated by the FDA:
  - Change from baseline in the rescored 4-domain NPC clinical severity scale (R4DNPCCSS) score at month 12 in the subgroup of

patients who also received miglustat (on a scale from 0 to 20 with higher scores indicating more severe impairment)

- Results:
  - The least squares mean change in the R4DNPCCSS score was -0.2 points for patients who received arimoclomol plus miglustat compared to an increase of 2 points for patients who received placebo plus miglustat (treatment difference: -2.2; 95% CI: -3.8, -0.6)

Cost Comparison: NPC Products[12]

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Miplyffa™ (arimoclomol) 124mg capsule	**$1,178.00**	**$106,020.00***	**$1,272,240.00**
Aqneursa™ (levacetylleucine) 1g packet	**$480.36**	**$57,643.20⁺**	**$691,718.40**
Zavesca® (miglustat) 100mg capsule	$187.74	$33,793.20Δ	$405,518.40
Yargesa® (miglustat) 100mg capsule (branded generic)	$267.90	$48,222.00Δ	$578,664.00
miglustat 100mg capsule (generic)	$267.90	$48,222.00Δ	$578,664.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = each capsule or packet
*Cost per 30 days based on the FDA approved max dose of 124mg 3 times a day.
⁺Cost per 30 days based on the FDA approved max dose of 4g per day.
ΔCost per 30 days based on a dose of 200mg 3 times a day.

Recommendations

The College of Pharmacy recommends the prior authorization of Aqneursa™ (levacetylleucine), Lenmeldy™ (atidarsagene autotemcel), and Miplyffa™ (arimoclomol) with the following criteria (shown in red):

Aqneursa™ (Levacetylleucine) Approval Criteria:

1. An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Will not be approved for concomitant use with Miplyffa™ (arimoclomol); and
5. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective

contraception during treatment and for 7 days after the last dose of Aqneursa™; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Lenmeldy™ (Atidarsagene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of metachromatic leukodystrophy (MLD) confirmed by:
    a. Arylsulfatase A (ARSA) enzyme activity below the normal range in peripheral blood mononuclear cells or fibroblasts (results of assay must be submitted); and
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *ARSA* gene of known polymorphisms (results of genetic testing must be submitted); or
        i. If novel *ARSA* variant(s) are identified, a 24-hour urine collection must demonstrate increased urinary excretion of sulfatides (results must be submitted); and
2. Member must have 1 of the following forms of MLD as determined by the prescriber (clinical documentation must be submitted with the request):
    a. Pre-symptomatic late infantile (PSLI) MLD with expected disease onset ≤30 months of age; or
    b. Pre-symptomatic early juvenile (PSEJ) MLD with expected disease onset >30 months and <7 years of age; or
    c. Early symptomatic early juvenile (ESEJ) MLD with disease onset >30 months and <7 years of age; and
3. Member must be younger than 18 years of age; and
4. Must be prescribed by a geneticist, hematologist/oncologist, neurologist, or other specialist with expertise in the treatment of MLD and the administration of Lenmeldy™; and
5. Member must not have a history of prior hematopoietic stem cell transplantation (HSCT); or
    a. If member has had a HSCT, there is no evidence of residual cells of donor origin; and
6. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Lenmeldy™); and
7. Member must have a negative serology test for human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), cytomegalovirus (CMV), and mycoplasma prior to apheresis; and

8. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lenmeldy™ administration; and
9. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lenmeldy™; and
10. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
11. Prescriber must verify the member has been evaluated for and counseled on all warnings and precautions related to Lenmeldy™, including the risk of thrombosis and thromboembolic events, serious infections, and veno-occlusive disease; and
12. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed annually and integration site analysis as warranted for at least 15 years after treatment with Lenmeldy™; and
13. Must be administered at a Lenmeldy™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Lenmeldy™ dose from receipt to storage to administration; and
14. Approvals will be for 1 dose per member per lifetime.

Miplyffa™ (Arimoclomol) Approval Criteria:

1. An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Must be used in combination with Zavesca® (miglustat); and
    a. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. A patient-specific, clinically significant reason why the member cannot use Aqneursa™ (levacetylleucine) must be provided; and
6. Will not be approved for concomitant use with Aqneursa™; and

7. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Prescriber must verify that females of reproductive potential have been counseled on the potential risks of embryofetal harm when administered during pregnancy; and
9. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the approval criteria for Brineura® (cerliponase alfa) based on the recent FDA approved age expansion and label updates (changes shown in red):

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of ~~late infantile~~ neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency confirmed by:
   a. Enzyme assay demonstrating a deficiency of TPP-1 enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *TPP1* gene (results of genetic testing must be submitted); and
2. Member must be ~~3 years of age or older~~ at least 37 weeks post-menstrual age (i.e., gestational age at birth plus post-natal age) and weigh ≥2.5kg; and
3. Brineura® must be prescribed by a specialist with expertise in the treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
4. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration and prepared to manage anaphylaxis; and
5. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
6. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
7. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
8. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and

9. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
10. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by ≤2 point decline in Motor plus Language CLN2 score from baseline. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Lastly, the College of Pharmacy recommends updating the approval criteria for Zavesca® (miglustat) based on net cost and to allow use in patients with NPC (changes and new criteria shown in red):

Zavesca® (Miglustat) Approval Criteria [Gaucher Disease Diagnosis]:

1. An FDA approved diagnosis of mild/moderate type 1 Gaucher disease (GD1) confirmed by:
   a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
   a. Cerezyme® (imiglucerase); or
   b. Elelyso® (taliglucerase alfa); or
   c. Vpriv® (velaglucerase alfa); and
3. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and
5. Prescriber must verify the member will not take Zavesca® concurrently with another therapy for GD1; and
6. A quantity limit of 90 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Zavesca® (Miglustat) Approval Criteria [Niemann-Pick Disease Type C (NPC) Diagnosis]:

1. A diagnosis of NPC confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. For members younger than 12 years of age, 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; and
6. A quantity limit of 180 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Utilization Details of Lysosomal Storage Disease Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CEREZYME INJ 400 UNIT	40	4	$1,013,418.80	$25,335.47	10	26.42%
ELAPRASE INJ 6MG/3ML	37	4	$1,324,715.36	$35,803.12	9.25	34.53%
GALAFOLD CAP 123MG	27	3	$791,142.07	$29,301.56	9	20.62%
FABRAZYME INJ 5MG	19	1	$178,687.96	$9,404.63	19	4.66%
MIGLUSTAT CAP 100MG	11	1	$265,309.99	$24,119.09	11	6.92%
VPRIV INJ 400 UNIT	10	1	$263,044.90	$26,304.49	10	6.86%
TOTAL	**144**	**14***	**$3,836,319.08**	**$26,641.10**	**10.29**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GALAFOLD CAP 123MG	1	1	$29,901.41	$29,901.41	1	100%
TOTAL	**1**	**1***	**$29,901.41**	**$29,901.41**	**1**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VPRIV INJ 400 UNIT	3	1	$90,607.55	$30,202.52	3	94.61%
CEREZYME INJ 400 UNIT	1	1	$5,162.29	$5,162.29	1	5.39%
TOTAL	**4**	**2***	**$95,769.84**	**$23,942.46**	**2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ELAPRASE INJ J1743	70	3	$292,629.02	$4,180.41	23.33
LUMIZYME INJ J0221	43	1	$760,475.70	$17,685.48	43
VPRIV INJ J3385	36	2	$499,112.16	$13,864.23	18
FABRAZYME INJ J0180	20	1	$304,364.20	$15,218.21	20
TOTAL	**169**	**7**	**$1,856,581.08**	**$10,985.69**	**24.14**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Humana Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ELAPRASE INJ J1743	2	1	$6,514.68	$3,257.34	2
TOTAL	**2**	**1**	**$6,514.68**	**$3,257.34**	**2**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
CEREZYME INJ J1786	4	2	$65,031.20	$16,257.80	2
TOTAL	**4**	**2**	**$65,031.20**	**$16,257.80**	**2**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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Appendix K

Fiscal Year 2024 Annual Review of Parathyroid Medications and 30-Day Notice to Prior Authorize Yorvipath® (Palopegteriparatide)

Oklahoma Health Care Authority
December 2024

Current Prior Authorization Criteria

Hectorol® (Doxercalciferol Capsule) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a documented failure or a clinically significant reason why the member cannot use calcitriol.

Natpara® (Parathyroid Hormone Injection) Approval Criteria:

1. An FDA approved indication for use as an adjunct to calcium and vitamin D to control hypocalcemia in members with hypoparathyroidism; and
   a. Natpara® is not FDA approved for hypoparathyroidism caused by calcium-sensing receptor mutations; and
   b. Natpara® is not FDA approved for hypoparathyroidism due to acute post-surgery; and
2. Magnesium deficiency must be ruled out; and
3. Member must have pretreatment serum calcium >7.5mg/dL before starting Natpara®; and
4. Prescriber must verify the member has sufficient 25-hydroxyvitamin D level per standard of care; and
5. Member must be unable to be adequately well controlled on calcium supplements and active forms of vitamin D alone; and
6. Health care provider and dispensing pharmacy must be certified through the Natpara® Risk Evaluation and Mitigation Strategies (REMS) program; and
7. A quantity limit of 2 cartridges [each package contains (2) 14-day cartridges] per 28 days will apply. The maximum covered dose will be 100mcg per day.

Parsabiv® (Etelcalcetide Injection) Approval Criteria:

1. An FDA approved indication for the treatment of secondary hyperparathyroidism (SHPT) in adult members with chronic kidney disease (CKD) on hemodialysis; and
2. Parsabiv® will not be approved for parathyroid carcinoma, primary hyperparathyroidism, or in members with CKD who are not on

hemodialysis (Parsabiv® is not recommended for use in these populations); and
3. Member's corrected serum calcium should be at or above the lower limit of normal (≥8.3mg/dL) prior to initiation, dose increase, or re-initiation of Parsabiv®; and
4. Parsabiv® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
5. Member must have a documented failure or a clinically significant reason why the member cannot use available generic vitamin D analogs including calcitriol; and
6. Member must have a documented failure or a clinically significant reason why the member cannot use Sensipar® (cinacalcet); and
7. A quantity limit of 12 vials per month will apply.

Rayaldee® [Calcifediol Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved indication for the treatment of secondary hyperparathyroidism (SHPT) in adults with chronic kidney disease (CKD) stage 3 or 4; and
2. Member must not have CKD stage 5 or end-stage renal disease on dialysis; and
3. Member should have a serum total 25-hydroxyvitamin D level <30ng/mL before starting treatment; and
4. Member should have a serum calcium level <9.8mg/dL before initiating treatment; and
5. Rayaldee® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
6. Member must have a documented failure or clinically-significant reason why the member cannot use available generic vitamin D analogs including calcitriol; and
7. Initial approval will be for 30mcg daily for 3 months; and
    a. After 3 months, approval for 60mcg daily for 12 months can be considered if intact parathyroid hormone (iPTH) is above the treatment goal and serum calcium is <9.8mg/dL, phosphorus is <5.5mg/dL, and 25-hydroxyvitamin D is <100ng/mL; and
    b. Additional approvals will not be granted if iPTH is persistently abnormally low, serum calcium is consistently above the normal range, or serum 25-hydroxyvitamin D is consistently >100ng/mL; and
8. A quantity limit of 60 capsules per 30 days will apply.

Zemplar® (Paricalcitol Capsule) Approval Criteria:

1. An FDA approved indication for the prevention and treatment of secondary hyperparathyroidism (SHPT) associated with 1 of the following:

    a. Chronic kidney disease (CKD) stage 3 or 4; or
    b. CKD stage 5 in members on hemodialysis or peritoneal dialysis; and
        i. Members with CKD stage 5 should have a corrected total serum calcium ≤9.5mg/dL before initiating treatment; and
2. Member must be 10 years of age or older; and
3. Zemplar® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
4. Member must have a documented failure or a clinically significant reason why the member cannot use other generic vitamin D analogs available without prior authorization including calcitriol and Zemplar® injection; and
5. A quantity limit of 30 capsules per 30 days will apply.

Utilization of Parathyroid Medications: Fiscal Year 2024

Comparison of Fiscal Years: Calcimimetics and Vitamin D Analogs (All Plans)

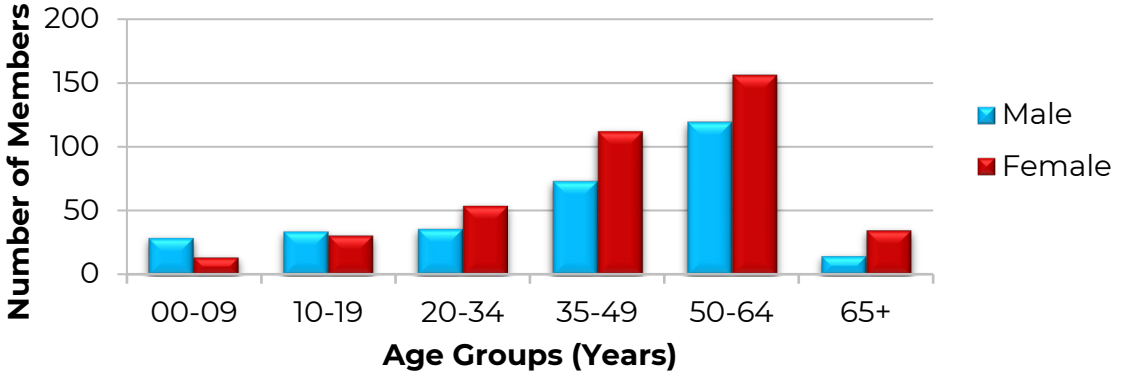
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	701	2,630	$91,617.01	$34.84	$0.84	127,769	108,874
2023 Total	**701**	**2,630**	**$91,617.01**	**$34.84**	**$0.84**	**127,769**	**108,874**
Fiscal Year 2024							
FFS	666	2,361	$79,439.08	$33.65	$0.78	120,072	101,307
Aetna	54	98	$3,837.76	$39.16	$1.33	4,774	2,887
Humana	57	112	$4,838.92	$43.20	$1.43	4,501	3,383
OCH	67	134	$3,272.59	$24.42	$0.91	4,745	3,585
2024 Total	**708**	**2,705**	**$91,388.35**	**$33.78**	**$0.82**	**134,092**	**111,162**
% Change	**1.00%**	**2.90%**	**-0.20%**	**-3.00%**	**-2.40%**	**4.90%**	**2.10%**
Change	**7**	**75**	**-$228.66**	**-$1.06**	**-$0.02**	**6,323**	**2,288**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: There were no paid claims for Natpara® during fiscal years 2023 or 2024.

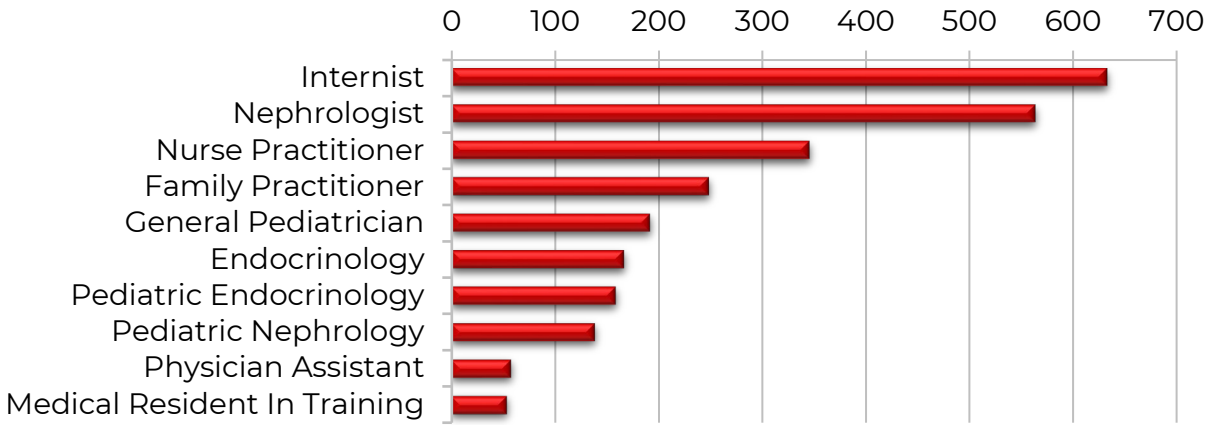
- Aggregate drug rebates collected during fiscal year 2024 for the parathyroid medications totaled $33,991.57.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[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 Parathyroid Medications (All Plans)



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



Prior Authorization of Parathyroid Medications

There were 60 prior authorization requests submitted for parathyroid medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	19	33%	26	45%	13	22%	**58**
Aetna	1	100%	0	0%	0	0%	**1**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	1	100%	0	0%	0	0%	**1**
Total	**21**	**35%**	**26**	**43%**	**13**	**22%**	**60**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Sensipar® (cinacalcet tablets): September 2026
- Rayaldee® [calcifediol extended-release (ER) capsules]: March 2034
- Parsabiv® (etelcalcetide injection): June 2034

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

- **August 2024:** The FDA approved Yorvipath® (palopegteriparatide) subcutaneous (sub-Q) injection for the treatment of hypoparathyroidism in adults.

News:

- **October 2022:** It was announced that Takeda will be discontinuing the manufacturing of Natpara® globally at the end of 2024. Supply issues concerning protein particle formation specific and unique to Natpara® led to a recall of Natpara® in 2019, and Takeda explored numerous ways to address the issue but determined that there was not a sustainable solution going forward. Takeda intends to supply available doses to patients currently on Natpara® until stock is expired or depleted.

Pipeline:

- **Eneboparatide:** Eneboparatide is an investigational therapeutic peptide that binds with high affinity to a specific combination of the parathyroid hormone (PTH) receptor being studied for the treatment of hypoparathyroidism. Eneboparatide is designed to have a short half-life to potentially preserve bone integrity. A Phase 3 trial is currently ongoing and has enrolled 165 patients treated with standard of care therapy. The FDA has granted Fast Track designation to eneboparatide.

Yorvipath® (Palopegteriparatide) Product Summary[5]

Therapeutic Class: PTH analog

Indication(s): Treatment of hypoparathyroidism in adults

- **Limitation(s) of Use:**
  - Not studied for acute post-surgical hypoparathyroidism
  - Titration scheme only evaluated in adults who first achieved an albumin-corrected serum calcium (Ca) of at least 7.8mg/dL using Ca and active vitamin D treatment

How Supplied: Single-patient use prefilled pens with labeled dosing that can administer 14 doses. Each box contains 2 prefilled pens in the following strengths:

- 168mcg/0.56mL, labeled doses of 6, 9, or 12mcg
- 294mcg/0.98mL, labeled doses of 15, 18, or 21mcg
- 420mcg/1.4mL, labeled doses of 24, 27, or 30mcg

Dosing and Administration:

- The recommended starting dose is 18mcg sub-Q once daily that can be titrated in 3mcg increments or decrements up to a maximum recommended dose of 30mcg sub-Q once daily.
- Only 1 injection should be used to achieve the once daily recommended dosage as using 2 injections increases the risks of unintended changes in serum calcium levels.
- The dose for Yorvipath® should be individualized based on serum Ca levels.

Efficacy: The efficacy of Yorvipath® was studied in a randomized, double-blind, placebo-controlled Phase 3 trial in 82 patients with hypoparathyroidism.

- <u>Key Inclusion Criteria:</u>
  - Postsurgical chronic hypoparathyroidism or auto-immune, genetic, or idiopathic hypoparathyroidism for at least 26 weeks
  - Treated with calcitriol ≥0.5mcg/d or alfacalcidola ≥1.0 mcg/d in addition to elemental Ca ≥800 mg/d for ≥12 weeks before screening, and on stable doses for ≥5 weeks
  - Albumin-adjusted serum Ca ≥7.8mg/dL, 25 (OH) vitamin D level of 20-80ng/mL, and a magnesium level ≥1.3mg/dL prior to randomization
  - 24-hour urinary Ca excretion >125mg/24 hours
- <u>Intervention(s):</u>
  - Randomized 3:1 to Yorvipath® or placebo at a starting dose of 18mcg/day co-administered with conventional therapy
    - Randomization was stratified based on etiology of hypoparathyroidism; and
    - Therapy was titrated based on album-corrected serum Ca levels

- Primary Endpoint(s):
  - Proportion of patients who achieved the following at week 26:
    - Albumin-corrected serum Ca within the normal range; and
    - Independence from conventional therapy; and
    - No increase in the trial drug at week 22; and
    - No missing active vitamin D and Ca at week 22; and
    - Trial drug dose of ≤30mcg once daily during week 26
- Results:
  - Overall response at week 26:
    - Achieved by 69% of patients who received Yorvipath® vs. 4.8% of patients on placebo [response rate difference: 64.2%; 95% confidence interval (CI): 49.5%, 78.8%]
  - Independence from active vitamin D:
    - Achieved by 80.3% of patients on Yorvipath® vs. 47.6% of those on placebo (response rate difference: 32.7%; 95% CI: 9.2%, 56.3%)
  - Independence from therapeutic dose of Ca:
    - Achieved by 86.9% of those on Yorvipath® vs. 4.8% on placebo (response rate difference: 82.2%; 95% CI: 70%, 94.4%)
  - No increase in study drug dose since week 22:
    - Achieved by 93.4% of patients on Yorvipath® vs. 57.1% on placebo (response rate difference: 36.4%; 95% CI: 14.2%, 58.5%)
  - Study drug dose </=30mcg/day up to week 26:
    - Achieved by 91.8% of patients on Yorvipath®.

Cost: The Wholesale Acquisition Cost (WAC) of Yorvipath® is $10,962.50 per mL. This results in an estimated cost of $21,925.00 per 28 days and $285,025.10 per year regardless of dose.

Recommendations

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

Yorvipath® (Palopegteriparatide) Approval Criteria

1. An FDA approved diagnosis of hypoparathyroidism; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify the following:
   a. Member has albumin-corrected serum calcium ≥7.8mg/dL and serum 25(OH) vitamin D is within the normal range; and
   b. Serum calcium will be measured within 7-10 days after the first dose and after any dose change in Yorvipath®, active vitamin D, or calcium supplements; and

c. Member or member's caregiver has been trained by a health care professional on proper storage, preparation, and subcutaneous (sub-Q) administration of Yorvipath®; and
d. Member must not have acute post-surgical hypoparathyroidism; and

4. Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and
5. A quantity limit of 2 pre-filled pens [each package contains (2) 14-day pre-filled pens] per 28 days will apply. The maximum covered dose will be 30mcg per day.

Additionally, the College of Pharmacy recommends the removal of SoonerCare coverage and the prior authorization criteria for Natpara® (parathyroid hormone) based on product discontinuation (changes shown in red):

~~**Natpara® (Parathyroid Hormone) Approval Criteria:**~~

~~1. An FDA approved indication for use as an adjunct to calcium and vitamin D to control hypocalcemia in members with hypoparathyroidism; and~~
~~a. Natpara is not FDA approved for hypoparathyroidism caused by calcium-sensing receptor mutations; and~~
~~b. Natpara is not FDA approved for hypoparathyroidism due to acute post-surgery; and~~
~~2. Magnesium deficiency must be ruled out; and~~
~~3. Member must have pretreatment serum calcium above 7.5mg/dL before starting Natpara; and~~
~~4. Prescriber must verify the member has sufficient 25-hydroxyvitamin D level per standard of care; and~~
~~5. Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and~~
~~6. Health care provider and dispensing pharmacy must be certified through the Natpara REMS Program; and~~
~~7. A quantity limit of two cartridges (each package contains two 14-day cartridges) per 28 days will apply. The maximum covered dose will be 100mcg per day.~~

Utilization Details of Parathyroid Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITAMIN D ANALOG PRODUCTS						
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	1,228	410	$22,719.71	$18.50	3	28.60%
CALCITRIOL CAP 0.5MCG	463	144	$12,257.28	$26.47	3.22	15.43%
CALCITRIOL SOL 1MCG/ML	145	44	$17,514.11	$120.79	3.3	22.05%
SUBTOTAL	**1,836**	**598**	**$52,491.10**	**$28.59**	**3.07**	**66.08%**
PARICALCITRIOL PRODUCTS						
PARICALCITOL CAP 1 MCG	15	2	$571.54	$38.10	7.5	0.72%
PARICALCITOL CAP 2 MCG	4	1	$285.64	$71.41	4	0.36%
SUBTOTAL	**19**	**3**	**$857.18**	**$45.11**	**6.33**	**1.08%**
CALCIFEDIOL PRODUCTS						
RAYALDEE CAP 30MCG	7	2	$8,205.21	$1,172.17	3.5	10.33%
SUBTOTAL	**7**	**2**	**$8,205.21**	**$1,172.17**	**3.5**	**10.33%**
VITAMIN D ANALOG SUBTOTAL	**1,862**	**603**	**$61,553.49**	**$33.06**	**3.09**	**77.49%**
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
CINACALCET TAB 30MG	335	99	$7,055.78	$21.06	3.38	8.88%
CINACALCET TAB 60MG	114	33	$3,559.23	$31.22	3.45	4.48%
CINACALCET TAB 90MG	49	16	$2,768.98	$56.51	3.06	3.49%
SUBTOTAL	**498**	**148**	**$13,383.99**	**$26.88**	**3.36**	**16.85%**
ETELCALCETIDE PRODUCTS						
PARSABIV INJ 2.5MG-0.5ML	1	1	$4,501.60	$4,501.60	1	5.67%
SUBTOTAL	**1**	**1**	**$4,501.60**	**$4,501.60**	**1**	**5.67%**
CALCIMIMETIC SUBTOTAL	**499**	**149**	**$17,885.59**	**$35.84**	**3.35**	**22.52%**
TOTAL	**2,361**	**666***	**$79,439.08**	**$33.65**	**3.55**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITAMIN D ANALOG PRODUCTS						
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	49	33	$881.22	$17.98	1.48	22.96%
CALCITRIOL CAP 0.5MCG	36	18	$872.72	$24.24	2	22.74%
CALCITRIOL SOL 1MCG/ML	3	1	$539.38	$179.79	3	14.05%
SUBTOTAL	**88**	**52**	**$2,293.32**	**$26.06**	**1.69**	**59.76%**
PARICALCITRIOL PRODUCTS						
PARICALCITOL CAP 1 MCG	2	1	$70.88	$35.44	2	1.85%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PARICALCITOL CAP 2 MCG	2	1	$178.22	$89.11	2	4.64%
SUBTOTAL	**4**	**2**	**$249.10**	**$62.28**	**2**	**6.49%**
CALCIFEDIOL PRODUCTS						
RAYALDEE CAP 30MCG	1	1	$1,176.03	$1,176.03	1	30.64%
SUBTOTAL	**1**	**1**	**$1,176.03**	**$1,176.03**	**1**	**30.64%**
VITAMIN D ANALOG SUBTOTAL	**93**	**55**	**$3,718.45**	**$39.98**	**1.69**	**96.89%**
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
CINACALCET TAB 60MG	3	1	$79.03	$26.34	3	2.06%
CINACALCET TAB 30MG	2	1	$40.28	$20.14	2	1.05%
CALCIMIMETIC SUBTOTAL	**5**	**2**	**$119.31**	**$23.86**	**2.5**	**3.11%**
TOTAL	**98**	**54***	**$3,837.76**	**$39.16**	**1.81**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITAMIN D ANALOG PRODUCTS						
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	60	32	$1,022.46	$17.04	1.88	21.13%
CALCITRIOL CAP 0.5MCG	30	15	$694.93	$23.16	2	14.36%
CALCITRIOL SOL 1MCG/ML	6	3	$503.79	$83.97	2	10.41%
SUBTOTAL	**96**	**50**	**$2,221.18**	**$23.14**	**1.92**	**45.90%**
CALCIFEDIOL PRODUCTS						
RAYALDEE CAP 30MCG	2	2	$2,360.44	$1,180.22	1	48.78%
SUBTOTAL	**2**	**2**	**$2,360.44**	**$1,180.22**	**1**	**48.78%**
VITAMIN D ANALOG SUBTOTAL	**98**	**52**	**$4,581.62**	**$46.75**	**1.88**	**94.68%**
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
CINACALCET TAB 30MG	14	6	$257.30	$18.38	2.33	5.32%
CALCIMIMETIC SUBTOTAL	**14**	**6**	**$257.30**	**$18.38**	**2.33**	**5.32%**
TOTAL	**112**	**57***	**$4,838.92**	**$43.20**	**1.96**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITAMIN D ANALOG PRODUCTS						
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	83	44	$1,374.63	$16.56	1.89	42.00%
CALCITRIOL CAP 0.5MCG	27	15	$618.87	$22.92	1.8	18.91%
CALCITRIOL SOL 1MCG/ML	9	6	$869.72	$96.64	1.5	26.58%
SUBTOTAL	**119**	**65**	**$2,863.22**	**$24.06**	**1.83**	**87.49%**
PARICALCITRIOL PRODUCTS						
PARICALCITOL CAP 2 MCG	3	1	$214.23	$71.41	3	6.55%
SUBTOTAL	**3**	**1**	**$214.23**	**$71.41**	**3**	**6.55%**
VITAMIN D ANALONG SUBTOTAL	**122**	**66**	**$3,077.45**	**$25.23**	**1.85**	**94.04%**
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
CINACALCET TAB 30MG	12	4	$195.14	$16.26	3	5.96%
CALCIMIMETIC SUBTOTAL	**12**	**4**	**$195.14**	**$16.26**	**3**	**5.96%**
TOTAL	**134**	**67***	**$3,272.59**	**$24.42**	**2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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Appendix L

Fiscal Year 2024 Annual Review of Osteoporosis Medications and 30-Day Notice to Prior Authorize Jubbonti® (Denosumab-bbdz)

Oklahoma Health Care Authority
December 2024

Current Prior Authorization Criteria

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax®)	alendronate + vitamin D tabs (Fosamax® + D)	abaloparatide inj (Tymlos®)
calcium + vitamin D†	risedronate tabs (Actonel®)	alendronate effervescent tabs (Binosto®)
ibandronate tabs (Boniva®)		alendronate soln (Fosamax®)
zoledronic acid inj (Reclast®)		alendronate 40mg tabs (Fosamax®)
		denosumab inj (Prolia®)
		ibandronate inj (Boniva® IV)
		risedronate 30mg tabs (Actonel®)
		risedronate DR tabs (Atelvia®)
		romosozumab-aqqg (Evenity®)
		teriparatide inj (Forteo®)
		teriparatide inj (Bonsity®)

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

Osteoporosis Medications Tier-2 Approval Criteria:

1. A trial of at least 1 Tier-1 bisphosphonate medication, compliantly used for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
2. Hypersensitivity to or intolerable adverse effect(s) with all Tier-1 bisphosphonate medications; and

3. Quantity limits apply based on FDA approved maximum doses.

Actonel® (Risedronate 30mg Tablets), Atelvia® [Risedronate Delayed-Release (DR) Tablets], and Binosto® (Alendronate Effervescent Tablets) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other available Tier-1 and Tier-2 bisphosphonate medications must be provided; or
2. Members with a diagnosis of Paget's disease in claims history will not require prior authorization.

Boniva® [Ibandronate Intravenous (IV) Solution] and Prolia® (Denosumab) Approval Criteria:

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

Evenity® (Romosozumab-aqqg) Approval Criteria:

1. An FDA approved diagnosis of osteoporosis in postmenopausal women at high-risk for fracture; and
2. Member meets 1 of the following:
    a. History of osteoporotic fracture; or
    b. Multiple risk factors for fracture (e.g., T-score ≤-2.5 at the total hip or femoral neck, smoking, corticosteroid use, rheumatoid arthritis); or
    c. Failure of or intolerance to other available osteoporosis therapies; and
3. Prescriber must verify member has not had a myocardial infarction or stroke within the preceding year; and
4. Prescriber must verify calcium levels will be monitored and pre-existing hypocalcemia will be corrected prior to starting therapy; and
5. Prescriber must verify that the member will take adequate calcium and vitamin D supplements during treatment with Evenity® to reduce the risk of hypocalcemia; and
6. Evenity® must be administered by a health care provider; and
7. Approval will be limited to a total duration of 1 year of therapy.

Forteo® (Teriparatide) and Teriparatide Approval Criteria:

1. Diagnosis of 1 of the following:
    a. Treatment of postmenopausal women with osteoporosis at high risk for fracture; or
    b. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or

    c. Treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy at high risk for fracture; or
    d. Treatment of non-healing fracture (this indication only pertains to Forteo®); and
2. A minimum 12-month trial with a bisphosphonate plus adequate calcium and vitamin D or a patient-specific, clinically significant reason why the member cannot use a bisphosphonate must be provided; and
3. Use of teriparatide will require a patient-specific, clinically significant reason why the member cannot use Forteo® (teriparatide); and
4. The diagnosis of non-healing fracture may be approved for 6 months; and
5. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime; and
6. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy.

Fosamax® (Alendronate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of osteoporosis or Paget's disease; and
2. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation must be provided.

Fosamax® (Alendronate 40mg Tablets) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other available Tier-1 and Tier-2 bisphosphonate medications including a 35mg alendronate tablet in combination with a 5mg alendronate tablet to achieve a 40mg dose must be provided; or
2. Members with a diagnosis of Paget's disease in claims history will not require prior authorization.

Tymlos® (Abaloparatide) Approval Criteria:

1. Diagnosis of postmenopausal osteoporosis confirmed by the following:
    a. History of vertebral fracture(s) or low trauma or fragility fracture(s) (e.g., prior fracture from minor trauma such as falling from standing height or less) within the past 5 years; or
    b. A bone mineral density (BMD) test (T-score at or below -2.5) within the last month in the spine, femoral neck, total hip, or 33% radius; or
    c. A T-score between -1.0 and -2.5 in the spine, femoral neck, total hip, or 33% radius, with a FRAX® 10-year probability for major osteoporotic fracture ≥20% or the 10-year probability of hip fracture ≥3%; and
2. One of the following [if a 12-month bisphosphonate trial is inappropriate for the member, the member must have a trial of Prolia® or a selective estrogen receptor modulator (SERM) or a patient-specific,

clinically significant reason why Prolia® or a SERM is not appropriate must be provided]:
   a. A minimum 12-month trial with a bisphosphonate medication plus adequate calcium and vitamin D; or
   b. A 12-month trial of Prolia® (denosumab), unless contraindicated, intolerant, or allergic, that did not yield adequate results; or
   c. A 12-month trial of a SERM, unless contraindicated, intolerant, or allergic, that did not yield adequate results; and
3. A patient-specific, clinically significant reason why the member cannot use Forteo® (teriparatide) must be provided; and
4. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the member's lifetime; and
5. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy; and
6. A quantity limit of 1 pen per 30 days will apply.

Utilization of Osteoporosis Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	1,018	3,108	$403,916.78	$129.96	$2.20	30,576	183,763
2023 Total	**1,018**	**3,108**	**$403,916.78**	**$129.96**	**$2.20**	**30,576**	**183,763**
Fiscal Year 2024							
FFS	977	2,695	$441,917.16	$163.98	$2.76	30,065	160,167
Aetna	61	72	$9,665.97	$134.25	$2.04	736	4,738
Humana	93	172	$16,749.21	$97.38	$2.91	737	5,746
OCH	56	89	$26,883.46	$302.06	$8.87	410	3,030
2024 Total	**1,032**	**3,028**	**$495,215.80**	**$163.55**	**$2.85**	**31,948**	**173,681**
% Change	**1.40%**	**-2.60%**	**22.60%**	**25.80%**	**29.50%**	**4.50%**	**-5.50%**
Change	**14**	**-80**	**$91,299.02**	**$33.59**	**$0.65**	**1,372**	**-10,082**

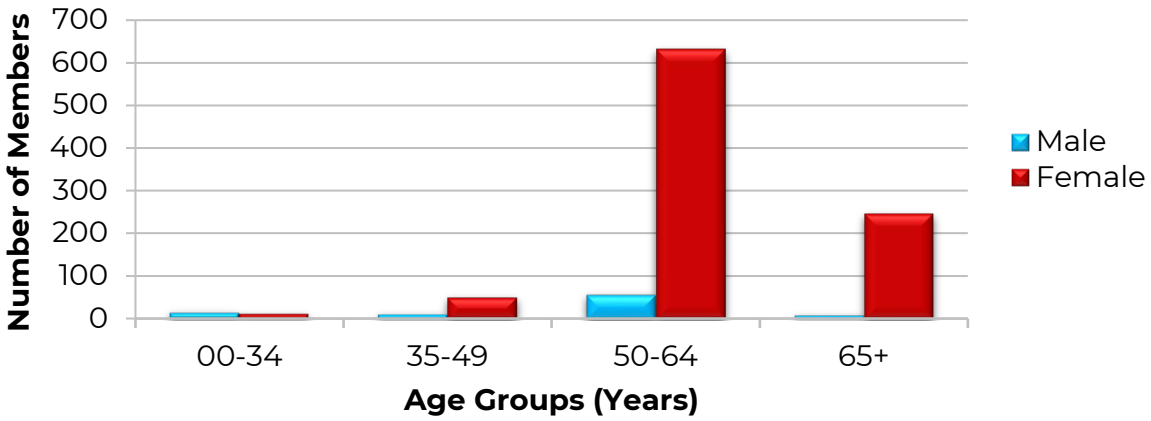
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Comparison of Fiscal Years: Medical Claims (All Plans)

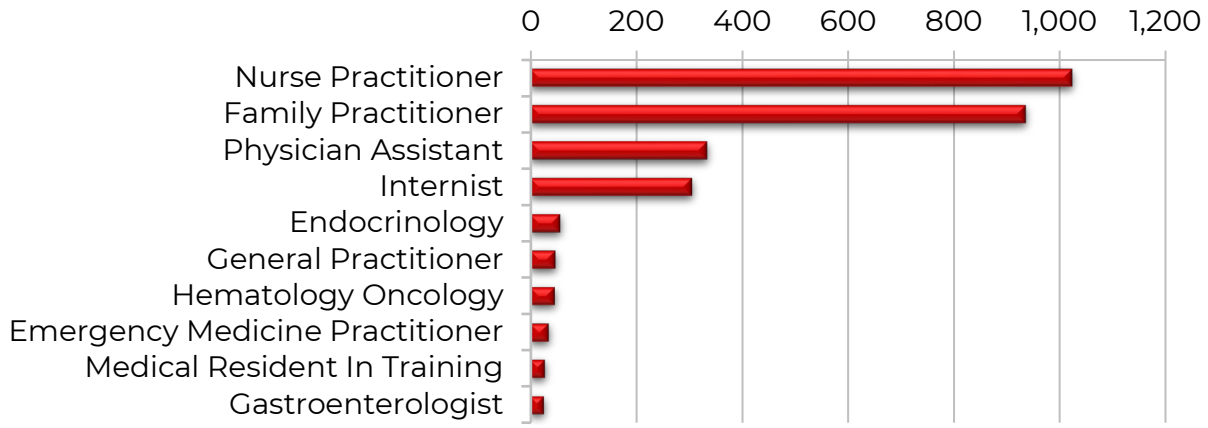
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	243	533	$145,388.76	$272.77	2.19
2023 Total	**243**	**533**	**$145,388.76**	**$272.77**	**2.19**
Fiscal Year 2024					
FFS	299	528	$173,117.41	$327.87	1.77
Aetna	3	3	$3,051.16	$1,017.05	1
Humana	2	2	$56.60	$28.30	1
OCH	10	11	$3,267.05	$297.00	1.1
2024 Total	**306**	**544**	**$179,492.22**	**$329.95**	**1.78**
% Change	**25.93%**	**2.06%**	**23.46**	**20.96%**	**-18.72%**
Change	**63**	**11**	**$34,103.46**	**$57.18**	**-0.41**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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



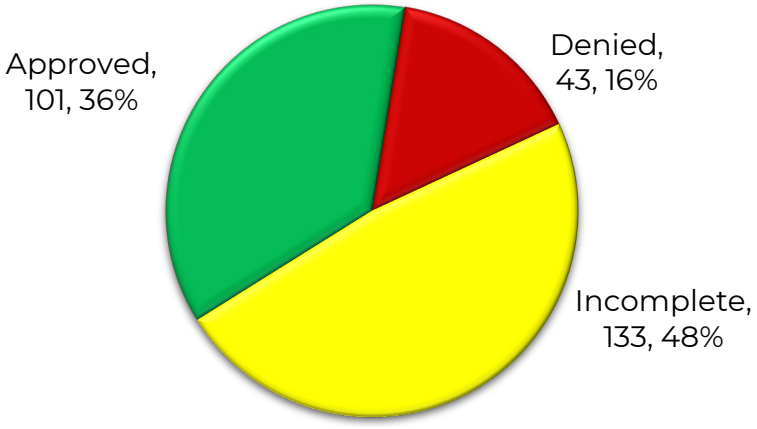
Top Prescriber Specialties of Osteoporosis Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Osteoporosis Medications

There were 277 prior authorization requests submitted for osteoporosis medications during fiscal year 2024. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. Please note: The status of petitions below includes prior authorization requests for Prolia® (denosumab) only when submitted as a pharmacy claim. When billed as a medical claim, Prolia® (denosumab) and Xgeva® (denosumab) are billed using the same procedure code. The status of petitions for all denosumab products submitted as a medical claim was included in the Fiscal Year 2023 Annual Review of Xgeva® (denosumab), which is included in the State Fiscal Year 2023 Quarter 3 Print Annual Reviews Drug Utilization Review (DUR) Board Packet. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	91	35%	133	51%	37	14%	**261**
Aetna	3	60%	0	0%	2	40%	**5**
Humana	5	56%	0	0%	4	44%	**9**
OCH	2	100%	0	0%	0	0%	**2**
Total	**101**	**36%**	**133**	**48%**	**43**	**16%**	**277**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Forteo® (teriparatide injection): March 2025
- Atelvia® [risedronate sodium delayed-release (DR) tablet]: January 2028
- Binosto® (alendronate effervescent tablet): December 2031
- Tymlos® (abaloparatide injection): January 2040

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

- **January 2024:** The FDA announced the addition of a *Boxed Warning* for Prolia® (denosumab) that includes an increased risk of severe hypocalcemia in patients with advanced chronic kidney disease (CKD), including those on dialysis. The investigation found that patients with advanced CKD developed severe hypocalcemia 2 to 10 weeks after each Prolia® injection, with the greatest risk during weeks 2 through 5.
- **March 2024:** The FDA approved Jubbonti® (denosumab-bbdz) injection as the first interchangeable biosimilar to Prolia® (denosumab). Jubbonti® was approved for all currently approved indications for Prolia®.

Pipeline:

- **HLX14:** In October 2024, Organon announced that the FDA accepted the Biologic License Application (BLA) for HLX14, an investigational biosimilar to Prolia® (denosumab). The application is supported by a double-blind, randomized, parallel-controlled, single-dose study that evaluated the pharmacokinetic equivalence of the investigational subcutaneous injection with Prolia® and by a Phase 3 study comparing the safety, efficacy, tolerability, and immunogenicity of HLX14 with Prolia® in postmenopausal women with osteoporosis at high risk for fracture.

Recommendations

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

1. Updating the Osteoporosis Medications Tier-2 Approval Criteria to clarify the requirement for hypersensitivity or intolerance to Tier-1 bisphosphonates; and
2. The prior authorization and placement of Jubbonti® (denosumab-bbdz) into the Special PA Tier chart with unique criteria for use of a biosimilar product; and
3. Adding Bonsity® (teriparatide) to the Forteo® (teriparatide) additional Special PA Approval Criteria for clarity; and
4. Designating Forteo® (teriparatide) as brand preferred and preferring Forteo® (teriparatide) and generic teriparatide over Bonsity® (teriparatide) based on net costs.

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax®)	alendronate + vitamin D tabs (Fosamax® + D)	abaloparatide inj (Tymlos®)
calcium + vitamin D†	risedronate tabs (Actonel®)	alendronate effervescent tabs (Binosto®)
ibandronate tabs (Boniva®)		alendronate soln (Fosamax®)
zoledronic acid inj (Reclast®)		alendronate 40mg tabs (Fosamax®)
		denosumab inj (Prolia®)
		denosumab-bbdz inj (Jubbonti®)
		ibandronate inj (Boniva® IV)
		risedronate 30mg tabs (Actonel®)
		risedronate DR tabs (Atelvia®)
		romosozumab-aqqg (Evenity®)
		teriparatide inj (Forteo®) – **Brand Preferred**
		teriparatide inj (Bonsity®)

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

Osteoporosis Medications Tier-2 Approval Criteria:

1. A trial of at least 1 Tier-1 bisphosphonate medication, compliantly used for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
2. Hypersensitivity to or intolerable adverse effect(s) with all Tier-1 bisphosphonate medications (including oral and intravenous routes of administration); and
3. Quantity limits apply based on FDA approved maximum doses.

Boniva® [Ibandronate Intravenous (IV) Solution], Jubbonti® (Denosumab-bbdz), and Prolia® (Denosumab) Approval Criteria:

1. A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or
2. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and
3. For Jubbonti®, a patient-specific, clinically significant reason why the member cannot use Prolia® (denosumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Bonsity® (Teriparatide) and Forteo® (Teriparatide) ~~and Teriparatide~~ Approval Criteria:

1. Diagnosis of 1 of the following:
   a. Treatment of postmenopausal women with osteoporosis at high risk for fracture; or
   b. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or
   c. Treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy at high risk for fracture; or
   d. Treatment of non-healing fracture (this indication only pertains to Forteo®); and
2. A minimum 12-month trial with a bisphosphonate plus adequate calcium and vitamin D or a patient-specific, clinically significant reason why the member cannot use a bisphosphonate must be provided; and
3. Use of generic teriparatide will require a patient-specific, clinically significant reason why the member cannot use the brand formulation, Forteo® (teriparatide); and

4. Use of Bonsity® (teriparatide) will require a patient-specific, clinically significant reason why the member cannot use Forteo® (teriparatide) or generic teriparatide formulations; and
5. The diagnosis of non-healing fracture may be approved for 6 months; and
6. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime; and
7. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy.

Utilization Details of Osteoporosis Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ALENDRONATE PRODUCTS						
ALENDRONATE TAB 70MG	2,113	758	$26,408.34	$12.50	2.79	5.98%
ALENDRONATE TAB 35MG	116	44	$1,392.12	$12.00	2.64	0.32%
ALENDRONATE TAB 10MG	70	34	$1,057.69	$15.11	2.06	0.24%
SUBTOTAL	**2,299**	**836**	**$28,858.15**	**$12.55**	**2.75**	**6.53%**
IBANDRONATE PRODUCTS						
IBANDRONATE TAB 150MG	186	77	$3,326.53	$17.88	2.42	0.75%
SUBTOTAL	**186**	**77**	**$3,326.53**	**$17.88**	**2.42**	**0.75%**
ZOLEDRONIC ACID PRODUCTS						
RECLAST INJ 5MG/100ML	1	1	$56.84	$56.84	1	0.01%
ZOLEDRONIC INJ 5MG/100ML	1	1	$45.08	$45.08	1	0.01%
SUBTOTAL	**2**	**2**	**$101.92**	**$50.96**	**1**	**0.02%**
TIER-1 SUBTOTAL	**2,487**	**915**	**$32,286.60**	**$12.98**	**2.72**	**7.30%**
TIER-2 PRODUCTS						
RISEDRONATE PRODUCTS						
RISEDRONATE TAB 35MG	12	2	$210.33	$17.53	6	0.05%
RISEDRONATE TAB 5MG	9	1	$558.82	$62.09	9	0.13%
RISEDRONATE TAB 150MG	8	2	$164.32	$20.54	4	0.04%
TIER-2 SUBTOTAL	**29**	**5**	**$933.47**	**$32.19**	**5.8**	**0.22%**
SPECIAL PA PRODUCTS						
TERIPARATIDE PRODUCTS						
FORTEO INJ 600MCG/2.4ML	54	14	$219,790.51	$4,070.19	3.86	49.74%
TERIPARATIDE INJ 600MCG/2.4ML	21	7	$55,506.44	$2,643.16	3	12.56%
SUBTOTAL	**75**	**21**	**$275,296.95**	**$3,670.63**	**3.57**	**62.30%**
DENOSUMAB PRODUCTS						
PROLIA INJ 60MG/ML	65	49	$96,539.37	$1,485.22	1.33	21.85%
SUBTOTAL	**65**	**49**	**$96,539.37**	**$1,485.22**	**1.33**	**21.85%**
ALENDRONATE PRODUCTS						
ALENDRONATE SOL 70MG/75ML	26	3	$5,761.28	$221.59	8.67	1.30%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**26**	**3**	**$5,761.28**	**$221.59**	**8.67**	**1.30%**
ROMOSOZUMAB PRODUCTS						
EVENITY INJ 105MG	13	2	$31,099.49	$2,392.27	6.5	7.04%
SUBTOTAL	**13**	**2**	**$31,099.49**	**$2,392.27**	**6.5**	**7.04%**
SPECIAL PA SUBTOTAL	**179**	**75**	**$408,697.09**	**$2,283.22**	**2.39**	**92.48%**
TOTAL	**2,695**	**977***	**$441,917.16**	**$163.98**	**2.76**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PA = prior authorization; SOL = solution; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ALENDRONATE PRODUCTS						
ALENDRONATE TAB 70MG	62	52	$858.59	$13.85	1.19	8.88%
ALENDRONATE TAB 35MG	2	2	$30.11	$15.06	1	0.31%
ALENDRONATE TAB 10MG	2	2	$34.02	$17.01	1	0.35%
SUBTOTAL	**66**	**56**	**$922.72**	**$13.98**	**1.18**	**9.55%**
IBANDRONATE PRODUCTS						
IBANDRONATE TAB 150MG	2	2	$35.94	$17.97	1	0.37%
SUBTOTAL	**2**	**2**	**$35.94**	**$17.97**	**1**	**0.37%**
TIER-1 SUBTOTAL	**68**	**58**	**$958.66**	**$14.10**	**1.17**	**9.92%**
SPECIAL PA PRODUCTS						
TERIPARATIDE PRODUCTS						
TERIPARATIDE INJ 600MCG/2.4ML	3	2	$7,184.56	$2,394.85	1.5	74.33%
SUBTOTAL	**3**	**2**	**$7,184.56**	**$2,394.85**	**1.5**	**74.33%**
DENOSUMAB PRODUCTS						
PROLIA INJ 60MG/ML	1	1	$1,522.75	$1,522.75	1	15.75%
SUBTOTAL	**1**	**1**	**$1,522.75**	**$1,522.75**	**1**	**15.75%**
SPECIAL PA SUBTOTAL	**4**	**3**	**$8,707.31**	**$2,176.83**	**1.33**	**90.08%**
TOTAL	**72**	**61***	**$9,665.97**	**$134.25**	**1.18**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PA = prior authorization; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ALENDRONATE PRODUCTS						
ALENDRONATE TAB 70MG	125	67	$1,563.25	$12.51	1.87	9.33%
ALENDRONATE TAB 35MG	12	5	$151.74	$12.65	2.4	0.91%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALENDRONATE TAB 10MG	4	2	$58.37	$14.59	2	0.35%
SUBTOTAL	**141**	**74**	**$1,773.36**	**$12.58**	**1.91**	**10.59%**
IBANDRONATE PRODUCTS						
IBANDRONATE TAB 150MG	21	11	$310.87	$14.80	1.91	1.86%
SUBTOTAL	**21**	**11**	**$310.87**	**$14.80**	**1.91**	**1.86%**
TIER-1 SUBTOTAL	**162**	**85**	**$2,084.23**	**$12.87**	**1.91**	**12.44%**
TIER-2 PRODUCTS						
RISEDRONATE PRODUCTS						
RISEDRONATE TAB 150MG	1	1	$22.65	$22.65	1	0.14%
TIER-2 SUBTOTAL	**1**	**1**	**$22.65**	**$22.65**	**1**	**0.14%**
SPECIAL PA PRODUCTS						
TERIPARATIDE PRODUCTS						
TERIPARATIDE INJ 600MCG/2.4ML	4	3	$6,692.60	$1,673.15	1.33	39.96%
SUBTOTAL	**4**	**3**	**$6,692.60**	**$1,673.25**	**1.33**	**39.96%**
DENOSUMAB PRODUCTS						
PROLIA INJ 60MG/ML	5	5	$7,949.73	$1,589.95	1	47.46%
SUBTOTAL	**5**	**5**	**$7,949.73**	**$1,589.95**	**1**	**47.46%**
SPECIAL PA SUBTOTAL	**9**	**8**	**$14,642.33**	**$1,626.93**	**1.13**	**87.42%**
TOTAL	**172**	**93***	**$16,749.21**	**$97.38**	**1.85**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PA = prior authorization; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ALENDRONATE PRODUCTS						
ALENDRONATE TAB 70MG	65	41	$806.04	$12.40	1.59	3.00%
ALENDRONATE TAB 35MG	8	5	$101.02	$12.63	1.6	0.38%
ALENDRONATE TAB 10MG	3	1	$43.65	$14.55	3	0.16%
SUBTOTAL	**76**	**47**	**$950.71**	**$12.51**	**1.62**	**3.54%**
IBANDRONATE PRODUCTS						
IBANDRONATE TAB 150MG	5	4	$74.45	$14.89	1.25	0.28%
SUBTOTAL	**5**	**4**	**$74.45**	**$14.89**	**1.25**	**0.28%**
TIER-1 SUBTOTAL	**81**	**51**	**$1,025.16**	**$12.66**	**1.59**	**3.82%**
SPECIAL PA PRODUCTS						
TERIPARATIDE PRODUCTS						
FORTEO INJ 600MCG/2.4ML	5	2	$20,786.08	$4,157.22	2.5	77.32%
SUBTOTAL	**5**	**2**	**$20,786.08**	**$4,157.22**	**2.5**	**77.32%**
DENOSUMAB PRODUCTS						
PROLIA INJ 60MG/ML	3	3	$5,072.22	$1,690.74	1	18.87%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**3**	**3**	**$5,072.22**	**$1,690.74**	**1**	**18.87%**
SPECIAL PA SUBTOTAL	**8**	**5**	**$25,858.30**	**$3,232.29**	**1.6**	**96.19%**
TOTAL	**89**	**56***	**$26,883.46**	**$302.06**	**1.59**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PA = prior authorization; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Fee-For-Service Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZOLEDRONIC ACID (J3489)	419	222	$12,273.61	$29.24	1.90
PROLIA (J0897)	109	77	$160,843.80	$1,364.39	1.48
TOTAL	**528**	**299**	**$173,117.41**	**$327.87**	**1.77**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZOLEDRONIC ACID (J3489)	1	1	$27.76	$27.76	1
PROLIA (J0897)	2	2	$3,023.40	$1,511.70	1
TOTAL	**3**	**3**	**$3,051.16**	**$1,017.05**	**1**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Humana Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZOLEDRONIC ACID (J3489)	2	2	$56.60	$23.80	1
TOTAL	**2**	**2**	**$56.60**	**$23.80**	**1**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect Plans.

OK Complete Health Medical Claims

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZOLEDRONIC ACID (J3489)	8	7	$244.25	$30.36	1.14
PROLIA (J0897)	3	3	$3,022.80	$1,007.60	1
TOTAL	**11**	**10**	**$3,267.05**	**$297.00**	**1.1**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect Plans.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 11/2024. Last accessed 11/25/2024

[2] U.S. FDA. FDA Adds Boxed Warning for Increased Risk of Severe Hypocalcemia in Patients with Advanced Chronic Kidney disease Taking Osteoporosis Medicine Prolia® (Denosumab). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-severe-hypocalcemia-patients-advanced-chronic-kidney-disease. Last revised 02/01/2024. Last accessed 11/25/2024.

[3] U.S. FDA. FDA Approves First Interchangeable Biosimilars to Prolia® and Xgeva® to Treat Certain Types of Osteoporosis and Prevent Bone Events in Cancer. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-prolia-and-xgeva-treat-certain-types-osteoporosis-and. Issued 03/05/2024. Last accessed 11/25/2024.

[4] Jubbonti® (Denosumab-bbdz) Prescribing Information. Sandoz, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761362s000lbl.pdf. Last revised 03/2024. Last accessed 11/25/2024.

[5] Organon. U.S. FDA Accepts Biologics License Application (BLA) for HLX14, Biosimilar Candidate of Prolia®/Xgeva® (Denosumab). Available online at: https://www.organon.com/news/us-fda-accepts-biologics-license-application-bla-for-hlx14-biosimilar-candidate-of-prolia-xgeva-denosumab/. Issued 10/30/2024. Last accessed 11/25/2024.

Appendix M

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

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: November 14, 2024

FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency

The FDA approved Kebilidi™ (eladocagene exuparvovec-tneq), an adeno-associated virus vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi™ is the first FDA-approved gene therapy for treatment of AADC deficiency. AADC deficiency is a rare genetic disorder that affects the production of some neurotransmitters. Affected individuals may experience symptoms such as delays in gross motor function, hypotonia, and developmental and cognitive delays.

Kebilidi™ is administered via 4 infusions in 1 surgical session into a large structure in the brain involved in motor control. Kebilidi™ should be administered in a medical center that specializes in pediatric stereotactic neurosurgery, a technique that uses imaging and special equipment to deliver therapies to specific areas in the brain. After infusion of Kebilidi™, treatment results in the expression of AADC and subsequent increase in the production of dopamine, a critical neurotransmitter in the brain associated with movement, attention, learning, and memory.

The safety and effectiveness of Kebilidi™ were demonstrated in an open-label, single-arm clinical study in 13 pediatric patients with a confirmed diagnosis of AADC deficiency. At the start of the study, all patients had no gross motor function (the most severe presentation of AADC deficiency) and decreased AADC activity in the plasma. Patients treated with Kebilidi™ were compared to untreated patients (natural history). Motor milestone assessments were completed for 12 of the 13 patients at week 48 after receiving the treatment. The efficacy of Kebilidi™ was demonstrated based on gross motor function improvement in 8 of 12 treated patients, which has not been reported in untreated patients with the severe presentation of AADC deficiency.

The most common adverse reactions of Kebilidi™ are dyskinesia , fever, low blood pressure, anemia, increased saliva production, insomnia, low levels of potassium, phosphate, and/or magnesium, and procedural complications such as respiratory and cardiac arrest. It is also contraindicated in patients who have not achieved skull maturity assessed by neuroimaging.

Kebilidi™ was approved using the Accelerated Approval pathway. Accelerated approval allows the FDA to approve certain products for serious

or life-threatening conditions based on evidence of a product's effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit. In the FDA's evaluation of Kebilidi™ for accelerated approval, evidence of effectiveness is based on early improvements in gross motor function measured at 48 weeks after treatment. Continued approval for this indication may be contingent upon verification and description of clinical benefit of the product, such as the durability of the improvements, in a confirmatory clinical trial. A confirmatory trial is ongoing to verify Kebilidi™'s clinical benefit.

The application received Priority Review and Orphan Drug designation and was granted a rare pediatric disease priority review voucher by the FDA. The FDA also authorized the SmartFlow® Neuro Cannula, an infusion tube inserted into a target in the brain (parenchymal tissue), to deliver Kebilidi™. The SmartFlow® Neuro Cannula is currently the only FDA authorized device indicated for use to administer Kebilidi™. The FDA granted authorization of the SmartFlow® Neuro Cannula to ClearPoint Neuro, Inc. The FDA granted approval of Kebilidi™ to PTC Therapeutics, Inc.

FDA NEWS RELEASE

For Immediate Release: November 7, 2024

FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review

The FDA announced it is proposing to remove oral phenylephrine as an active ingredient that can be used in over-the-counter (OTC) monograph drug products for the temporary relief of nasal congestion after an agency review of the available data determined that oral phenylephrine is not effective for this use. For now, companies may continue to market OTC monograph drug products containing oral phenylephrine as a nasal decongestant. This is a proposed order. Only a final order will affect what products can be marketed. The proposed order is based on effectiveness concerns, not on safety concerns.

Currently, oral phenylephrine is widely used as a nasal decongestant active ingredient in many OTC monograph drug products. It is important to note that some products only contain oral phenylephrine as a single, active ingredient. Others contain oral phenylephrine and another active ingredient (e.g., acetaminophen or dextromethorphan), and the presence of oral phenylephrine in these medicines does not affect how other active ingredients work to treat the symptoms for which they are intended.

The FDA conducted a comprehensive review of all available data on the safety and efficacy of oral phenylephrine, including the historical data that were used to support the determination made 30 years ago that oral phenylephrine was effective as a nasal decongestant, as well as newer clinical data on oral phenylephrine that have since become available.

Last fall, the FDA also held a Nonprescription Drug Advisory Committee meeting to discuss the "Generally Recognized as Safe and Effective" (GRASE) status of oral phenylephrine as a nasal decongestant. The committee discussed new data on the effectiveness of orally administered phenylephrine and unanimously concluded that the current scientific data do not support that the recommended dosage in the OTC cold, cough, allergy, bronchodilator, and anti-asthmatic drug products monograph for orally administered phenylephrine's effectiveness as a nasal decongestant.

Because a variety of different drug products may be sold under the same brand name, consumers should always read the Drug Facts label to determine which ingredients are in a medication, and to be aware of important warnings and directions for use. Phenylephrine is also an ingredient in nasal sprays to treat congestion. The FDA's action is only related to orally administered phenylephrine and not the nasal spray form.

The FDA is seeking public comments on this proposed order. Instructions on how to submit comments are found in the proposed order available on OTC Monographs@FDA. If, after considering the comments, the FDA concludes oral phenylephrine is not effective as a nasal decongestant, the FDA will issue a final order removing oral phenylephrine from the OTC monograph, and drug products thereafter could no longer contain oral phenylephrine as a nasal decongestant. The FDA would provide manufacturers with appropriate time to either reformulate drugs containing oral phenylephrine or remove such drugs from the market.

Current Drug Shortages Index (as of November 27, 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***
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***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***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***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection, Syringes	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Indocyanine Green Injection	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lactated Ringers 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***
Mefloquine Hydrochloride Tablet	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Peritoneal Dialysis Solution	***Currently in Shortage***
Potassium Acetate 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***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***

Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium Tc-99m Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***