OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
October 9, 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 – October 9, 2024

DATE: October 2, 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 October meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on the Medication Coverage Authorization Unit/Fall 2024 Pipeline Update – Appendix B

Action Item – Vote to Prior Authorize Wainua™ (Eplontersen) and Update the Approval Criteria for Amyloidosis Medications – Appendix C

Action Item – Vote to Prior Authorize Hercessi™ (Trastuzumab-strf) and Truqap™ (Capivasertib) and Update the Approval Criteria for the Breast Cancer Medications – Appendix D

Action Item – Annual Review of Myeloproliferative Neoplasm (MPN) Medications – Appendix E

Action Item – Annual Review of Hepatitis C Medications – Appendix F

Annual Review of Targeted Immunomodulator Agents and 30-Day Notice 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) – Appendix G

Annual Review of Hyperoxaluria Medications and 30-Day Notice to Prior Authorize Rivfloza® (Nedosiran) – Appendix H

Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution) – Appendix I

Annual Review of Synagis® (Palivizumab) – Appendix J

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – October 9, 2024 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

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https://oklahoma.zoom.us/webinar/register/WN_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. September 11, 2024 DUR Board Meeting Minutes
   B. September 11, 2024 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Fall 2024 Pipeline Update – See Appendix B**
   A. Pharmacy Help Desk Activity for September 2024
   B. Medication Coverage Activity for September 2024
   C. Fall 2024 Pipeline Update

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

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

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

6. **Action Item – Vote to Prior Authorize Hercessi™ (Trastuzumab-strf) and Truqap™ (Capivasertib) and Update the Approval Criteria for the Breast Cancer Medications – See Appendix D**

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

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

7. **Action Item – Annual Review of Myeloproliferative Neoplasm (MPN) Medications – See Appendix E**

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

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

8. **Action Item – Annual Review of Hepatitis C Medications – See Appendix F**

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

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

9. **Annual Review of Targeted Immunomodulator Agents and 30-Day Notice 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) – See Appendix G**

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

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

10. **Annual Review of Hyperoxaluria Medications and 30-Day Notice to Prior Authorize Rivfloza® (Nedosiran) – See Appendix H**

A. Current Prior Authorization Criteria
B. Utilization of Hyperoxaluria Medications
C. Prior Authorization of Hyperoxaluria Medications

D. Market News and Updates
E. Rivfloza® (Nedosiran) Product Summary
F. College of Pharmacy Recommendations

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

11. Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution) – See Appendix I

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

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

12. Annual Review of Synagis® (Palivizumab) – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of Synagis® (Palivizumab)
C. Prior Authorization of Synagis® (Palivizumab)
D. RSV Season Comparison
E. Market News and Updates
F. College of Pharmacy Recommendations
G. Utilization Details of Synagis® (Palivizumab)

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

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

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

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

A. Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications
B. Atopic Dermatitis Medications
C. Hereditary Angioedema (HAE) Medications
D. Multiple Myeloma Medications

*Future product and class reviews subject to change.

15. 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 SEPTEMBER 11, 2024

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

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
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	
Ryan Gillett, J.D.; Deputy General Counsel IV	X	
Josh Holloway, J.D.; Deputy General Counsel		X
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	

Paula Root, M.D.; Senior Medical Director, Chief Medical Officer		X
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Brielle Dozier, Artia Solutions	Rhonda Clark, Indivior
Lee Stout, Chiesi	John Omick, Travere
Phil Lohec, Viatris	Irene Chung, Aetna
Lauren Stroupe, Capital Results	Roberto Pedraza, Vertex
David Shirkey, ALK	Tyler Womack, OMES
Cheng Yuet, Amgen	Aaron Austin, Takeda
Matt John, Otsuka	Dawn Bey, Vertex
Craig Plauschinat, Eisai	Deidra Williams, Humana
Saurabh Patel, AbbVie	Todd Ness, AbbVie
Kristen Winters, Centene	Melissa Abbott, Eisai
James McAdams, Rigel	David Prather, Novo Nordisk
Bryan Steffan, Boehringer	Logan Poole, Novo Nordisk
Amanda Nowakowski, ViiV	Audrey Rattan, Alkermes
JJ Roth, Mirum	Frank Alvarado, Johnson & Johnson

PRESENT FOR PUBLIC COMMENT:	
Logan Poole, Novo Nordisk	

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:01 pm. 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 LOGAN POOLE

ACTION: NONE REQUIRED

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

3A: JULY 10, 2024 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Patatanian moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/DIRECT ORAL ANTICOAGULANT (DOAC) HEALTH CARE SYSTEM UTILIZATION FOLLOWING REMOVAL OF PRIOR AUTHORIZATION (PA) REQUIREMENT**

4A: PHARMACY HELPDESK ACTIVITY FOR AUGUST 2024

4B: MEDICATION COVERAGE ACTIVITY FOR AUGUST 2024

4C: DOAC HEALTH CARE SYSTEM UTILIZATION FOLLOWING REMOVAL OF PA REQUIREMENT

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE FILSUVEZ® (BIRCH TRITERPENES TOPICAL GEL) AND UPDATE THE APPROVAL CRITERIA FOR THE EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS
5A: MARKET NEWS AND UPDATES
5B: FILSUVEZ® (BIRCH TRITERPENES TOPICAL GEL) PRODUCT SUMMARY
5C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Mr. Foster moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE KISUNLA™ (DONANEMAB-AZBT) AND UPDATE THE APPROVAL CRITERIA FOR THE ALZHEIMER'S DISEASE MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: KISUNLA™ (DONANEMAB-AZBT) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Haymore moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE DEFENCATH® (TAUROLIDINE/HEPARIN)
7A: MARKET NEWS AND UPDATES
7B: DEFENCATH® (TAUROLIDINE/HEPARIN) 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

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE WEGOVY® (SEMAGLUTIDE)
8A: MARKET NEWS AND UPDATES
8B: WEGOVY® (SEMAGLUTIDE) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. West moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE AVZIVI® (BEVACIZUMAB-TNJN) AND FRUZAQLA® (FRUQUINTINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE COLORECTAL CANCER (CRC) MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: FRUZAQLA® (FRUQUINTINIB) PRODUCT SUMMARY
9C: COST COMPARISON: BEVACIZUMAB PRODUCTS
9D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Haymore moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE ACCRUFER® (FERRIC MALTOL) AND UPDATE THE APPROVAL CRITERIA FOR THE IRON PRODUCTS
10A: MARKET NEWS AND UPDATES
10B: ACCRUFER® (FERRIC MALTOL) PRODUCT SUMMARY

10C: COST COMPARISON: INTRAVENOUS (IV) IRON PRODUCTS
10D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE DORYX® MPC [DOXYCYCLINE DELAYED-RELEASE (DR) TABLET], EXBLIFEP® (CEFEPIME/ENMETAZOBACTAM), MEROPENEM 2G VIAL, PIVYA™ (PIVMECILLINAM), NITROFURANTOIN 50MG/ML SUSPENSION, TETRACYCLINE 250MG AND 500MG TABLET, AND ZEVTERA® (CEFTOBIPROLE MEDOCARIL SODIUM) AND UPDATE THE APPROVAL CRITERIA FOR THE VARIOUS SYSTEMIC ANTIBIOTICS
11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: 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

AGENDA ITEM NO. 12: VOTE TO PRIOR AUTHORIZE PENICILLAMINE 250MG TABLET AND TRIENTINE 500MG CAPSULE AND UPDATE THE APPROVAL CRITERIA FOR THE WILSON'S DISEASE MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: COST COMPARISONS
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Haymore moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: VOTE TO PRIOR AUTHORIZE EOHILIA™ (BUDESONIDE ORAL SUSPENSION) AND UPDATE THE APPROVAL CRITERIA FOR THE CORTICOSTEROID SPECIAL FORMULATIONS
13A: MARKET NEWS AND UPDATES
13B: EOHILIA™ (BUDESONIDE ORAL SUSPENSION) PRODUCT SUMMARY
13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Metts
Dr. West recommended listing the generic name instead of Flovent® in criteria #5 and #8c for Eohilia™ due to brand Flovent® no longer being available; Dr. Metts agreed with the update and the DUR Board voted on the amended criteria.
Dr. Haymore moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: VOTE TO PRIOR AUTHORIZE TRAMADOL 25MG TABLET AND UPDATE THE APPROVAL CRITERIA FOR THE OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
14A: COST COMPARISON: TRAMADOL
14B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. West moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE TOPICAL CORTICOSTEROIDS

15A: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 16: ANNUAL REVIEW OF ALLERGEN IMMUNOTHERAPIES

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ALLERGEN IMMUNOTHERAPIES
16C: PRIOR AUTHORIZATION OF ALLERGEN IMMUNOTHERAPIES
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS
16F: UTILIZATION DETAILS OF ALLERGEN IMMUNOTHERAPIES

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

AGENDA ITEM NO. 17: ANNUAL REVIEW OF BREAST CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HERCESSI™ (TRASTUZUMAB-STRF) AND TRUQAP™ (CAPIVASERTIB)

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF BREAST CANCER MEDICATIONS
17C: PRIOR AUTHORIZATION OF BREAST CANCER MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: TRUQAP™ (CAPIVASERTIB) PRODUCT SUMMARY
17F: COST COMPARISON: TRASTUZUMAB PRODUCTS
17G: COLLEGE OF PHARMACY RECOMMENDATIONS
17H: UTILIZATION DETAILS OF BREAST CANCER MEDICATIONS

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

AGENDA ITEM NO. 18: ANNUAL REVIEW OF AMYLOIDOSIS MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE WAINUA™ (EPLONTERSEN)

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF AMYLOIDOSIS MEDICATIONS
18C: PRIOR AUTHORIZATION OF AMYLOIDOSIS MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: WAINUA™ (EPLONTERSEN) PRODUCT SUMMARY
18F: COLLEGE OF PHARMACY RECOMMENDATIONS
18G: UTILIZATION DETAILS OF AMYLOIDOSIS MEDICATIONS

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

AGENDA ITEM NO. 19: ANNUAL REVIEW OF CYSTIC FIBROSIS (CF) MEDICATIONS

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF CF MEDICATIONS
19C: PRIOR AUTHORIZATION OF CF MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: COLLEGE OF PHARMACY RECOMMENDATIONS
19F: UTILIZATION DETAILS OF CF MEDICATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
21A: ANEMIA MEDICATIONS
21B: HEPATITIS C MEDICATIONS
21C: SYNAGIS® (PALIVIZUMAB)
21D: TARGETED IMMUNOMODULATOR AGENTS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 22: ADJOURNMENT
The meeting was adjourned at 5:22 pm.

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

Memorandum

Date: September 13, 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 September 11, 2024

Recommendation 1: Direct Oral Anticoagulant (DOAC) Health Care System Utilization Following Removal of Prior Authorization (PA) Requirement

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Filsuvez® (Birch Triterpenes Topical Gel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Filsuvez® (birch triterpenes 10% topical gel) with the following criteria (shown in red):

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

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB); and
2. Diagnosis must be confirmed by a pathogenic variant in the *COL7A1* gene for DEB or biallelic pathogenic variants in the *COL17A1*, *ITGA3*, *ITGA6*, *ITGB4*, *LAMA3*, *LAMB3*, or *LAMC2* genes for JEB (results of genetic testing must be submitted); and

3. Filsuvez® must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB or JEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB or JEB); and
4. Member must have the presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days; and
5. Filsuvez® must be applied to open partial-thickness wounds at dressing changes at least once every 4 days or up to once daily; and
6. Prescriber must attest that member and/or caregiver has been counseled on the appropriate administration and storage of Filsuvez® based on package labeling including that each sterile tube is for one-time use only; and
7. Member and/or caregiver has been advised on possible hypersensitivity reactions with Filsuvez® and to discontinue use and contact the prescriber if symptoms of a hypersensitivity reaction develop; and
8. Filsuvez® will not be approved for concomitant use with Vyjuvek® (beremagene geperpavec-svdt); and
9. A maximum approval quantity of 1 tube (23.4 grams) per day or 702 grams per 30 days will apply; and
    a. A quantity limit override will be considered for approval of quantities greater than 1 tube per day if the provider documents the number and size of wounds being treated to justify the need for a larger quantity; and
10. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Filsuvez® will not be applied to closed wounds.

Additionally, the College of Pharmacy recommends updating the prior authorization criteria for Vyjuvek® (beremagene geperpavec-svdt) based on the recent FDA approval of Filsuvez® (birch triterpenes 10% topical gel) and to ensure appropriate use (changes shown in red):

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek® must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and

4. Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering provider via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and
5. Vyjuvek® must be administered by a health care professional (HCP) trained in the administration of Vyjuvek®. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health); and
6. Prescriber must attest that Vyjuvek® gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and
7. Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek® that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings for 24 hours following administration; and
8. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy; and
9. Vyjuvek® will not be approved for concomitant use with Filsuvez® (birch triterpenes 10% topical gel); and
10. A maximum approval quantity of 1 carton (2.5mL) per week will apply; and
11. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Vyjuvek® will not be applied to closed wounds.

Recommendation 3: Vote to Prior Authorize Kisunla™ (Donanemab-azbt) and Update the Approval Criteria for the Alzheimer's Disease Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Kisunla™ (donanemab-azbt) with the following criteria (shown in red):

Kisunla™ (Donanemab-azbt) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
   a. Mini-Mental State Exam (MMSE) score between 20 and 28; or

   b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
   c. Montreal Cognitive Assessment (MoCA) score ≥19; or
   d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Kisunla™ 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. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing intracerebral hemorrhage with the concomitant use have been discussed and are acceptable to the member prior to initiating Kisunla™; and
8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or
    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Kisunla™ and prior to the 2nd, 3rd, 4th, and 7th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 12 weeks and throughout treatment with Kisunla™; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must

confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Kisunla™ must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and
    a. Kisunla™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 2nd, 3rd, 4th, and 7th infusions is required for continuation; and
16. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
17. Approval quantities will be dependent on dosing based on package labeling; and
18. The maximum approvable dose is 1,400mg per 28 days; and
19. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Additionally, the College of Pharmacy recommends the following changes to the Leqembi (lecanemab-irmb) criteria to be consistent with the package labeling (changes shown in red):

Leqembi® (Lecanemab-irmb) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 22 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Leqembi® 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. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing intracerebral hemorrhage ~~ARIA~~ with the concomitant use have been discussed and are acceptable to the member prior to initiating Leqembi®; and
8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or
    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Leqembi® and prior to the 5th, 7th, and 14th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with Leqembi®; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Leqembi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and

a. Leqembi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and

15. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 5th and 7th infusions is required for continuation; and
17. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
18. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
19. The maximum dose approvable is 10mg/kg per 14 days; and
20. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Finally, the College of Pharmacy recommends the following changes to the Namzaric® [memantine extended release (ER)/donepezil] criteria to be consistent with the other Alzheimer's disease medications (changes shown in red):

Namzaric® [Memantine Extended-Release (ER)/Donepezil] Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe Alzheimer's type dementia; and
2. Member must have a patient-specific, clinically significant reason why the separate immediate-release products which do not require prior authorization cannot be used over this combination product; and
3. A quantity limit of 30 capsules per 30 days will apply.

Recommendation 4: Vote to Prior Authorize Defencath® (Taurolidine/ Heparin)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Defencath® (taurolidine/heparin) with the following criteria (shown in red):

Defencath® (Taurolidine/Heparin) Approval Criteria:

1. An FDA approved indication of reducing the incidence of catheter-related bloodstream infections (CRBSIs) in adult members with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC); and

2. Member must be 18 years of age or older; and
3. Must be used for prevention of CRBSIs; and
4. Prescriber must verify Defencath® is used only as a catheter lock solution (CLS) in CVCs and will not be administered systemically or used as a catheter lock flush product (i.e., it must be aspirated from the catheter and discarded prior to the next utilization of the CVC); and
5. Member must not have a known history of heparin-induced thrombocytopenia (HIT) or known hypersensitivity to pork products, taurolidine, heparin, or other components of Defencath®; and
6. A quantity limit of 2 vials per HD session or 24 vials per 28 days will apply; and
    a. For requests exceeding the quantity limit, supporting documentation (e.g., HD schedule, number of CVC lumens, CVC lumen volumes) must be provided for a quantity limit override; and
7. Approvals will be granted for 1 year.

Recommendation 5: Vote to Prior Authorize Wegovy® (Semaglutide)

MOTION CARRIED by unanimous approval.

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

Wegovy® (Semaglutide) Approval Criteria [Cardiovascular (CV) Risk Reduction Indication Only]:

1. An FDA approved indication to reduce the risk of major adverse cardiovascular (CV) events in members with established CV disease (CVD) and either obesity or overweight; and
    a. Wegovy® will not be approved for obese or overweight members in the absence of established CVD; and
2. Member must be 45 years of age or older; and
3. Member must have established CVD with a history of 1 of the following (documentation must be submitted with the request):
    a. Previous myocardial infarction; or
    b. Previous stroke; or
    c. Symptomatic peripheral arterial disease confirmed by 1 of the following:
        i. Intermittent claudication with ankle-brachial index <0.85 at rest; or
        ii. Peripheral arterial revascularization procedure; or
        iii. Amputation due to atherosclerotic disease; and
4. Member has a body mass index (BMI) ≥27kg/m^2; and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Member has a hemoglobin A1C (HbA1c) <6.5%; and

7. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
8. Member is currently receiving guideline-directed management and therapy (GDMT) for CVD (e.g., antihypertensives, lipid-lowering agents, antiplatelets), as documented in the member's pharmacy claims history, unless contraindicated; and
9. Wegovy® must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and
11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing all of the following in conjunction with Wegovy®:
        i. Reduced calorie diet; and
        ii. Increased physical activity; and
        iii. GDMT for CVD where applicable; and
12. A quantity limit of 4 pens per 28 days will apply; and
13. Wegovy® should be discontinued in members who cannot tolerate at least the 1.7mg once weekly maintenance dosing.

Recommendation 6: Vote to Prior Authorize Avzivi® (Bevacizumab-tnjn) and Fruzaqla® (Fruquintinib) and Update the Approval Criteria for the Colorectal Cancer (CRC) Medications

MOTION CARRIED by unanimous approval.

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

Fruzaqla® (Fruquintinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic CRC; and
2. Previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and

3. Previously treated with an anti-vascular endothelial growth factor (VEGF) therapy; and
4. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy.

The College of Pharmacy also recommends the prior authorization of Avzivi® (bevacizumab-tnjn) and recommends updating the approval criteria for the bevacizumab products based on net costs (changes shown in red):

Alymsys® (Bevacizumab-maly), Avzivi® (Bevacizumab-tnjn), ~~Mvasi® (Bevacizumab-awwb)~~, and Vegzelma® (Bevacizumab-adcd) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use ~~Alymsys® (bevacizumab-maly),~~ Avastin® (bevacizumab), Mvasi® (bevacizumab-awwb), ~~Vegzelma® (bevacizumab-adcd),~~ or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, 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.

Recommendation 7: Vote to Prior Authorize Accrufer® (Ferric Maltol) and Update the Approval Criteria for the Iron Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Accrufer® (ferric maltol) with the following criteria (shown in red):

Accrufer® (Ferric Maltol) Approval Criteria:

1. Diagnosis of iron deficiency anemia (IDA); and
2. Lab results verifying IDA must be submitted; and
3. Member must be 18 years of age or older; and
4. Member must have a documented diagnosis of chronic kidney disease (CKD) or inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis); and
5. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
6. A recent, failed trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
7. A patient-specific clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided; and

8. Initial approvals will be for the duration of 3 months of treatment. Subsequent approvals (for 3 months of treatment) will require updated recent laboratory results documenting continued IDA.

Additionally, the College of Pharmacy recommends removing the prior authorization requirement for Feraheme® (ferumoxytol), and updating the Injectafer® (ferric carboxymaltose) and Monoferric® (ferric derisomaltose) approval criteria based on net costs (changes shown in red):

~~**Feraheme® (Ferumoxytol) Approval Criteria:**~~

~~1. An FDA approved indication of 1 of the following:~~
~~a. Iron deficiency anemia (IDA); or~~
~~b. IDA with chronic kidney disease (CKD); and~~
~~2. Documented lab results verifying IDA; and~~
~~3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and~~
~~4. Prescriber must verify the member does not have a previous history of allergic reaction to any intravenous iron medications; and~~
~~5. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided.~~

Injectafer® (Ferric Carboxymaltose) Approval Criteria [Iron Deficiency Anemia (IDA) Diagnosis]:

1. An FDA approved indication of 1 of the following:
   a. IDA; or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided.

Injectafer® (Ferric Carboxymaltose) Approval Criteria [Iron Deficiency Diagnosis]:

1. An FDA approved indication of iron deficiency in adult members with New York Heart Association (NYHA) class II-III heart failure (HF) to improve exercise capacity; and
2. Member must be 18 years of age or older; and
3. Documented lab results verifying iron deficiency; and
4. Prescriber must verify member is already receiving optimal background therapy for HF; and
5. Member must have left ventricular ejection fraction (LVEF) <45%; and

6. Member's current weight (kg) and hemoglobin (Hb) (g/dL) must be provided to ensure appropriate dosing according to package labeling; and
7. A recent trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
8. Initial approvals will be for 1 or 2 doses only (depending on member's weight and Hb) according to package labeling; and
9. Subsequent requests for maintenance doses at weeks 12, 24, and 36 will require submission of updated lab results verifying continued iron deficiency for each dose and will be approved for (1) 500mg dose at a time.

Monoferric® (Ferric Derisomaltose) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Iron deficiency anemia (IDA); or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
5. A patient-specific, clinically significant reason why the member cannot utilize ~~Feraheme® (ferumoxytol) and Injectafer® (ferric carboxymaltose)~~ all other forms of intravenous (IV) iron must be provided.

Recommendation 8: Vote to Prior Authorize Doryx® MPC [Doxycycline Hyclate Delayed Release (DR)], Exblifep® (Cefepime/ Enmetazobactam), Meropenem 2 Gram Vial, Pivya™ (Pivmecillinam), Nitrofurantoin 50mg/5mL Suspension, Tetracycline 250mg and 500mg Tablets, and Zevtera® (Ceftobiprole Medocaril Sodium) and Update the Approval Criteria for the Various Systemic Antibiotics

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Exblifep® (cefepime/enmetazobactam), meropenem 2 gram vial, Pivya™ (pivmecillinam), and Zevtera® (ceftobiprole medocaril sodium) with the following criteria (shown in red):

Exblifep® (Cefepime/Enmetazobactam) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including pyelonephritis, caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta-lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Member's recent estimated glomerular filtration rate (eGFR) must be provided to ensure appropriate dosing in accordance with package labeling; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Meropenem 2 Gram Vial Approval Criteria:

1. An FDA approved diagnosis of bacterial meningitis; and
2. Member must be 3 months of age or older; and
3. A patient-specific, clinically significant reason why the meropenem 1 gram or 500mg vials, which are available without a prior authorization, cannot be used must be provided.

Pivya™ (Pivmecillinam) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection caused by designated susceptible isolates of *Escherichia coli, Proteus mirabilis*, and *Staphylococcus saprophyticus* (culture/sensitivity results must be submitted); and
2. Member must be a female 18 years of age or older; and
3. Member must not have any of the following contraindications:
    a. Serious hypersensitivity reactions (e.g., anaphylaxis, Stevens-Johnson syndrome) to Pivya™ or to other beta-lactam antibacterial drugs (e.g., penicillins, cephalosporins); and
    b. Primary or secondary carnitine deficiency resulting from inherited disorders of mitochondrial fatty acid oxidation and carnitine metabolism and other inborn errors of metabolism (e.g., methylmalonic aciduria, propionic acidemia); and
    c. Acute porphyria; and
4. Provider must verify that concurrent treatment with valproic acid, valproate, or other pivalate-generating drugs will be avoided due to increased risk of carnitine depletion; or
    a. If concomitant use is necessary, member must be counseled to monitor for and report adverse reactions associated with carnitine depletion (e.g., hypoglycemia, muscle aches, fatigue, confusion); and

5. Pivya™ must not be used when prolonged antibacterial treatment (i.e., longer than the FDA-approved treatment duration of up to 7 days) is necessary; and
6. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
7. A quantity limit of 21 tablets per 7 days will apply.

Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and
2. Member must be 3 months of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. 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
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [*Staphylococcus aureus* Bloodstream Infection (Bacteremia) (SAB) Diagnosis]:

1. An FDA approved diagnosis of SAB caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and
2. Member must be 18 years of age or older; and

3. For methicillin-resistant *Staphylococcus aureus* (MRSA), a patient-specific, clinically significant reason why the member cannot use vancomycin or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. For methicillin-susceptible *Staphylococcus aureus* (MSSA), a patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., nafcillin, oxacillin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

The College of Pharmacy also recommends the prior authorization of tetracycline 250mg and 500mg tablets based on net costs with criteria similar to tetracycline 250mg and 500mg capsules (changes shown in red):

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

1. Approval requires a patient-specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s); and
2. For the tablet formulation, approval also requires a patient-specific, clinically significant reason why the member requires the tablet formulation and cannot use the capsule formulation.

Additionally, the College of Pharmacy recommends the prior authorization of Doryx® MPC (doxycycline hyclate DR) and doxycycline monohydrate 75mg capsule based on net costs within the Oral Antibiotic Special Formulation Approval Criteria (changes shown in red):

Oral Antibiotic Special Formulation Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.
2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:
   - Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)
   - Cephalexin 250mg and 500mg tablets
   - Cephalexin 750mg capsules
   - Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)
   - Doxycycline hyclate 50mg tablet (Targadox®)
   - Doxycycline hyclate delayed-release (DR) tablets (Doryx®, Doryx® MPC)
   - Doxycycline monohydrate 75mg capsules
   - Doxycycline monohydrate 150mg capsules and tablets
   - Doxycycline monohydrate DR 40mg capsules (Oracea®)
   - Minocycline ER capsules (Ximino®)

- Minocycline ER tablets (Minolira™)
- Minocycline ER tablets (Solodyn®)
- Nitrofurantoin 50mg/5mL suspension

Lastly, the College of Pharmacy recommends updating the approval criteria for Avycaz® (ceftazidime/avibactam) based on the updated FDA-approved package labeling and to be consistent with clinical practice and recommends updating the approval criteria for Fetroja® (cefiderocol), Recarbrio™ (imipenem/cilastatin/relebactam), Vabomere® (meropenem/vaborbactam injection), Xacduro® (sulbactam/durlobactam) and Zerbaxa® (ceftolozane/tazobactam) to be consistent with clinical practice (changes shown in red):

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be at least 31 weeks gestational age ~~3 months of age~~ or older; and
3. For the diagnosis of cIAI, Avycaz® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   b. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination

(e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Recarbrio™ (Imipenem/Cilastatin/Relebactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI); or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. A quantity limit of 56 vials per 14 days will apply.

Vabomere® (Meropenem/Vaborbactam Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI) or pyelonephritis (culture/sensitivity results must be submitted); and
2. A patient-specific, clinically significant reason why the member cannot use piperacillin/tazobactam or other cost effective therapeutic equivalent alternative(s) must be provided; and
3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Xacduro® (Sulbactam/Durlobactam) Approval Criteria:

1. An FDA approved diagnosis of hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (culture/sensitivity results must be submitted); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use a carbapenem, ampicillin/sulbactam, polymyxin B, or other cost effective therapeutic equivalent alternative(s) must be provided; ~~and~~ or

   a. A clinical exception will apply for infections caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB), in which case Xacduro® will be approved; and
4. ~~For members with carbapenem-resistant *Acinetobacter baumannii* (CRAB), a patient-specific, clinically significant reason why the member cannot us high dose ampicillin/sulbactam in combination with polymyxin B, minocycline, or tigecycline must be provided; and~~
5. The prescriber must confirm that the member will be treated for other pathogens present, if applicable; and
6. Approval quantity will be based on Xacduro® package labeling and FDA approved dosing regimen(s).

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. For the diagnosis of HABP/VABP, member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Recommendation 9: Vote to Prior Authorize Penicillamine 250mg Tablet and Trientine Hydrochloride 500mg Capsule and Update the Approval Criteria for the Wilson's Disease Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of penicillamine 250mg tablet and trientine hydrochloride 500mg capsule with the following criteria (shown in red):

Penicillamine 250mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use penicillamine 250mg capsule must be provided.

Trientine Hydrochloride (HCl) 500mg Capsule Approval Criteria:

1. An FDA approved diagnosis of Wilson's disease; and
2. A patient-specific, clinically significant reason why the member cannot use trientine HCl 250mg capsule must be provided.

Additionally, the College of Pharmacy recommends updating the Cuvrior® (trientine tetrahydrochloride) criteria to be consistent with the other Wilson's disease medications (changes shown in red):

Cuvrior® (Trientine Tetrahydrochloride) Approval Criteria:

1. An FDA approved diagnosis of Wilson's disease; and
   a. Diagnosis must be confirmed by a Leipzig score ≥4; and
2. Member must be 18 years of age or older; and
3. Cuvrior® must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of Wilson's disease (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of Wilson's disease); and
4. Member must be clinically stable, de-coppered, and tolerant to penicillamine as indicated by 1 of the following:
   a. Serum non-ceruloplasmin copper (NCC) level 25-150mcg/L; or
   b. Urinary copper excretion (UCE) level 200-500mcg/24 hours; and
5. Prescriber must verify the member will discontinue therapy with penicillamine or other copper chelating agents prior to starting therapy with Cuvrior®; and
6. A patient-specific, clinically significant reason why the member cannot use generic penicillamine 250mg capsule, generic trientine hydrocholoride 250mg capsule, and Galzin® (zinc acetate), which are available without a prior authorization, must be provided; and
7. A quantity limit of 288 tablets per 28 days will apply.

Recommendation 10: Vote to Prior Authorize Eohilia™ (Budesonide Oral Suspension) and Update the Approval Criteria for the Corticosteroid Special Formulations

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Eohilia™ (budesonide oral suspension) with the following criteria, including updating the swallowed respiratory corticosteroids to the generic name (e.g., updating Flovent® to fluticasone) due to unavailability of some brand name products as recommended by the DUR Board (shown in red):

Eohilia™ (Budesonide Oral Suspension) Approval Criteria:

1. An established diagnosis of eosinophilic esophagitis (EoE) defined as:
   a. The presence of clinical symptoms of EoE ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
   b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf)] in the esophagus; and
2. Member must be 11 years of age or older; and
3. 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 an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. Member must have a documented trial for a minimum of 8 weeks that resulted in failure with 1 high-dose proton pump inhibitor (i.e., omeprazole 20-40mg twice daily or equivalent in adults or 1-2mg/kg of omeprazole daily or equivalent in children) or have a contraindication or documented intolerance; and
5. A patient specific, clinically significant reason why the member cannot use a swallowed respiratory corticosteroid (e.g., budesonide, fluticasone) must be provided; and
6. Approvals will be for (1) 3-month treatment course; and
7. A quantity limit of 600mL per 30 days will apply; and
8. Eohilia™ will not be approved for maintenance treatment. Reauthorization for additional 3-month treatment course(s) may be considered if the prescriber documents the following:
   a. The member had a positive initial response to Eohilia™; and
   b. Is now experiencing recurrent worsening symptoms of EoE after completing the treatment course with Eohilia™; and
   c. A patient specific, clinically significant reason why the member still cannot use a swallowed respiratory corticosteroid (e.g., budesonide, fluticasone) must be provided.

The College of Pharmacy also recommends updating the approval criteria for Millipred™ (prednisolone sodium phosphate 10mg/5mL oral solution), Veripred™ 20 (prednisolone sodium phosphate 20mg/5mL oral solution), and Orapred ODT® [prednisolone sodium phosphate orally disintegrating tablet (ODT)] to be consistent with clinical practice (changes shown in red):

Millipred™ (Prednisolone Sodium Phosphate 10mg/5mL Oral Solution) and Veripred™ 20 (Prednisolone Sodium Phosphate 20mg/5mL Oral Solution) Approval Criteria:

1. Approval of Millipred™ or Veripred™ 20 requires a patient-specific, clinically significant reason why the member cannot use ~~a tablet or~~ an alternative strength liquid formulation of generic prednisolone oral solution including the 5mg/5mL, 15mg/5mL, and 25mg/5mL strengths which are available without a prior authorization.

Orapred ODT® [Prednisolone Sodium Phosphate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use ~~prednisone tablets~~ an alternative oral corticosteroid tablet or generic prednisolone oral solutions (5mg/5mL, 15mg/5mL, and 25mg/5mL strengths) that are available without a prior authorization; and
2. A quantity ~~limit~~ of 10 ODTs ~~per 30 days~~ will be available without prior authorization for members 10 years of age or younger.

Recommendation 11: Vote to Prior Authorize Tramadol 25mg Tablet and Update the Approval Criteria for the Opioid Analgesics and Medication Assisted Treatment (MAT) Medications

MOTION CARRIED by unanimous approval.

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

1. Adding tramadol 25mg tablet to the Special PA Tier based on net cost with the following additional criteria; and
2. Moving methadone oral solution and Xodol® from Tier-3 to the Special PA Tier to be consistent with clinical practice with the following additional criteria; and
3. Moving Nalocet® and Prolate® from Tier-3 to Special PA based on net cost with the following additional criteria; and
4. Removing Abstral®, Apadaz®, Onsolis®, and Oxaydo® due to product discontinuations.

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	**methadone soln (Dolophine®)**
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tapentadol ER tab 50mg (Nucynta® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	tapentadol ER tab 100mg, 150mg, 200mg, 250mg (Nucynta® ER)	hydromorphone ER tab (Exalgo®)	
	tramadol ER tab (Ultram ER®, Ryzolt®)	methadone tab ~~& soln~~ (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		oxycodone ER cap (Xtampza® ER)	
Short-Acting			
APAP/butalbital/ caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)	~~**benzhydrocodone/ APAP tab (Apadaz®)**~~	APAP/butalbital/ caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	dihydrocodeine/ APAP/caff cap (Trezix®)	APAP/codeine elixir & soln
codeine tab		~~**hydrocodone/APAP tab (Xodol®)**~~	celecoxib 56mg/tramadol 44mg (Seglentis®)
codeine/APAP tab (Tylenol® with Codeine)		~~**oxycodone/APAP tab (Nalocet®)**~~	hydrocodone/ APAP soln
hydrocodone/ APAP tab (Norco®)		~~**oxycodone/APAP tab & soln (Prolate®)**~~	**hydrocodone/ APAP tab (Xodol®)**
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)		~~**oxycodone tab (Oxaydo®)**~~	levorphanol tab
hydromorphone tab & soln (Dilaudid®)		oxycodone tab (RoxyBond™)	**oxycodone/APAP tab (Nalocet®)**

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
meperidine tab & soln (Demerol®)			**oxycodone/APAP tab & soln (Prolate®)**
morphine IR tab & soln (MSIR®)			tramadol **25mg &** 100mg tab
oxycodone/APAP tab & soln (Percocet®)			tramadol soln (Qdolo™)
oxycodone/ASA tab (Percodan®)			
oxycodone IR cap (Oxy IR®)			***Oncology Only:***
oxycodone IR tab & soln (Roxicodone®)			~~**fentanyl buccal film (Onsolis®)**~~
tapentadol IR (Nucynta®)			fentanyl buccal tab (Fentora®)
tramadol 50mg tab (Ultram®)			~~**fentanyl SL tab (Abstral®)**~~
tramadol/APAP (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

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

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. ~~Abstral®;~~ Actiq®~~;~~ and Fentora®~~, and Onsolis®~~ are approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
   a. Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use of these products despite the medication being contraindicated for the member's age; or
   b. For members older than 12 years of age, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:

a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.

5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
   a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; ~~and~~ or
   b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; ~~or~~ and
   c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
6. Levorphanol Tablet Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
7. Methadone Oral Solution Approval Criteria:
   a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or
   b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.
8. Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:
   a. For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and
   b. For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.
9. Oxymorphone ER Tablet Approval Criteria:

a. A patient specific, clinically significant reason why the member cannot use any other available extended-release opioid analgesic must be provided.

10. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    c. A quantity limit of 2,400mL per 30 days will apply.
11. Seglentis® (Celecoxib 56mg/Tramadol 44mg Tablet) Approval Criteria:
    a. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
    b. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
    c. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
    d. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    e. A quantity limit of 28 tablets for a 7-day supply will apply.
12. Tramadol 25mg and 100mg Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose or split a tramadol 50mg tablet to achieve a 25mg dose must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

The College of Pharmacy also recommends the following changes to the MAT medications approval criteria to be consistent with clinical practice and current guidelines (changes noted in red in the following criteria):

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

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

High-Dose Buprenorphine Medication-Assisted Treatment (MAT) Products Approval Criteria:

1. Each request for ~~>16mg~~ >24mg bioequivalent buprenorphine per day will be evaluated on a case-by-case basis; and
2. A taper schedule, dates of an attempted taper with reason(s) for failure, or a patient-specific, clinically significant reason why a taper attempt is not appropriate for the member should be documented on the prior authorization request; and

3. Opioid urine drug screens should be submitted with high-dose requests that plan to continue high-dose treatment longer than the duration of 1 month; and
    a. Urine drug screens must show the absence of opioid medications other than buprenorphine products for continued approval; or
    b. Prescriber must document a patient-specific reason the member should continue therapy, reason for opioid use, and document a plan for member to discontinue opioid use; and
4. Symptoms associated with withdrawal at lower doses or symptoms requiring high doses should be listed on the prior authorization request; and
5. Each approval will be for the duration of 1 month. If urine drug screen and other documentation are submitted indicating high-dose therapy is necessary, an approval can be granted for the duration of 3 months; and
6. Continued high-dose authorization after the 3-month approval will require a new (recent) urine drug screen; and
7. For Opioid Treatment Programs (OTPs), high-dose authorization will be approved for 1 year if urine drug screen and other documentation are submitted indicating high-dose therapy is necessary.

Recommendation 12: Vote to Update the Approval Criteria for the Topical Corticosteroids

MOTION CARRIED by unanimous approval.

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

1. Ultra-High to High Potency:
    a. Move clobetasol propionate 0.05% (Clobex®) spray from Tier-3 to Tier-2; and
    b. Move halcinonide 0.1% (Halog®) cream, ointment, and solution from Tier-2 to Tier-3; and
    c. Remove clobetasol propionate 0.05% (Impeklo®) lotion due to product discontinuation.
2. Medium-High to Medium Potency:
    a. Move hydrocortisone valerate 0.2% (Westcort®) cream from Tier-3 to Tier-1; and
    b. Move betamethasone dipropionate/calcipotriene 0.064%/0.005% (Taclonex®) ointment, spray, and suspension and clocortolone pivalate 0.1% (Cloderm®) cream from Tier-2 to Tier-3; and
    c. Move hydrocortisone butyrate 0.1% cream and lotion and flurandrenolide 0.05% cream, lotion, and ointment from Tier-2 to Tier-3; and
    d. Move fluticasone 0.05% (Cutivate®) lotion from Tier-2 to Tier-3.

3. Low Potency:
    a. Move alclometasone dipropionate 0.05% (Aclovate®) ointment from Tier-3 to Tier-2; and
    b. Remove hydrocortisone/urea 1%/10% (U-Cort®) cream due to product discontinuation.

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,O	amcinonide 0.1%	C,L	~~**clobetasol propionate 0.05% (Clobex®)**~~	~~**Spr**~~
betamethasone dipropionate 0.05% (Diprosone®)	C,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G,L	clobetasol propionate 0.05% (Olux-E®, Tovet®)	F
clobetasol propionate 0.05% (Olux®)	F	clobetasol propionate 0.05% (Clobex®)	L,Sh,**Spr**	~~**Clobetasol propionate 0.05% (Impeklo™)**~~	~~**L**~~
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	desoximetasone 0.25% (Topicort®)	Spr
desoximetasone 0.25% (Topicort®)	C,O	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
fluocinonide 0.05%	C,O,So	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon E®)	C
fluocinonide 0.1% (Vanos®)	C	flurandrenolide tape 0.05% (Cordran®)	Tape	**halcinonide 0.1% (Halog®)**	**C,O,So**
halobetasol propionate 0.05% (Ultravate®)	C,O	~~**halcinonide 0.1% (Halog®)**~~	~~**C,O,So**~~	halobetasol propionate 0.01% (Bryhali®)	L
		halobetasol propionate 0.05% (Ultravate®)	L	halobetasol propionate 0.05%	F
		halobetasol propionate/lactic acid 0.05%/10% (Ultravate X®)	C		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	~~**betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)**~~	~~**O,Spr, Sus**~~	**betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)**	**O,Spr, Sus**

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.12% (Luxiq®)	F	**clocortolone pivalate 0.1% (Cloderm®)**	**C**
fluticasone propionate 0.005% (Cutivate®)	O	betamethasone valerate 0.1% (Beta-Val®)	L	desoximetasone 0.05% (Topicort LP®)	C,O
fluticasone propionate 0.05% (Cutivate®)	C	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F	**flurandrenolide 0.05%**	**C,L,O**
hydrocortisone valerate 0.2% (Westcort®)	**C**	~~**clocortolone pivalate 0.1% (Cloderm®)**~~	~~**C**~~	**fluticasone propionate 0.05% (Cutivate®)**	**L**
mometasone furoate 0.1% (Elocon®)	C,L,O, So	fluocinolone acetonide 0.025% (Synalar®)	C,O	**hydrocortisone butyrate 0.1%**	**C,L**
triamcinolone acetonide 0.025%	O	fluocinonide emollient 0.05% (Lidex E®)	C	hydrocortisone valerate 0.2% (Westcort®)	~~**C**~~,O
triamcinolone acetonide 0.1%	C,L,O	~~**flurandrenolide 0.05%**~~	~~**C,L,O**~~	triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr
triamcinolone acetonide 0.5%	C,O	~~**fluticasone propionate 0.05% (Cutivate®)**~~	~~**L**~~		
		hydrocortisone butyrate 0.1%	~~**C,L**~~,O, So		
		hydrocortisone probutate 0.1% (Pandel®)	C		
		prednicarbate 0.1% (Dermatop®)	C,O		
		triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,**O**	~~**alclometasone dipropionate 0.05% (Aclovate®)**~~	~~**O**~~
fluocinolone acetonide 0.01% (Capex®)	Sh	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05%	L

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	hydrocortisone/pramoxine 1%/1% (Pramosone®)	C,L	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O				
~~**hydrocortisone/urea 1%/10% (U-Cort®)**~~	~~**C**~~				
triamcinolone acetonide 0.025%	C,L				

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

Recommendation 13: Annual Review of Annual Review of Allergen Immunotherapies

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Palforzia® (peanut allergen powder-dnfp) based on the new FDA-approved age expansion (changes shown in red):

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

1. Member must be ~~4~~ 1 to 17 years of age to initiate initial dose escalation (maintenance dosing may be continued for members ~~4~~ 1 year~~s~~ of age and older); and
2. Member must have a diagnosis of peanut allergy confirmed by a positive skin test, positive *in vitro* test for peanut-specific immunoglobulin E (IgE), or positive clinician-supervised oral food challenge; and
3. Prescriber must confirm member will use Palforzia® with a peanut-avoidant diet; and
4. Member must not have severe uncontrolled asthma; and
5. Member must not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
6. Member must not have had severe or life-threatening anaphylaxis within the previous 60 days; and
7. Member or caregiver must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and

9. Prescriber, health care setting, and pharmacy must be certified in the Palforzia® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Palforzia® REMS program; and
11. Palforzia® must be administered under the direct observation of a health care provider in a REMS certified health care setting with an observation duration in accordance with the Palforzia® *Prescribing Information*; and
12. After successful completion of initial dose escalation and all levels of up-dosing as documented by the prescriber, initial approvals of maintenance dosing will be for 6 months. For continued approval, the member must be compliant, and prescriber must verify the member is responding well to treatment.

Recommendation 14: Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Hercessi™ (Trastuzumab-strf) and Truqap™ (Capivasertib)

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

Recommendation 15: Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Wainua™ (Eplontersen)

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

Recommendation 16: Annual Review of Cystic Fibrosis (CF) Medications

NO ACTION REQUIRED.

Recommendation 17: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

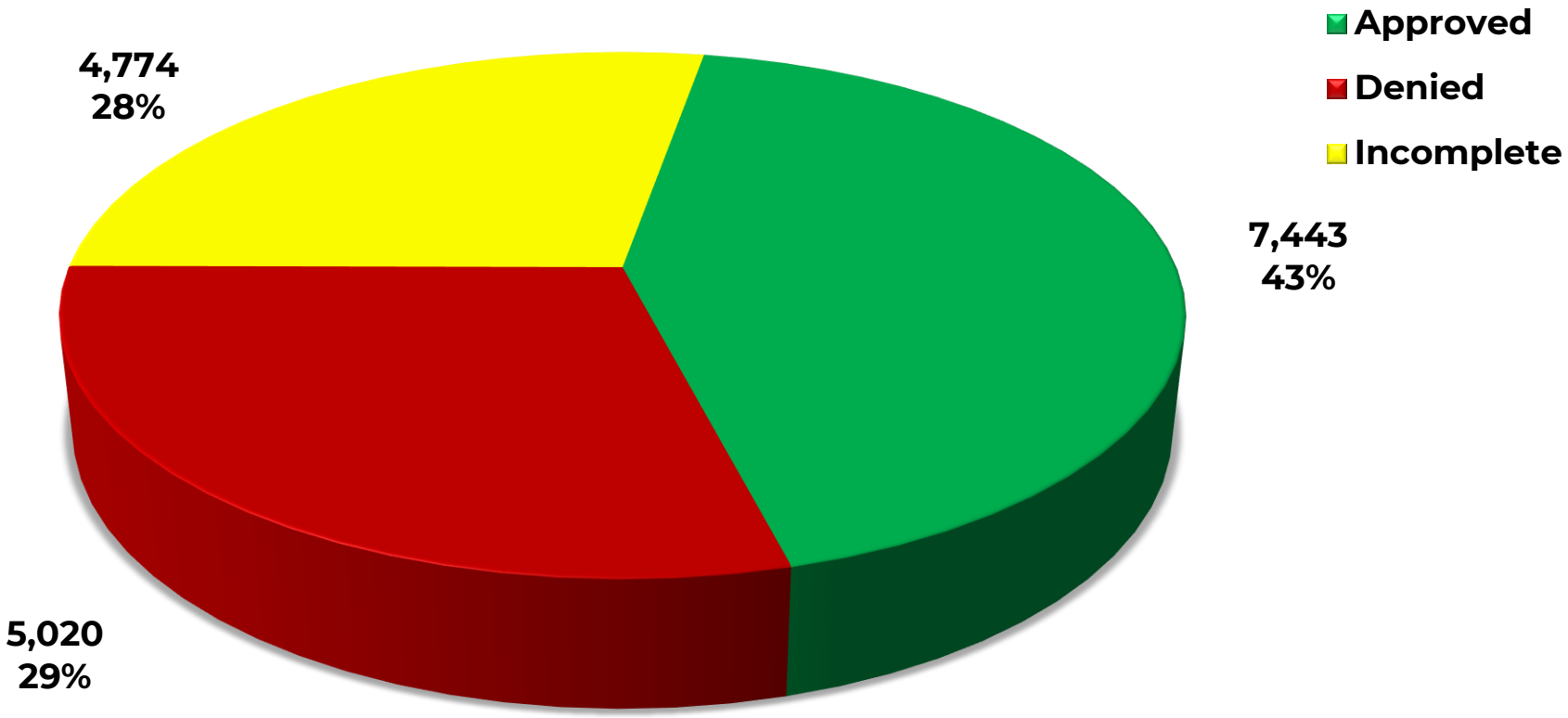
NO ACTION REQUIRED.

Recommendation 18: Future Business

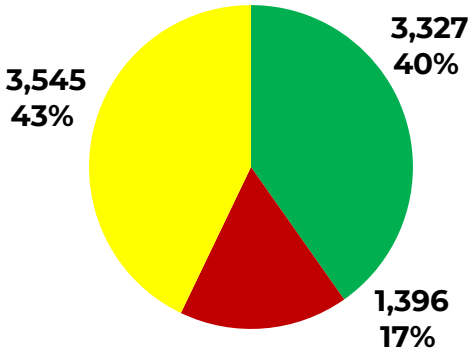
NO ACTION REQUIRED.

Appendix B

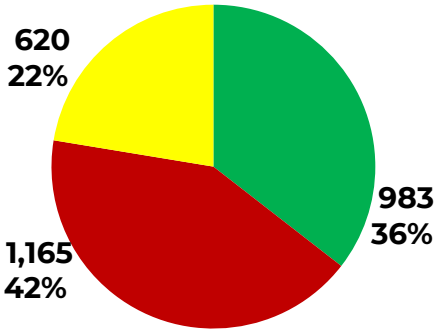
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: SEPTEMBER 2024



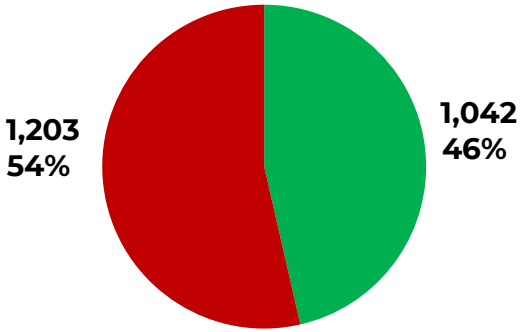
SoonerCare FFS



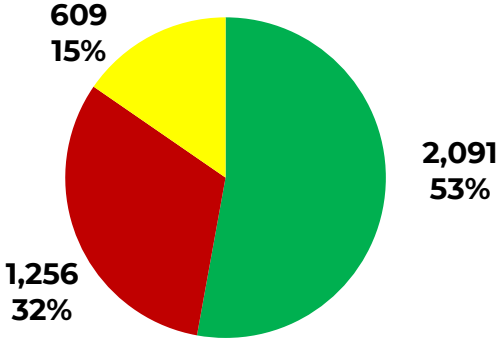
SoonerSelect Aetna



SoonerSelect Humana

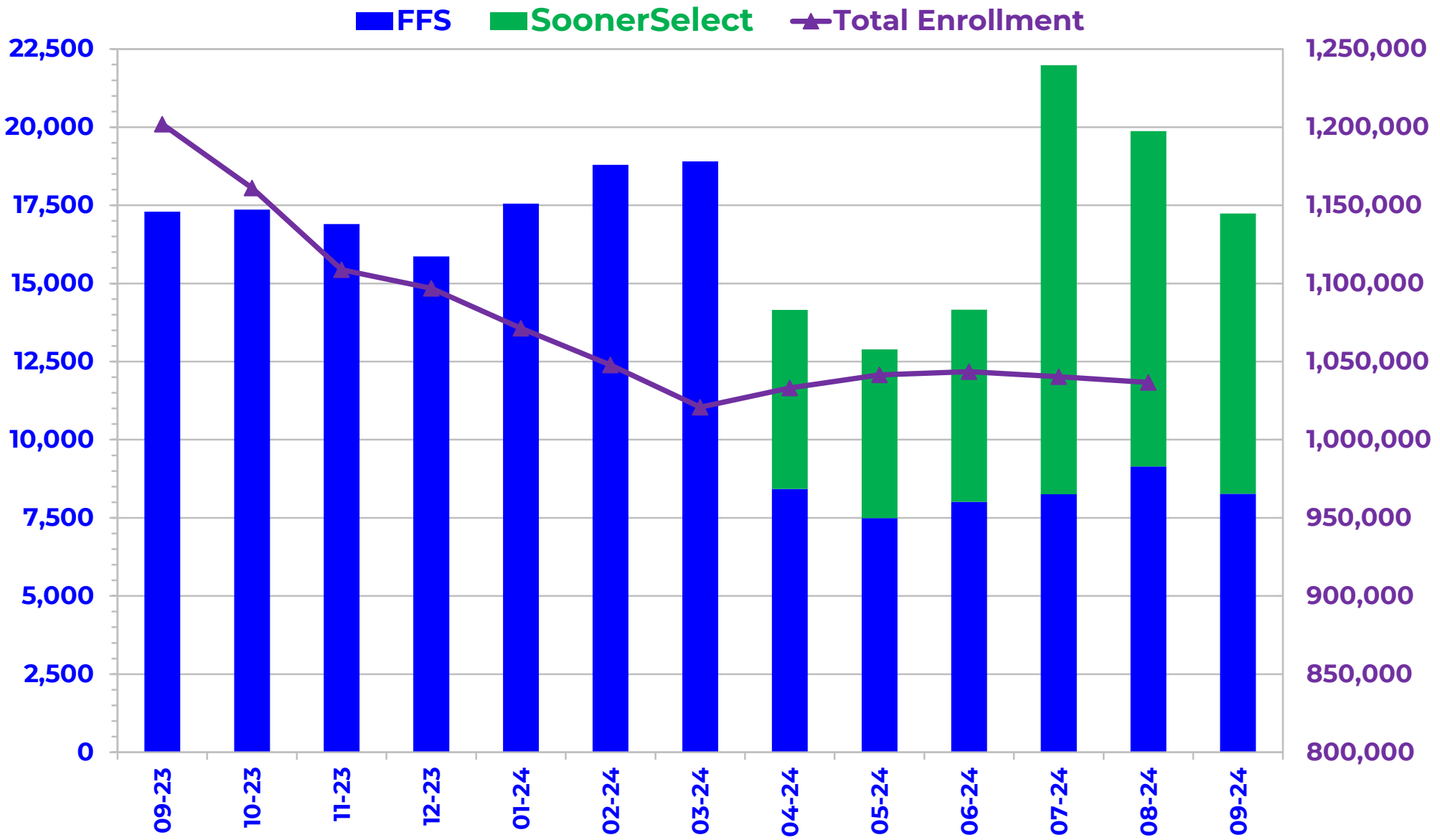


SoonerSelect OK Complete Health



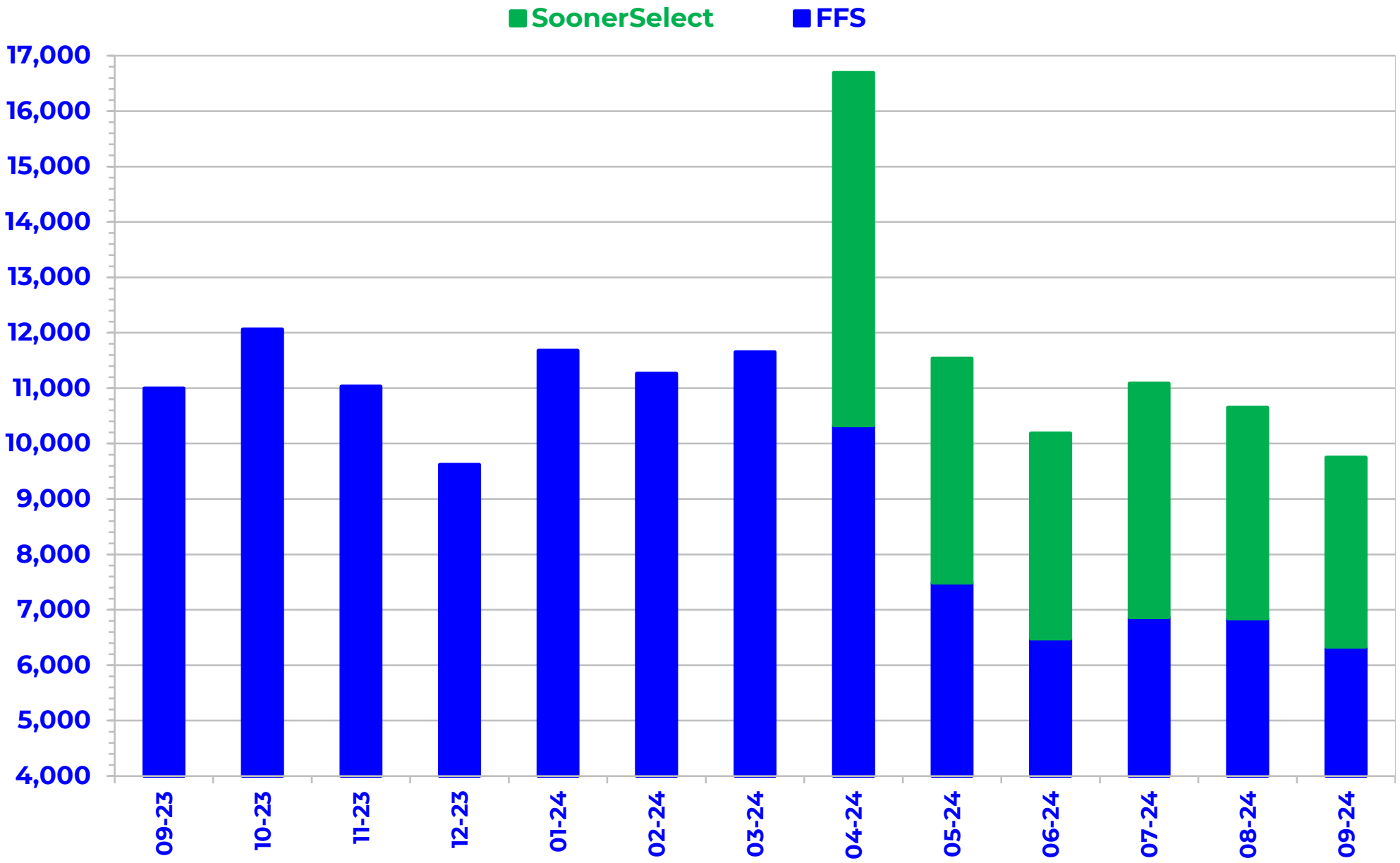
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: SEPTEMBER 2023 – SEPTEMBER 2024



SoonerCare FFS Prior Authorization Activity

9/1/2024 Through 9/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	566	345	10	211	348
Analgesics - Anti-Inflammatory	221	87	40	94	317
Analgesics - NonNarcotic	6	0	0	6	0
Analgesics - Opioid	392	193	31	168	144
Androgens - Anabolic	100	18	31	51	336
Anorectal and Related Products	2	0	1	1	0
Anorexiants Non-Amphetamine	3	0	3	0	0
Anthelmintics	9	1	2	6	1
Anti-Infective Agents - Misc.	32	6	9	17	128
Anti-Obesity Agents	26	0	22	4	0
Antianginal Agents	1	0	0	1	0
Antianxiety Agents	26	4	4	18	350
Antiarrhythmics	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	486	138	88	260	350
Antibiotics	29	10	2	17	222
Anticoagulants	16	3	3	10	242
Anticonvulsants	189	94	14	81	304
Antidepressants	198	59	29	110	313
Antidiabetics	1,363	417	298	648	353
Antidotes and Specific Antagonists	3	3	0	0	357
Antiemetics	15	0	3	12	0
Antifungals	9	3	0	6	157
Antihistamines	27	10	4	13	359
Antihyperlipidemics	66	10	22	34	195
Antihypertensives	18	4	3	11	357
Antineoplastics and Adjunctive Therapies	206	140	7	59	181
Antiparkinson and Related Therapy Agents	6	0	1	5	0
Antipsychotics/Antimanic Agents	295	95	37	163	348
Antivirals	24	8	6	10	44
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	212	159	18	35	349
Beta Blockers	9	4	0	5	359
Calcium Channel Blockers	8	2	1	5	274
Cardiovascular Agents - Misc.	99	40	11	48	336
Contraceptives	28	13	4	11	312
Corticosteroids	11	4	2	5	274
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	385	112	119	154	226
Diagnostic Products	44	25	3	16	175
Dietary Products/Dietary Management Products	2	0	0	2	0
Digestive Aids	2	1	0	1	360
Diuretics	10	2	0	8	363
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	0	1	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	152	73	17	62	232
Estrogens	9	1	2	6	360
Gastrointestinal Agents - Misc.	262	64	78	120	247
Genitourinary Agents - Misc.	4	3	0	1	359
Gout Agents	8	2	2	4	359
Hematological Agents - Misc.	15	8	1	6	318
Hematopoietic Agents	47	19	14	14	115
Hypnotics/Sedatives/Sleep Disorder Agents	54	5	8	41	213
Laxatives	25	6	6	13	161
Medical Devices and Supplies	228	69	44	115	265
Migraine Products	294	48	102	144	262
Minerals and Electrolytes	14	1	5	8	360
Miscellaneous Therapeutic Classes	51	22	9	20	308
Mouth/Throat/Dental Agents	1	0	1	0	0
Multivitamins	11	5	0	6	342
Musculoskeletal Therapy Agents	49	2	15	32	55
Nasal Agents - Systemic and Topical	32	2	13	17	360
Neuromuscular Agents	85	28	38	19	311
Nutrients	1	0	0	1	0
Ophthalmic Agents	50	11	6	33	275
Other*	27	12	6	9	260
Otic Agents	27	2	5	20	6
Passive Immunizing and Treatment Agents	1	0	0	1	0
Pharmaceutical Adjuvants	1	1	0	0	84
Progestins	4	0	0	4	0
Psychotherapeutic and Neurological Agents - Misc.	222	79	44	99	227
Respiratory Agents - Misc.	21	11	2	8	310
Stimulants - Misc.	160	75	15	70	342
Thyroid Agents	24	7	2	15	320
Ulcer Drugs/Antispasmodics/Anticholinergics	57	13	9	35	223
Urinary Antispasmodics	103	13	29	61	339
Vaccines	2	0	0	2	0
Vasopressors	3	0	0	3	0
Vitamins	23	1	15	7	84
Total	**7,214**	**2,593**	**1,316**	**3,305**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Brand	20	16	0	4	274
Compound	9	9	0	0	12
Cumulative Early Refill	2	1	0	1	23
Diabetic Supplies	2	2	0	0	179
Dosage Change	174	155	1	18	14
High Dose	2	1	1	0	358
Ingredient Duplication	3	2	0	1	12
Lost/Broken Rx	47	38	5	4	12
MAT Override	9	5	0	4	68
NDC vs Age	230	153	39	38	297
NDC vs Sex	21	15	0	6	254
Nursing Home Issue	52	51	0	1	12
Opioid MME Limit	57	15	4	38	132
Opioid Quantity	23	13	4	6	164
Other	36	26	4	6	27
Prescriber Temp Unlock	1	1	0	0	360
Quantity vs Days Supply	305	195	15	95	260
STBS/STBSM	18	13	2	3	51
Step Therapy Exception	16	7	5	4	311
Stolen	3	2	0	1	14
Temporary Unlock	1	1	0	0	8
Third Brand Request	23	13	0	10	43
Overrides Total	**1,054**	**734**	**80**	**240**	
Total Regular PAs + Overrides	**8,268**	**3,327**	**1,396**	**3,545**	

Denial Reasons	
Unable to verify required trials.	2,960
Does not meet established criteria.	1,425
Lack required information to process request.	622
Other PA Activity	
Duplicate Requests	1,009
Letters	32,954
No Process	0
Helpdesk Initiated Prior Authorizations	353
PAs Missing Information	482
Pharmacotherapy	84
Changes to Existing PAs	509

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

SoonerSelect Aetna Prior Authorization Activity

9/1/2024 Through 9/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	228	162	29	37	364
Analgesics - Anti-Inflammatory	115	71	23	21	338
Analgesics - Nonnarcotic	1	0	1	0	0
Analgesics - Opioid	144	67	50	27	176
Androgens-Anabolic	48	14	33	1	365
Anorectal and Related Products	1	0	0	1	0
Anthelmintics	8	4	4	0	28
Ati-Infective Agents - Misc.	18	10	8	0	64
Anti-Obesity Agents	9	0	4	5	0
Antianxiety Agents	19	5	5	9	365
Antiasthmatic and Bronchodilator Agents	145	42	64	39	347
Antibiotics	24	3	12	9	253
Anticoagulants	4	1	0	3	181
Anticonvulsants	48	21	16	11	314
Antidepressants	166	44	79	43	295
Antidiabetics	419	93	244	82	323
Antiemetics	1	1	0	0	181
Antifungals	5	2	2	1	69
Antihistamines	19	4	15	0	365
Antihyperlipidemics	28	5	12	11	239
Antihypertensives	19	1	2	16	365
Atineoplastics and Adjunctive Therapies	25	12	1	12	295
Antiparkinson and Related Therapy Agents	4	1	1	2	91
Antipsychotics/Antimanic Agents	122	31	66	25	354
Antivirals	8	1	5	2	91
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	70	46	19	5	365
Beta Blockers	18	1	0	17	365
Calcium Channel Blockers	14	2	1	11	365
Cardiovascular Agents - Misc.	34	12	14	8	345
Contraceptives	10	4	5	1	365
Corticosteroids	8	1	1	6	365
Dermatologicals	241	87	112	42	249
Diagnostic Products	39	19	6	14	351
Dietary Products/Dietary Management Products	1	1	0	0	365
Digestive Aids	3	2	0	1	365
Diuretics	7	0	0	7	0
Endocrine and Metabolic Agents - Misc.	36	22	11	3	286
Estrogens	6	4	1	1	365
Gastrointestinal Agents - Misc.	69	20	45	4	269
Gout Agents	2	0	0	2	0
Hematological Agents - Misc.	5	3	1	1	253
Hematopoietic Agents	4	2	1	1	228
Hypnotics/Sedatives/Sleep Disorder Agents	19	5	5	9	255
Laxatives	11	2	7	2	198
Medical Devices and Supplies	78	22	29	27	332

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Migraine Products	160	34	121	5	247
Minerals and Electrolytes	2	0	1	1	0
Miscellaneous Therapeutic Classes	5	3	2	0	273
Multivitamins	4	4	0	0	365
Musculoskeletal Therapy Agents	28	3	9	16	142
Nasal Agents - Systemic and Topical	16	1	7	8	365
Neuromuscular Agents	12	3	3	6	365
Ophthalmic Agents	17	5	10	2	228
Other*	11	1	4	6	365
Otic Agents	14	1	13	0	30
Progestins	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	28	8	9	11	169
Respiratory Agents - Misc.	2	2	0	0	365
Stimulants - Misc.	74	48	21	5	349
Thyroid Agents	2	0	1	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	47	9	3	35	219
Urinary Antispasmodics	12	1	10	1	365
Vaccines	2	1	0	1	181
Vaginal and Related Products	4	0	2	2	0
Vitamins	24	8	15	1	331
****Total**	**2,768**	**983**	**1,165**	**620**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	2	2	0	0	228
Other	624	4	0	617	365
Quantity Limmit	28	28	0	0	205
Step Therapy	6	6	0	0	365
Overrides Total	**660**	**40**	**0**	**617**	

Denial Reasons	
Benefit	49
Experimental/Investigational	159
Lack Required Informationto Process Request	98
Medical Necessity	858
Other	1
Other PA Activity	
Duplicate Requests	10
Letters	3,416
No Process	258
Changes to Existing PAs	0
Heldesk Initiated PAs	7
PAs Missing Information	14

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

SoonerSelect Humana Prior Authorization Activity

9/1/2024 Through 9/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	2	2	0	273
Amphetamines	3	0	3	0	0
Analgesics - Anti-Inflammatory	58	46	12	0	356
Analgesics - Nonnarcotic	1	0	1	0	0
Analgesics - Opioid	69	38	31	0	252
Androgens - Anabolic	46	13	33	0	365
Anthelmintics	4	3	1	0	365
Anti-Infective Agents - Misc.	3	3	0	0	365
Anti-Obesity Agents	4	1	3	0	365
Antianxiety Agents	1	1	0	0	365
Antiasthmatic and Bronchodilator Agents	140	36	104	0	293
Antibiotics	12	4	8	0	365
Anticonvulsants	7	2	5	0	238
Antidepressants	35	16	19	0	308
Antidiabetics	186	69	117	0	365
Antifungals	3	1	2	0	365
Antihyperlipidemics	10	7	3	0	270
Antineoplastics and Adjunctive Therapies	45	34	11	0	228
Antiparkinson and Related Therapy Agents	5	2	3	0	365
Antivirals	5	3	2	0	225
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	14	7	7	0	365
Beta Blockers	1	1	0	0	365
Cardiovascular Agents - Misc.	18	10	8	0	365
Contraceptives	13	7	6	0	341
Corticosteroids	3	1	2	0	365
Dermatologicals	120	70	50	0	321
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	31	21	10	0	239
Estrogens	3	0	3	0	0
Gastrointestinal Agents - Misc.	85	31	54	0	229
Gout Agents	1	0	1	0	0
Hematopoietic Agents	18	3	15	0	239
Histamine H3-Receptor Antagonist/Inverse Agonists	4	0	4	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	11	0	11	0	0
Laxatives	5	0	5	0	0
Migraine Products	93	52	41	0	279
Miscellaneous Therapeutic classes	7	5	2	0	365
Musculoskeletal Therapy Agents	14	7	7	0	297
Nasal Agents - Systemic and Topical	2	0	2	0	0
Neuromuscular Agents	18	5	13	0	365
Nutrients	1	0	1	0	0
Ophthalmic Agents	8	1	7	0	365
Other*	19	10	9	0	365
Otic Agents	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	32	16	16	0	307
Respiratory Agents - Misc.	11	9	2	0	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Stimulants - Misc.	7	3	4	0	365
Thyroid Agents	1	0	1	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	6	2	4	0	365
Urinary Antispasmodics	26	9	17	0	365
Vaginal and Related Products	1	1	0	0	252
Vitamins	19	5	14	0	365
Total	**1,235**	**558**	**677**	**0**	

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Ingredient Duplication	74	32	42	0	364
MAT Override	7	5	2	0	671
NDC vs Age	186	148	38	0	366
Opioid MME Limit	3	1	2	0	96
Opioid Quantity	10	4	6	0	232
Other	130	12	118	0	340
Quantity vs Days Supply	196	110	86	0	345
STBS/STBSM	89	32	57	0	365
Step Therapy Exception	315	140	175	0	362
Overrides Total	**1,010**	**484**	**526**	**0**	
Total Regular PAs + Overrides	**2,245**	**1,042**	**1,203**	**0**	

Denial Reasons	
Benefit	372
Medical Necessity	831

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

SoonerSelect Oklahoma Complete Health Prior Authorization Activity

9/1/2024 Through 9/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	92	67	6	19	203
Analgesics - Anti-Inflammatory	78	40	30	8	367
Analgesics - Nonnarcotic	5	1	3	1	365
Analgesics - Opioid	278	95	137	46	185
Androgens - Anabolic	70	11	49	10	365
Anorectal and Related Products	4	0	4	0	0
Anorexiants Non-Amphetamine	3	0	3	0	0
Anthelmintics	4	1	3	0	365
Anti-Infective Agents - Misc.	7	5	1	1	365
Anti-Obesity Agents	33	0	27	6	0
Antianginal Agents	4	4	0	0	105
Antianxiety Agents	85	62	6	17	149
Antiasthmatic and Bronchodilator Agents	290	118	132	40	204
Antibiotics	7	4	3	0	276
Anticoagulants	8	3	2	3	190
Anticonvulsants	276	213	23	40	144
Antidepressants	344	232	56	56	182
Antidiabetics	651	353	203	95	272
Antiemetics	8	4	1	3	170
Antifungals	2	1	0	1	365
Antihistamines	17	2	9	6	367
Antihyperlipidemics	40	26	9	5	135
Antihypertensives	79	66	1	12	116
Antimalarials	2	0	0	2	0
Antineoplastics and Adjunctive Therapies	19	14	5	0	312
Antiparkinson and Related Therapy Agents	6	3	2	1	109
Antipsychotics/Antimanic Agents	180	106	46	28	212
Antiseptics and Disinfectants	1	0	1	0	0
Antivirals	6	2	3	1	107
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	40	18	19	3	202
Beta Blockers	53	41	0	12	108
Calcium Channel Blockers	30	27	0	3	168
Cardiovascular Agents - Misc.	43	17	20	6	365
Contraceptives	29	11	13	5	252
Corticosteroids	2	0	2	0	0
Cough/Cold/Allergy	1	1	0	0	110
Dermatologicals	240	92	105	43	278
Diagnostic Products	33	18	10	5	323
Dietary Products/Dietary Management Products	1	0	1	0	0
Digestive Aids	4	3	0	1	240
Diuretics	33	30	0	3	105
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	1	0	1	365
Endocrine and Metabolic Agents - Misc.	28	15	9	4	248
Estrogens	4	1	2	1	365
Gastrointestinal Agents - Misc.	64	19	38	7	292
Genitourinary Agents - Misc.	10	10	0	0	167
Hematological Agents - Misc.	5	3	0	2	234
Hematopoietic Agents	12	1	10	1	365
Histamine H3-Receptor Antagonist/Inverse Agonists	1	1	0	0	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	21	9	10	2	206
Laxatives	8	1	3	4	369
Medical Devices and Supplies	95	55	35	5	338
Migraine Products	132	33	76	23	301
Minerals and Electrolytes	1	0	1	0	0
Miscellaneous Therapeutic Classes	9	4	4	1	365
Multivitamins	4	3	1	0	365
Musculoskeletal Therapy Agents	21	8	9	4	269
Nasal Agents - Systemic and Topical	11	2	8	1	239
Neuromuscular Agents	2	0	2	0	0
Ophthalmic Agents	30	17	11	2	199
Other*	21	0	4	17	0
Otic Agents	47	19	25	3	275
Pharmaceutical Adjuvants	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	56	13	28	15	194
Respiratory Agents - Misc.	10	7	3	0	336
Stimulants - Misc.	104	74	19	11	253
Thyroid Agents	32	23	2	7	105
Ulcer Drugs/Antispasmodics/Anticholinergics	87	67	9	11	156
Urinary Antispasmodics	23	8	10	5	303
Vaccines	6	4	2	0	250
Vasopressors	1	1	0	0	103
Total**	**3,956**	**2,091**	**1,256**	**609**	

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

Denial Reasons	
Benefit	86
Medical Necessity	1,170

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

Fall 2024 Pipeline Update

Oklahoma Health Care Authority
October 2024

Introduction

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

Nerandomilast[1,2]

Anticipated Indication(s): Idiopathic pulmonary fibrosis (IPF)

Clinical Trial(s): In February 2022, the FDA granted Breakthrough Therapy designation for nerandomilast, a phosphodiesterase-4 (PDE-4) inhibitor for use in the treatment of IPF. The Phase 2 clinical trial for nerandomilast included patients both with and without background antifibrotic treatment (nintedanib or pirfenidone), provided they had a forced vital capacity (FVC) of at least 45% of the predicted value. In the prespecified mixed model with repeated measures (MMRM) analysis, among patients not using background antifibrotic therapy who received nerandomilast, the mean change in FVC was 6.1mL at week 12, compared to -95.6mL in the placebo group [difference: 101.7mL; 95% confidence interval (CI): 25, 178.4]. In patients who were using background antifibrotic therapy and received nerandomilast, the mean change in FVC from baseline to week 12 was 2.7mL, compared to -77.7mL in the placebo group (difference: 80.4mL; 95% CI: 20.9, 104.0). The most frequent side effect was diarrhea, experienced by 37% of the 97 patients who were randomized in the study. Nerandomilast also met its primary endpoint in the Phase 3 FIBRONEER-IPF clinical trial, which was the absolute change from baseline in FVC at week 52 versus placebo; full safety and efficacy data from the Phase 3 trial will be available in 2025.

Place in Therapy: Currently, IPF has no cure, but there are 2 medications, nintedanib and pirfenidone, that are used to slow the progression of the disease and reduce the frequency of acute exacerbations. Despite these

treatments, some patients may not see improvements in their FVC or may continue to experience disease progression. In such cases, introducing an additional agent specifically indicated for IPF could significantly enhance patient care. This new treatment option could offer potential benefits for those who have not responded adequately to existing therapies, helping to improve their FVC and potentially reduce the risk of adverse outcomes associated with the disease.

Projected FDA Decision: First half of 2025

SoonerCare Impact: During fiscal year 2024, there were 94 unique SoonerCare members with a reported diagnosed of IPF, and there were 30 members utilizing Ofev® (nintedanib) and 3 members utilizing Esbriet® (pirfenidone).

Crinecerfont[3,4]

Anticipated Indication(s): Classic congenital adrenal hyperplasia (CAH)

Clinical Trial(s): In December 2023, the FDA granted Breakthrough Therapy designation to crinecerfont for treating classic CAH in both pediatric and adult patients. The Phase 3 CAHtalyst trial included 176 patients assigned to the crinecerfont group and 60 patients in the placebo group. The primary efficacy endpoint was the percentage change in daily corticosteroid dosage from baseline to week 24, along with androstenedione control. At week 24, the crinecerfont group saw a -27.3% change in corticosteroid dose, compared to a -10.3% change in the placebo group. By week 4, androstenedione levels decreased by 299ng/dL in the crinecerfont group, while the placebo group increased by 45.5ng/dL.

Place in Therapy: CAH is a rare autosomal recessive condition that affects the adrenocorticotropic hormone (ACTH) and increases the excess production of adrenal androgens. CAH is classified into 2 subcategories, classical and non-classical, with classical being the more severe form. Classical CAH can lead to adrenal crisis and even death if not detected and treated. Corticosteroids are mainstay treatment for CAH but increased corticosteroid doses for CAH patients can cause multiple complications and decrease bone density. Crinecerfont is an oral corticotropin-releasing factor type 1 receptor (CRF-1) antagonist that enables the reduction of corticosteroid dose to a physiologic range and improves androgen control.

Projected FDA Decision: December 29, 2024

SoonerCare Impact: During fiscal year 2024, there were 72 unique SoonerCare members with a reported diagnosis of CAH. Crinecerfont has the potential to lower corticosteroids doses in members with classic CAH and

decrease complications associated with high-dose corticosteroids, ultimately enhancing health outcomes.

Glepaglutide[5]

Anticipated Indication(s): Short bowel syndrome (SBS)

Clinical Trial(s): The FDA granted Orphan Drug designation to glepaglutide for treating SBS. In the Phase 3 EASE-1 trial, a total of 106 patients with SBS with intestinal failure and dependence on parental support [parenteral nutrition and/or intravenous (IV) fluids/electrolytes] for at least 3 days per week were randomized to glepaglutide once weekly, glepaglutide twice weekly, or placebo. Glepaglutide administered twice weekly achieved statistical significance in the primary endpoint, reduction in the total weekly volume of parenteral support after 24 weeks compared to placebo, and was shown to be safe and well-tolerated. Additionally, 9 patients treated with glepaglutide were entirely weaned off parenteral support and achieved enteral autonomy.

Place in Therapy: SBS is a rare, malabsorption disorder caused by a lack of functional small intestines that often requires patients to rely on parenteral support to meet their caloric and/or fluid/electrolyte needs. Reliance on parenteral support not only limits quality of life but also carries significant risks of severe complications. Glepaglutide, an injectable glucagon-like peptide 2 (GLP-2) analogue, can alleviate the reliance on parenteral support for those with SBS and enhance overall health outcomes.

Projected FDA Decision: December 22, 2024

SoonerCare Impact: During fiscal year 2024, there were 9 unique SoonerCare members who were utilizing Gattex® (teduglutide) for SBS.

Pipeline Table[6,7]

Medication Name*	Manufacturer	Disease State	Route of Admin	Approval Status	Anticipated FDA Response
Marstacimab	Pfizer	Hemophilia A and B	SC	BLA; Fst Trk	10/11/2024
Sulopenem Etzadroxil/ Probenecid	Iterum Therapeutics	UTI	PO	Fst Trk	10/25/2024
Lebrikizumab	Eli Lilly	AD	SC	BLA	10/2024
Human Acellular Vessel	Humacyte	ESRD	Implant	BLA	11/10/2024
Eladocagene Exuparvovec	PTC Therapeutics	AADC Deficiency	Intra-cerebral	BLA; OD; RPD	11/13/2024
Govorestat	Applied Therapeutics	Galactos-emia	PO	NDA; Fst Trk; OD	11/28/2024
Acoramidis	BridgeBio	ATTR-CM	PO	NDA	11/29/2024
Garadacimab	CSL Limited	HAE	SC	BLA	12/14/2024
Revakinagene Taroretcel	Neurotech	MacTel Type 2	Implant	BLA	12/17/2024
Elarasan	Ionis	FCS	SC	BLA; Brk Thru; OD	12/19/2024
Glepaglutide	Zealand Pharma	SBS	SC	NDA	12/22/2024
Crinecerfront	Neurocrine Biosciences	Classic CAH	PO	NDA	12/29/2024
Vanazacaftor/ Tezacaftor/ Deutivacaftor	Vertex	Cystic Fibrosis	PO	NDA	01/02/2025
Remestemcel-L	Mesoblast/Novartis	Acute GVHD	IV	BLA; Fst Trk	01/07/2025
Elamipretide	Stealth	Barth Syndrome	IV	NDA; Fst Trk; OD	01/29/2025
Suzetrigine	Vertex	Acute pain	PO	NDA; Fst Trk; Brk Thru	01/30/2025
Concizumab	Novo Nordisk	Hemophilia A and B	SC	BLA	01/2025
Apomorphine	Supernus Pharmaceuticals	Parkinson's Disease	SC	NDA	02/01/2025
Bentracimab	SFJ Pharmaceuticals	Antiplatelet drug toxicity	IV	BLA	02/02/2025
Diazoxide Choline CR	Soleno Therapeutics	PWS	PO	NDA	02/28/2025
Condoliase	Ferring Pharmaceuticals/ Seikagaku	Pain	Intra-thecal	BLA	03/14/2025

Medication Name*	Manufacturer	Disease State	Route of Admin	Approval Status	Anticipated FDA Response
Etripamil	Milestone	Arrhythmia	IN	NDA	03/26/2025
Fitusiran	Alnylam/Sanofi	Hemophilia A and B	SC	Brk Thru	03/28/2025
Atrasentan	Novartis	IgA Nephro-pathy	PO	NDA	06/2025
Chenodeoxy-cholic Acid	Mirum Pharmaceuticals	CTX	PO	NDA	06/28/2025

*Most biosimilars and oncology medications are excluded from the table. Medications known to have received a Complete Response Letter (CRL) from the FDA that have not resubmitted were also excluded. AADC = Aromatic L-Amino Acid Decarboxylase; AATR-CM = Transthyretin Amyloid Cardiomyopathy; BLA = Biologic License Application; Brk Thru = Breakthrough; CAH = Congenital Adrenal Hyperplasia; CR = Controlled-Release; CTX = Cerebrotendinous Xanthomathosis; ESRD = end stage renal disease; FCS = familial chylomicronemia syndrome; Fst Trk = Fast Track; GVHD = graft-versus-host disease; HAE = Hereditary Angioedema; IN = intranasal; IV = intravenous; MacTel= macular telangiectasia; NDA = New Drug Application; OD = Orphan Drug; PO = by mouth; PWS = Prader-Willi Syndrome; RPD = Rare Pediatric Disease; SC = subcutaneous; SBS = Short Bowel Syndrome; UTI = urinary tract infection

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[3] Neurocrine Biosciences, Inc. Neurocrine Biosciences Announces U.S. FDA Accepts New Drug Applications and Grants Priority Review for Crinecerfont for Pediatric and Adult Patients with CAH. Available online at: https://neurocrine.gcs-web.com/news-releases/news-release-details/neurocrine-biosciences-announces-us-fda-accepts-new-drug-0. Issued 07/01/2024. Last accessed 09/24/2024.

[4] National Organization for Rare Disease. Congenital Adrenal Hyperplasia. Available online at: https://rarediseases.org/rare-diseases/congenital-adrenal-hyperplasia/. Last updated 06/08/2023. Last accessed 10/02/2024.

[5] Zealand Pharma, Inc. Zealand Pharma Announces Positive Results from Phase 3 Trial of Glepaglutide in Patients with Short Bowel Syndrome (EASE 1). Available online at: https://www.globenewswire.com/news-release/2022/09/30/2525830/0/en/Zealand-Pharma-Announces-Positive-Results-from-Phase-3-Trial-of-Glepaglutide-in-Patients-with-Short-Bowel-Syndrome-EASE-1.html. Issued 09/30/2022. Last accessed 09/16/2024.

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Appendix C

Vote to Prior Authorize Wainua™ (Eplontersen) and Update the Approval Criteria for the Amyloidosis Medications

Oklahoma Health Care Authority
October 2024

Market News and Updates[1]

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

- **December 2023:** The FDA approved Wainua™ (eplontersen), a transthyretin-directed antisense oligonucleotide, for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) in adults.

Wainua™ (Eplontersen) Product Summary[2,3]

Therapeutic Class: Transthyretin-directed antisense oligonucleotide (ASO)

Indication(s): Treatment of hATTR-PN in adults

How Supplied: 45mg/0.8mL single-dose autoinjector

Dosing and Administration: Recommended dose is 45mg every 4 weeks via subcutaneous (sub-Q) injection into the abdomen or upper thigh (back of the upper arm may be used if administered by a health care provider or caregiver)

Efficacy: The efficacy of Wainua™ was evaluated from the 35-week interim analysis of data from a Phase 3, randomized, open-label, multicenter trial in adult patients diagnosed with hATTR-PN.

- Key Inclusion Criteria:
  - Diagnosis of hATTR-PN with *TTR* gene mutation
  - Neuropathy Impairment Scale (NIS) score ≥10 and ≤130
  - Familial Amyloid Neuropathy (FAP) or Coutinho stage 1 or 2
- Key Exclusion Criteria:
  - Karnofsky Performance Scale status ≤50
  - Prior liver transplant or anticipated liver transplant within 1 year of screening
  - Alternative causes of sensorimotor or autonomic neuropathy
  - New York Heart Association (NYHA) Functional Classification ≥3
  - Current treatment with any approved drug for hATTR
  - Previous treatment with any other ASO or ribonucleic acid (RNA) therapy

- Treatment with tafamidis, tafamidis meglumine, or diflunisal must have been discontinued ≥2 weeks prior to trial day 1

- Intervention(s):
  - Wainua™ 45mg sub-Q once every 4 weeks vs. historical placebo group (population attained from NEURO-TTR trial which evaluated inotersen for FDA approval)
  - Patients were also randomized 6:1 to receive Wainua™ vs. inotersen 284mg sub-Q once per week (as a small, cross-trial comparison group)
  - All patients were required to take approximately 3000 IU/day of vitamin A
- Primary Endpoint(s):
  - Change in modified Neuropathy Impairment Scale+7 (mNIS+7) and Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) from baseline at week 35
- Results:
  - The least square mean change in mNIS+7 from baseline at week 35 was 0.2 [standard error of the mean (SEM): 1.9] for the Wainua™ group (n=140) vs. 9.2 (SEM: 1.9) for the placebo group (n=59), resulting in a treatment difference of -9.0 [95% confidence interval (CI): -13.5, -4.5; P <0.001]
  - The least square mean change in Norfold QoL-DN from baseline at week 35 was -3.1 (SEM: 2.1) for the Wainua™ group (n=140) vs. 8.7 (SEM: 2.1) for the placebo group (n=59), resulting in a treatment difference of -11.8 (95% CI: -16.8, -6.8; P <0.001)

Cost Comparison:

Product	Cost Per mL	Cost Per Year*
Wainua™ (eplontersen) 45mg/0.8mL autoinjector	**$51,979.16**	**$540,583.26**
Onpattro® (patisiran) 10mg/5mL single-dose vial	$1,957.00	$528,390.00
Tegsedi® (inotersen) 284mg/1.5mL prefilled syringe	$6,240.21	$486,736.38
Amvuttra® (vutrisiran) 25mg/0.5mL prefilled syringe	$238,702.00	$477,404.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per year is based on the FDA recommended dosing for Wainua™ 45mg every 4 weeks, Onpattro® 30mg (based on max dose for 100kg patient) every 3 weeks, Tegsedi® 284mg once weekly, and Amvuttra® 25mg every 3 months.

Recommendations

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

Wainua™ (Eplontersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by, or in consultation with, a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Wainua™; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Wainua™ will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
9. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 0.8mL per 28 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Amvuttra® (vutrisiran), Onpattro (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), and Vyndaqel® (tafamidis meglumine) to be more consistent with clinical practice (changes shown in red):

Amvuttra® (Vutrisiran) and Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by ~~the following:~~
   ~~a. Tissue (fat pad) biopsy confirming amyloid deposits; or~~
   b. Genetic ~~confirmation of~~ testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and

4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. For Onpattro®, prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
9. Amvuttra® will not be approved for concomitant use with Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), ~~or~~ Vyndamax® (tafamidis), or Wainua™ (eplontersen); and
10. Authorization for Amvuttra® will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and
11. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua™ (eplontersen); and
12. For Onpattro®, 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
13. For Amvuttra®, a quantity limit of 0.5mL per 90 days will apply; and
14. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by ~~the following:~~
   ~~a. Tissue (fat pad) biopsy confirming amyloid deposits; or~~
   b. Genetic ~~confirmation of~~ testing identifying a transthyretin (*TTR*) gene mutation (e.g., Val30Met) (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Tegsedi® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a

supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua™ (eplontersen); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
13. A quantity limit of 4 syringes per 28 days will apply.

Vyndamax® (Tafamidis) and Vyndaqel® (Tafamidis Meglumine) Approval Criteria:

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
    b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
    a. Nuclear scintigraphy; or
    b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and

6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® or Vyndaqel® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Vyndamax® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), ~~or~~ Tegsedi® (inotersen), or Wainua™ (eplontersen); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

[1] Ionis Pharmaceuticals, Inc. Wainua™ (Eplontersen) Granted Regulatory Approval in the U.S. for the Treatment of Adults with Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis. *PRNewswire*. Available online at: https://www.prnewswire.com/news-releases/wainua-eplontersen-granted-regulatory-approval-in-the-us-for-the-treatment-of-adults-with-polyneuropathy-of-hereditary-transthyretin-mediated-amyloidosis-302021385.html. Issued 12/21/2023. Last accessed 09/18/2024.
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[3] Coelho T, Marques Jr. W, Dasgupta NR, et. al. Eplontersen for Hereditary Transthyretin Amyloidosis with Polyneuropathy. *JAMA* 2023; 330(15):1448-1458. doi: 10.1001/jama.2023.18688.

Appendix D

Vote to Prior Authorize Hercessi™ (Trastuzumab-strf) and Truqap™ (Capivasertib) and Update the Approval Criteria for the Breast Cancer Medications

Oklahoma Health Care Authority
October 2024

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

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

- **March 2023:** The FDA approved Verzenio® (abemaciclib) for an expanded indication for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, in combination with an aromatase inhibitor as initial endocrine-based therapy. This new indication removes the previous requirement that it be used in postmenopausal women.
- **November 2023:** The FDA approved Truqap™ (capivasertib), in combination with fulvestrant, for the treatment of adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer with 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test following progression on at least 1 endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.
- **January 2024:** The FDA approved Piqray® (alpelisib) for an expanded indication, in combination with fulvestrant, for the treatment of adults with HR-positive, HER2-negative, *PIK3CA*-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. This new indication removes the previous requirement that it be used in postmenopausal women, allowing for the use of alpelisib in pre- and perimenopausal women.
- **April 2024:** The FDA granted accelerated approval for Enhertu® (fam-trastuzumab deruxtecan-nxki) for a new indication for the treatment of adult patients with unresectable or metastatic HER2-positive [immunohistochemistry (IHC) 3+] solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.
- **April 2024:** The FDA approved Hercessi™ (trastuzumab-strf), a new biosimilar to Herceptin® (trastuzumab), for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Hercessi™ will

be available as a 150mg lyophilized powder in a single-dose vial for reconstitution.
- **July 2024:** The FDA approved Kisqali® (ribociclib) for an expanded indication for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer, in combination with fulvestrant, as initial endocrine-based therapy or with disease progression following endocrine therapy. This new indication removes the previous requirement that it be used in postmenopausal women.
- **September 2024:** The FDA approved Kisqali® (ribociclib), in combination with an aromatase inhibitor, for the adjuvant treatment of adults with HR-positive, HER2-negative stage II and III early breast cancer at high risk of recurrence. Additionally, the FDA approved Kisqali® Femara® Co-Pack (ribociclib/letrozole) for the same indication.

Guideline Update(s):
- The National Comprehensive Cancer Network (NCCN) guidelines for colon and rectal cancer allow the use of Enhertu® (fam-trastuzumab deruxtecan-nxki) for HER2-amplified disease with IHC 3+ without the need for *BRAF* or *RAS* wild-type mutation.
- The NCCN guidelines for cervical, endometrial, ovarian, vaginal, and vulvar cancer allow the use of Enhertu® (fam-trastuzumab deruxtecan-nxki) as a single agent for HER2-amplified disease with IHC 2+ or 3+.
- The NCCN guidelines for breast cancer allow the use of Halaven® (eribulin) in combination with Margenza® (margetuximab-cmkb) for the treatment of advanced or metastatic HER2-positive disease that is either HR-negative or HR-positive with or without endocrine therapy.
- The NCCN guidelines for breast cancer allow the use of Ixempra® for locally advanced or metastatic HER2-positive disease in combination with trastuzumab as fourth-line therapy or beyond.
- The NCCN guidelines for breast cancer allow the use of Orserdu® for advanced or metastatic, estrogen-receptor (ER)-positive, HER2-negative disease with *ESR1* mutation that has progressed after at least 1 prior endocrine therapy in pre-menopausal women treated with ovarian ablation/suppression.

Truqap™ (Capivasertib) Product Summary[16]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment, in combination with fulvestrant, of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test following progression on at least 1 endocrine-based regimen in the

metastatic setting or recurrence on or within 12 months of completing adjuvant therapy

How Supplied: 160mg and 200mg oral tablets

Dosing and Administration: The recommended dose is 400mg [(2) 200mg tablets] twice daily (approximately 12 hours apart) with or without food, for 4 days followed by 3 days off, in combination with fulvestrant. Truqap™ should be continued until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is $358.16 per 200mg tablet, resulting in a cost of $22,922.24 per 28 days or $297,989.12 per year based on the recommended dosing.

Cost Comparison: Trastuzumab Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Herceptin® (trastuzumab) 150mg vial	$78.08	$3,513.60	$63,244.80
Herzuma® (trastuzumab-pkrb) 150mg vial	$62.63	$2,818.35	$50,730.30
Ogivri® (trastuzumab-dkst) 150mg vial	$55.78	$2,510.10	$45,181.80
Ontruzant® (trastuzumab-dttb) 150mg vial	$32.46	$1,460.70	$26,292.60
Kanjinti® (trastuzumab-anns) 150mg vial	$19.34	$870.30	$15,665.40
Trazimera® (trastuzumab-qyyp) 150mg vial	$12.64	$568.80	$10,238.40

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 21 days based on a dose of 6mg/kg every 3 weeks for a member weighing 75kg
Please note: Cost information is not yet available for Hercessi™ (trastuzumab-strf) to allow for a cost comparison.

Recommendations

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

Truqap™ (Capivasertib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic breast cancer; and
2. Hormone receptor (HR)-positive; and
3. Human epidermal growth factor receptor 2 (HER2)-negative; and
4. Used in combination with fulvestrant; and
5. Contains 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test; and
6. Member meets 1 of the following:
    a. Progressed following at least 1 endocrine-based regimen in the metastatic setting; or
    b. Progressed within 12 months of completing adjuvant therapy.

The College of Pharmacy also recommends updating the approval criteria for Enhertu® (fam-trastuzumab deruxtecan-nxki), Kisqali® (ribociclib), Kisqali® Femara® Co-Pack (Ribociclib/Letrozole), Piqray® (alpelisib), and Verzenio® (abemaciclib) based on recent FDA approvals (changes and new criteria noted in red):

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of an unresectable or metastatic human epidermal receptor type 2 (HER2)-positive immunohistochemistry (IHC) 3+ solid tumor; and
2. Has received prior systemic treatment with no satisfactory alternative treatment options.

Kisqali® (Ribociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Hormone receptor (HR) positive; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Used in 1 of the following settings:
    a. Diagnosis of stage II or III early breast cancer at high risk for recurrence as adjuvant therapy; and
        i. In combination with an aromatase inhibitor; or
    b. Diagnosis of advanced or metastatic breast cancer, as initial therapy; and
        i. In combination with an aromatase inhibitor; or
    c. Diagnosis of advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy; and
        i. In combination with fulvestrant~~; and~~
        ~~ii. Must be used in postmenopausal women only.~~

Kisqali® Femara® Co-Pack (Ribociclib/Letrozole) Approval Criteria [Breast Cancer Diagnosis]:

1. Hormone receptor (HR) positive; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Used in 1 of the following settings:
    a. Diagnosis of stage II or III early breast cancer at high risk of recurrence, as adjuvant therapy; or
    b. Diagnosis of advanced or metastatic breast cancer, as initial therapy.

Piqray® (Alpelisib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer that has progressed on or after an endocrine-based regimen ~~in men or in postmenopausal women~~; and
2. Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative; and

3. PIK3CA-mutated disease; and
4. In combination with fulvestrant.

Verzenio® (Abemaciclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
    a. Hormone receptor positive disease; and
    b. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in 1 of the following settings:
            1. In combination with an aromatase inhibitor as initial endocrine-based therapy ~~for postmenopausal women~~; or
            2. In combination with fulvestrant with disease progression following endocrine therapy; or
            3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or
2. Diagnosis of early-stage breast cancer; and
    a. Hormone receptor positive disease; and
    b. HER2-negative disease; and
    c. Node-positive disease high risk for recurrence; and
    d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the Enhertu® (fam-trastuzumab deruxtecan-nxki), Halaven® (eribulin), Ixempra® (ixabepilone), and Orserdu® (elacestrant) approval criteria based on NCCN recommendations (changes and new criteria noted in red):

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic disease; and
2. Disease has progressed on prior therapy; and
3. Human epidermal receptor type 2 (HER2)-amplified disease with immunohistochemistry (IHC) 3+; and
4. ~~RAS and BRAF mutation negative; and~~
5. Used as a single agent.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Cervical, Endometrial, Ovarian, Vaginal, or Vulvar Cancer Diagnosis]:

1. Diagnosis of advanced, recurrent, or metastatic cervical, endometrial, ovarian, vaginal, or vulvar cancer; and
2. Human epidermal receptor type 2 (HER2)-positive with immunohistochemistry (IHC) 2+ or 3+; and
3. Used as a single agent.

Halaven® (Eribulin) Approval Criteria [Recurrent or Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Used in 1 of the following settings:
    a. Previously received ≥2 chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting; or
    b. In combination with margetuximab-cmkb or trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease that is:
        i. Hormone receptor (HR) negative; or
        ii. HR positive with or without endocrine therapy; or
    c. As a single-agent for HER2-negative disease that is:
        i. HR negative; or
        ii. HR positive with visceral crisis or endocrine therapy refractory.

Ixempra® (Ixabepilone) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic or locally advanced breast cancer; and
2. Used in combination with capecitabine; and
    a. After failure of an anthracycline and a taxane unless anthracycline contraindicated; or
3. Used as a single agent; and
    a. Used in 1 of the following settings:
        i. After failure of capecitabine, an anthracycline, and a taxane; or
        ii. In members with no response to preoperative systemic therapy; or
        iii. After at least 1 line of therapy for recurrent unresectable (local or regional) disease; or
        iv. Disease is human epidermal growth factor receptor 2 (HER2)-negative; or
4. Used in combination with trastuzumab; and
    a. Disease is HER2-positive; and
    b. ~~Third-line~~ Fourth-line or subsequent therapy.

Orserdu® (Elacestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and
3. Tumor is positive for ESR1-mutation; and
4. Female members must be postmenopausal or, if pre-menopausal, member must be treated with ovarian ablation/suppression; and

5. Has progressed after at least 1 prior endocrine therapy.

Lastly, the College of Pharmacy recommends the prior authorization of Hercessi™ (trastuzumab-strf) and updating the approval criteria for the trastuzumab products based on net costs (changes and additions shown in red):

Herceptin® (Trastuzumab), Herceptin Hylecta™ (Trastuzumab/ Hyaluronidase-oysk), Hercessi™ (Trastuzumab-strf), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Preferred trastuzumab products include ~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ or Trazimera® (trastuzumab-qyyp)]. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Herceptin® (Trastuzumab), Hercessi™ (Trastuzumab-strf), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with pertuzumab, lapatinib, or tucatinib; and
4. Used in 1 of the following settings:
    a. If first-line therapy, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression; and
5. Preferred trastuzumab products include ~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-

pkrb), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ or Trazimera® (trastuzumab-qyyp)]. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Herceptin® (Trastuzumab), Hercessi™ (Trastuzumab-strf), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include ~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ or Trazimera® (trastuzumab-qyyp)]. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

[1] Eli Lilly and Company. U.S. FDA Broadens Indication for Verzenio® (Abemaciclib) in HR+, HER2-, Node-Positive, High Risk Early Breast Cancer. Available online at: https://investor.lilly.com/news-releases/news-release-details/us-fda-broadens-indication-verzenior-abemaciclib-hr-her2-node. Issued 03/03/2023. Last accessed 09/23/2024.
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Appendix E

Fiscal Year 2024 Annual Review of Myeloproliferative Neoplasm (MPN) Medications

Oklahoma Health Care Authority
October 2024

Current Prior Authorization Criteria

Utilization data for Reblozyl® (luspatercept-aamt) and approval criteria for indications other than MPN can be found in the October 2024 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the anemia medications.

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

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

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

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

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

1. Diagnosis of MF in adult members; and
2. Intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia).

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

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

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

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

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

1. Diagnosis of PV; and

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

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

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

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

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

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

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

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

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and
    a. Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6 months if there is no evidence of disease progression or adverse drug reactions; and
2. The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:
    a. Any request for an oncology medication which does not meet approval criteria; or
    b. Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or
    c. Any level-1 appeal request for an oncology medication; or
    d. Any peer-to-peer request for an oncology medication.

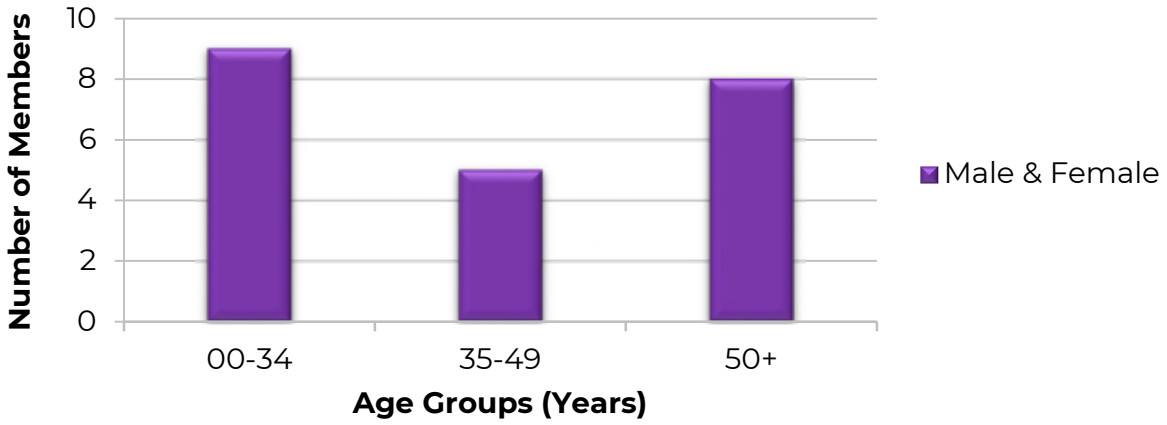
Utilization of MPN Medications: Fiscal Year 2024

Comparison of Fiscal Years (All Plans)

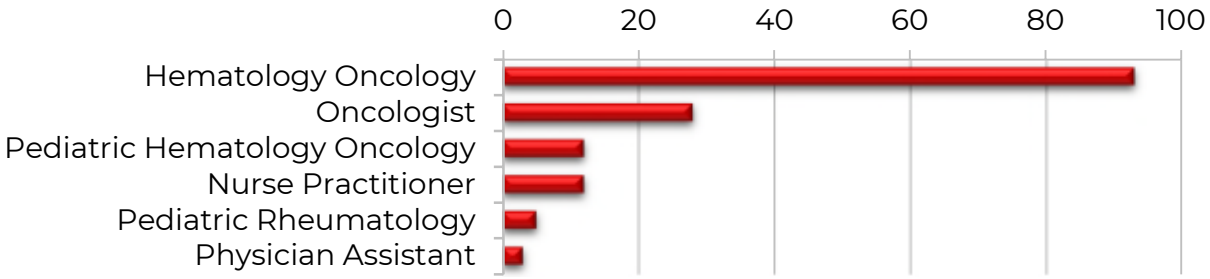
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	28	211	$3,379,741.86	$16,017.73	$520.84	12,340	6,489
2023 Total	**28**	**211**	**$3,379,741.86**	**$16,017.73**	**$520.84**	**12,340**	**6,489**
Fiscal Year 2024							
FFS	22	136	$2,120,188.85	$15,589.62	$513.99	7,560	4,125
Aetna	2	3	$51,484.23	$17,161.41	$572.05	180	90
Humana	4	8	$202,438.46	$25,304.81	$843.49	540	240
OCH	2	6	$102,968.46	$17,161.41	$572.05	360	180
2024 Total	**22**	**153**	**$2,477,080.00**	**$16,190.07**	**$534.43**	**8,640**	**4,635**
% Change	**-21.40%**	**-27.50%**	**-26.70%**	**1.10%**	**2.60%**	**-30.00%**	**-28.60%**
Change	**-6**	**-58**	**-$902,661.86**	**$172.34**	**$13.59**	**-3,700**	**-1,854**

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 SoonerSelect plans.

Demographics of Members Utilizing MPN Medications (All Plans)



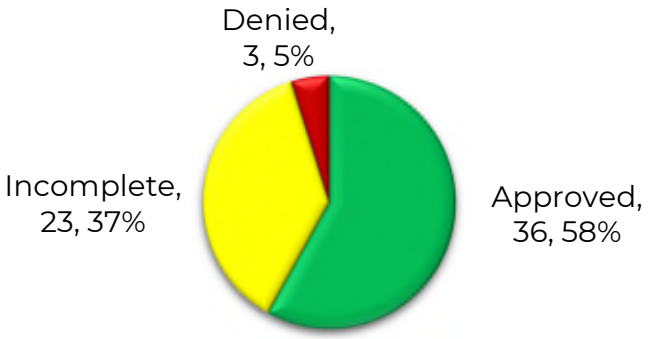
Top Prescriber Specialties of MPN Medications by Number of Claims (All Plans)



Prior Authorization of MPN Medications

There were 62 prior authorization requests submitted for MPN medications during fiscal year 2024. The following charts show 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	%	Number	%	Number	%	
FFS	33	57%	22	38%	3	5%	**58**
Aetna	0	0%	1	100%	0	0%	**1**
Humana	1	100%	0	0%	0	0%	**1**
OCH	2	100%	0	0%	0	0%	**2**
Total	**36**	**58%**	**23**	**37%**	**3**	**5%**	**62**

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]

Anticipated Patent Expiration(s):

- Jakafi® (ruxolitinib): December 2028
- Vonjo (pacritinib): March 2030
- Inrebic® (fedratinib): September 2039
- Ojjaara (momelotinib): December 2040

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

- **July 2024:** The FDA approved a supplemental New Drug Application (sNDA) for Inrebic® (fedratinib) to add additional information to the label regarding the use of thiamine. The updated label now lists thiamine as a required concomitant medication, and states that all patients should receive prophylaxis with thiamine 100mg orally daily during treatment with Inrebic®.

Recommendations

The College of Pharmacy recommends updating the approval criteria for Inrebic® (fedratinib) based on the recent FDA label update with the following changes (shown in red):

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

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

Utilization Details of MPN Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RUXOLITINIB PRODUCTS						
JAKAFI TAB 20MG	48	8	$721,975.27	$15,041.15	6	34.05%
JAKAFI TAB 5MG	31	8	$608,637.21	$19,633.46	3.88	28.71%
JAKAFI TAB 10MG	25	7	$331,938.25	$13,277.53	3.57	15.66%
JAKAFI TAB 15MG	24	5	$322,160.84	$13,423.37	4.8	15.19%
JAKAFI TAB 25MG	8	1	$135,477.28	$16,934.66	8	6.39%
TOTAL	**136**	**22***	**$2,120,188.85**	**$15,589.62**	**6.18**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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
RUXOLITINIB PRODUCTS						
JAKAFI TAB 20MG	2	1	$34,322.82	$17,161.41	2	66.67%
JAKAFI TAB 25MG	1	1	$17,161.41	$17,161.41	1	33.33%
TOTAL	**3**	**2***	**$51,484.23**	**$17,161.41**	**1.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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
RUXOLITINIB PRODUCTS						
JAKAFI TAB 15MG	3	1	$99,481.41	$33,160.47	3	49.14%
JAKAFI TAB 5MG	2	1	$68,622.82	$34,311.41	2	33.90%
JAKAFI TAB 20MG	2	1	$17,172.82	$8,586.41	2	8.48%
JAKAFI TAB 25MG	1	1	$17,161.41	$17,161.41	1	8.48%
TOTAL	**8**	**4***	**$202,438.46**	**$25,304.81**	**2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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
RUXOLITINIB PRODUCTS						
JAKAFI TAB 15MG	3	1	$51,484.23	$17,161.41	3	50.00%
JAKAFI TAB 20MG	3	1	$51,484.23	$17,161.41	3	50.00%
TOTAL	**6**	**2***	**$102,968.46**	**$17,161.41**	**3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 09/2024. Last accessed 09/18/2024.
[2] U.S. FDA. Inrebic® (Fedratinib) Supplemental New Drug Application (sNDA) Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/212327Orig1s006ltr.pdf. Issued 07/30/2024. Last accessed 09/18/2024.
[3] Inrebic® (Fedratinib) Prescribing Information. Bristol-Myers Squibb Company. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/212327s006lbl.pdf. Last revised 07/2024. Last accessed 09/18/2024.

Appendix F

Fiscal Year 2024 Annual Review of Hepatitis C Medications

Oklahoma Health Care Authority
October 2024

Current Prior Authorization Criteria

Mavyret® (glecaprevir/pibrentasvir) is the preferred direct-acting antiviral (DAA) for the treatment of chronic hepatitis C virus (HCV) based on net cost after supplemental rebate participation and value-based agreement (VBA) with the Oklahoma Health Care Authority (OHCA). DAAs for the treatment of chronic HCV are preferred based on the lowest net cost product(s) and may be moved to non-preferred if the net cost changes in comparison to the other available DAAs. Effective starting July 2022, as a result of the VBA and as part of an initiative by OHCA to cure HCV in the SoonerCare population, the prior authorization requirement was removed from Mavyret® (glecaprevir/pibrentasvir). Use of an alternative DAA medication for the treatment of HCV requires prior authorization and a patient-specific, clinically significant reason why the preferred DAA is not appropriate for the member. Mavyret® (glecaprevir/pibrentasvir) oral pellets are covered for pediatric members 3 to 11 years of age requiring that dosage formulation. The following is a template for standard prior authorization criteria for the non-preferred HCV DAA medications. The criteria for each medication is based on FDA approved regimens and American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) guidance-recommended regimens. Specific HCV medication criteria will vary based on product labeling, FDA approved indications, AASLD/IDSA guidance recommendations, drug interaction potential, and use in specific populations.

Hepatitis C Medication Approval Criteria:

1. An FDA approved age appropriate to the requested medication; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) and an FDA-indicated genotype (GT) appropriate to the requested medication; and
3. Requested hepatitis C medication must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
4. Hepatitis C virus (HCV) GT testing must be confirmed and indicated on the prior authorization request; and
5. Member has chronic HCV infection defined by:

a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent), then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
b. If the member has a liver fibrosis score <F1 (METAVIR equivalent), then the following must be met:
    i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
    ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

6. FDA approved regimens and requirements based on cirrhosis status, viral GT, treatment history, and viral load thresholds will apply; and
7. Member must sign and submit the Hepatitis C Intent to Treat Contract; and
8. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
9. Prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including sustained virologic response (SVR-12); and
10. Prescriber must agree to counsel members on the potential harms of illicit intravenous (IV) drug use or alcohol use and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
11. Documentation of initiation of immunization with the hepatitis A and B vaccines must be provided; and
12. Decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C) restrictions based on FDA approvals and safety recommendations will apply; and
13. Member must not have a limited life expectancy (<12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
14. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy; and
15. Member must not be taking any medications not recommended for use with the requested hepatitis C medication; and
16. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight-management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and

17. Prescriber must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
18. Member must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and
19. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 16 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

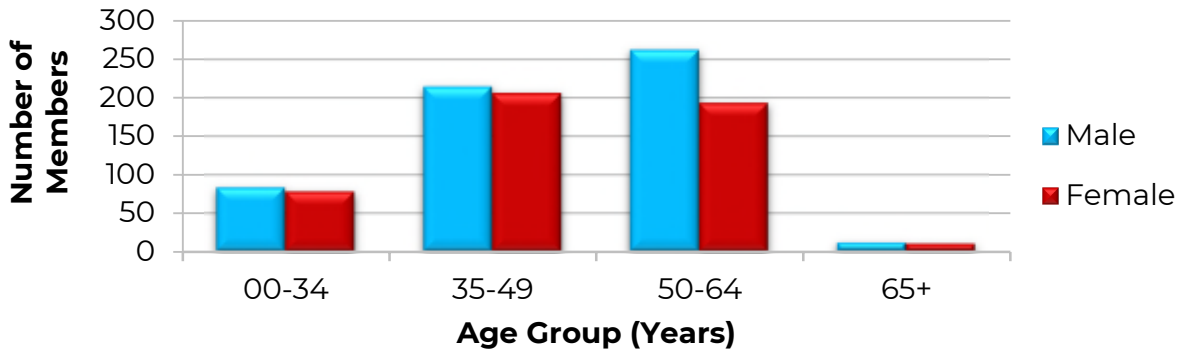
Utilization of Hepatitis C Medications: Fiscal Year 2024

Comparison of Fiscal Years (All Plans)

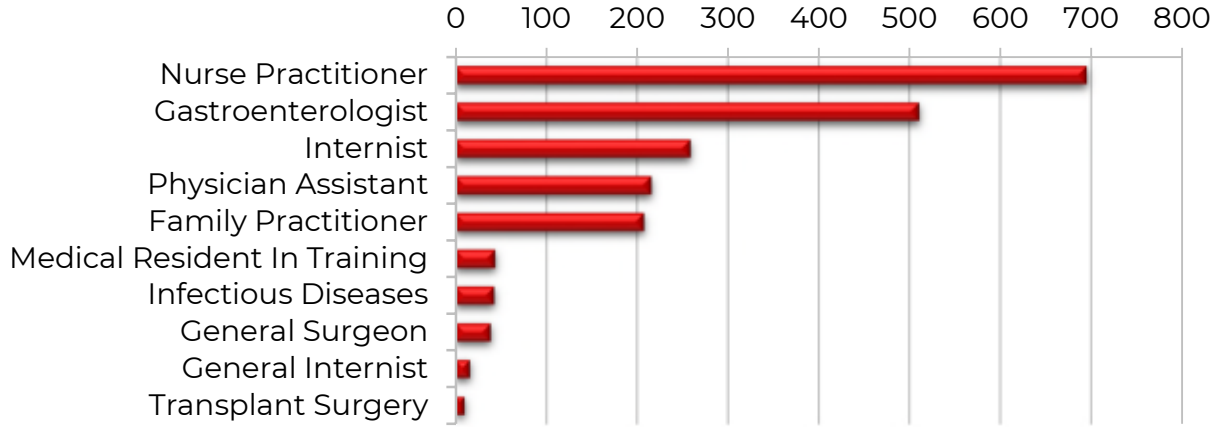
*Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	1,258	2,556	$30,368,868.57	$11,881.40	$424.25	190,923	71,582
2023 Total	**1,258**	**2,556**	**$30,368,868.57**	**$11,881.40**	**$424.25**	**190,923**	**71,582**
Fiscal Year 2024							
FFS	905	1,752	$21,865,844.89	$12,480.51	$446.44	138,498	48,978
Aetna	78	114	$1,374,745.84	$12,059.17	$429.88	8,968	3,198
Humana	70	95	$1,227,518.67	$12,921.25	$461.47	6,804	2,660
OCH	66	103	$1,366,298.67	$13,265.04	$473.75	7,980	2,884
2024 Total	**1,057**	**2064**	**$25,834,408.07**	**$12,516.67**	**$447.58**	**162,250**	**57,720**
% Change	**-15.98%**	**-19.25%**	**-14.93%**	**5.35%**	**5.50%**	**-15.02%**	**-19.37%**
Change	**-201**	**-492**	**-4,534,460.50**	**$635.27**	**$23.33**	**-28,673**	**-13,862**

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.

Demographics of Members Utilizing Hepatitis C Medications (All Plans)



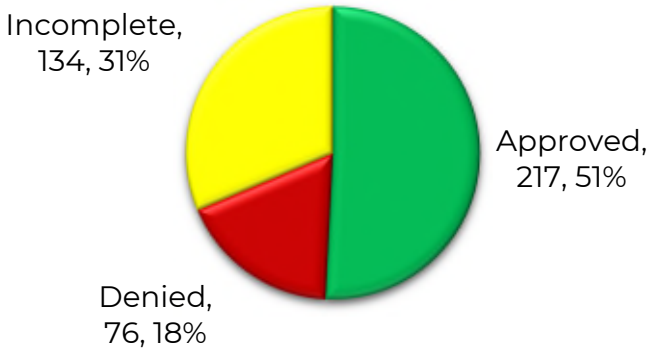
Top Prescriber Specialties of Hepatitis C Medications by Number of Claims (All Plans)



Prior Authorization of Hepatitis C Medications

There were 427 prior authorization requests submitted to all plans for hepatitis C medications during fiscal year 2024. The following charts show 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	186	51%	130	35%	51	14%	**367**
Aetna	7	46%	4	27%	4	27%	**15**
Humana	4	31%	0	0%	9	69%	**13**
OCH	20	62%	0	0%	12	38%	**32**
Total	**217**	**51%**	**134**	**31%**	**76**	**18%**	**427**

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]

Anticipated Patent Expiration(s):

- Zepatier® (elbasvir/grazoprevir tablets): May 2031
- Sovaldi® (sofosbuvir pellets and tablets): June 2031
- Harvoni® (ledipasvir/sofosbuvir pellets): March 2033
- Epclusa® (sofosbuvir/velpatasvir pellets and tablets): July 2034
- Harvoni® (ledipasvir/sofosbuvir tablets): July 2034
- Mavyret® (glecaprevir/pibrentasvir pellets): December 2035
- Mavyret® (glecaprevir/pibrentasvir tablets): December 2036
- Vosevi® (sofosbuvir/velpatasvir/voxilaprevir tablets): December 2037

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

- **October 2023:** The FDA approved updated package labeling for Mavyret® (glecaprevir/pibrentasvir) tablet and oral pellet with drug-drug interaction information regarding the coadministration of ethinyl estradiol-containing products. The previous labeling stated that coadministration of these products may increase the risk of alanine aminotransferase (ALT) elevations and is, therefore, not recommended. The revision, based on data supplied from a supplemental New Drug Application (sNDA), updates that Mavyret® may be used with products containing 20mcg or less of ethinyl estradiol and coadministration with products containing more than 20mcg of ethinyl estradiol may increase the risk of ALT elevations and is not recommended.

News:

- **June 2024:** The FDA granted marketing authorization to Cepheid for the first point-of-care hepatitis C virus (HCV) ribonucleic acid (RNA) test (Xpert HCV) and GeneXpert Xpress System. The test may be performed under a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver and delivers results from a fingertip blood sample in approximately 1 hour.

Pipeline:

- **Bemnifosbuvir/Ruzasvir:** Atea Pharmaceuticals is currently conducting a multinational Phase 2 clinical trial of bemnifosbuvir/ruzasvir, a once-daily oral nucleotide NS5B polymerase inhibitor/NS5A inhibitor combination, for the treatment of HCV infection in treatment-naïve patients without cirrhosis or with compensated cirrhosis across all genotypes. The safety and efficacy of an 8-week treatment course is being evaluated with the primary endpoint of sustained virologic response (SVR) at week 12 post-treatment. In June 2024, Atea released new data from the lead-in cohort of 60 patients without cirrhosis that showed 97% of these patients met the primary endpoint across all genotypes enrolled (full

demographic information is not published). There were no serious drug-related adverse events noted. Based on available data, Atea suggests a possible advantage of this investigational product over other available therapies is a lower risk of drug-drug interactions; however, studies are still in progress.

Recommendations

The College of Pharmacy recommends the following changes to Hepatitis C Medication Approval Criteria based on clinical practice and to be consistent with requirements concerning substance use disorder (SUD) under the Americans with Disabilities Act (ADA) (changes shown in red):

Hepatitis C Medication Approval Criteria:

1. An FDA approved age appropriate to the requested medication; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) and an FDA-indicated genotype (GT) appropriate to the requested medication; and
3. Requested hepatitis C medication must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
4. Hepatitis C virus (HCV) GT testing must be confirmed and indicated on the prior authorization request; and
5. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent), then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent), then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
6. FDA approved regimens and requirements based on cirrhosis status, viral GT, treatment history, and viral load thresholds will apply; and
7. Member must sign and submit the Hepatitis C Intent to Treat Contract; and
8. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
9. Prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including sustained virologic response (SVR-12); and

10. Prescriber must agree to counsel members on the potential harms of illicit intravenous (IV) drug use or alcohol use ~~and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy~~; and
11. Documentation of initiation of immunization with the hepatitis A and B vaccines must be provided; and
12. Decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C) restrictions based on FDA approvals and safety recommendations will apply; and
13. Member must not have a limited life expectancy (<12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
14. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy; and
15. Member must not be taking any medications not recommended for use with the requested hepatitis C medication; and
16. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight-management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
17. Prescriber must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
18. Member must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and
19. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 16 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Utilization Details of Hepatitis C Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLECAPREVIR/PIBRENTASVIR PRODUCTS						
MAVYRET TAB 100-40MG	1,541	838	$19,577,034.55	$12,704.11	1.84	89.53%
MAVYRET PAK 50-20MG	7	3	$63,438.75	$9,062.68	2.33	0.29%
SUBTOTAL	**1,548**	**841**	**$19,640,473.30**	**$12,687.64**	**1.84**	**89.82%**
SOFOSBUVIR/VELPATASVIR PRODUCTS						
SOF/VEL TAB 400-100MG	114	44	$873,812.85	$7,665.03	2.59	4.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
EPCLUSA TAB 400-100MG	33	15	$718,934.62	$21,785.90	2.2	3.29%
SUBTOTAL	**147**	**59**	**$1,592,747.47**	**$10,835.02**	**2.49**	**7.29%**
RIBAVIRIN PRODUCTS						
RIBAVIRIN TAB 200MG	20	8	$1,599.46	$79.97	2.5	0.01%
RIBAVIRIN CAP 200MG	9	3	$1,480.89	$164.54	3	0.01%
SUBTOTAL	**29**	**11**	**$3,080.35**	**$106.22**	**2.64**	**0.02%**
SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR PRODUCTS						
VOSEVI TAB 400-100-100MG	25	8	$620,613.59	$24,824.54	3.13	2.84%
SUBTOTAL	**25**	**8**	**$620,613.59**	**$24,824.54**	**3.13**	**2.84%**
PEGINTERFERON ALPHA-2A PRODUCTS						
PEGASYS INJ 180MCG/ML	2	1	$8,930.18	$4,465.09	2	0.04%
SUBTOTAL	**2**	**1**	**$8,930.18**	**$4,465.09**	**2**	**0.04%**
TOTAL	**1,751**	**904***	**$21,865,844.89**	**$12,487.63**	**1.94**	**100%**

Costs do not reflect rebated prices or net costs.
Only data from 04/01/2024 to 06/30/2024 are available.
*Total number of unduplicated utilizing members.
SOF/VEL = sofosbuvir/velpatasvir; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: During fiscal year 2024, Mavyret® was the preferred DAA product for SoonerCare, as reflected in the above data.

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLECAPREVIR/PIBRENTASVIR PRODUCTS						
MAVYRET TAB 100-40MG	95	71	$1,218,464.62	$12,825.94	1.34	88.63%
SUBTOTAL	**95**	**71**	**$1,218,464.62**	**$12,825.94**	**1.34**	**88.63%**
SOFOSBUVIR/VELPATASVIR PRODUCTS						
SOF/VEL TAB 400-100MG	11	7	$85,631.49	$7,784.68	1.57	6.23%
EPCLUSA TAB 400-100MG	2	1	$48,433.35	$24,216.68	2	3.52%
SUBTOTAL	**13**	**8**	**$134,064.84**	**$10,312.68**	**1.63**	**9.75%**
RIBAVIRIN PRODUCTS						
RIBAVIRIN TAB 200MG	3	1	$342.15	$114.05	3	0.02%
SUBTOTAL	**3**	**1**	**$342.15**	**$114.05**	**3**	**0.02%**
ELBASVIR/GRAZOPREVIR PRODUCTS						
ZEPATIER TAB 50-100MG	3	1	$21,874.23	$7,291.41	3	1.59%
SUBTOTAL	**3**	**1**	**$21,874.23**	**$7,291.41**	**3**	**1.59%**
TOTAL	**114**	**78***	**$1,374,745.84**	**$12,059.17**	**1.46**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
SOF/VEL = sofosbuvir/velpatasvir; 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.
Please note: During fiscal year 2024, Mavyret® was the preferred DAA product for SoonerCare, as reflected in the above data.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLECAPREVIR/PIBRENTASVIR PRODUCTS						
MAVYRET TAB 100-40MG 40MG	74	58	$949,093.78	$12,825.59	1.28	77.32%
SUBTOTAL	**74**	**58**	**$949,093.78**	**$12,825.59**	**1.28**	**77.32%**
SOFOSBUVIR/VELPATASVIR PRODUCTS						
SOF/VEL TAB 400-100MG	14	10	$108,953.97	$7,784.43	1.4	8.88%
EPCLUSA TAB 400-100MG	7	2	$169,470.92	$24,210.13	3.5	13.81%
SUBTOTAL	**21**	**12**	**$278,424.89**	**$13,258.33**	**1.75**	**22.69%**
TOTAL	**95**	**70***	**$1,227,518.67**	**$12,921.25**	**1.36**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
SOF/VEL = sofosbuvir/velpatasvir; 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.
Please note: During fiscal year 2024, Mavyret® was the preferred DAA product for SoonerCare, as reflected in the above data.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLECAPREVIR/PIBRENTASVIR PRODUCTS						
MAVYRET TAB 100-40MG	89	60	$1,140,517.44	$12,814.80	1.48	83.47%
MAVYRET PAK 50-20MG	2	1	$15,863.54	$7,931.77	2	1.16%
SUBTOTAL	**91**	**61**	**$1,156,380.98**	**$12,707.48**	**1.49**	**84.63%**
SOFOSBUVIR/VELPATASVIR PRODUCTS						
SOF/VEL TAB 400-100MG	7	2	$169,860.64	$24,265.81	3.5	12.43%
EPCLUSA TAB 400-100MG	5	3	$40,057.05	$8,011.41	1.67	2.93%
SUBTOTAL	**12**	**5**	**$209,917.69**	**$17,493.14**	**2.4**	**15.36%**
TOTAL	**103**	**66***	**$1,366,298.67**	**$30,200.62**	**1.56**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
PAK = pack; SOF/VEL = sofosbuvir/velpatasvir; 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.
Please note: During fiscal year 2024, Mavyret® was the preferred DAA product for SoonerCare, as reflected in the above data.

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[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 09/2024. Last accessed 09/23/2024.
[2] Mavyret® (Glecaprevir/Pibrentasvir) Prescribing Information. Abbvie. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209394s016,215110s003lbl.pdf. Last revised 10/25/2023. Last accessed 09/23/2024.
[3] U.S. FDA. FDA Permits Marketing of First Point-of-Care Hepatitis C RNA Test. Available online: https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-point-care-hepatitis-c-rna-test. Issued 06/27/2024. Last accessed 09/23/2024.
[4] Atea Pharmaceuticals. Combination of Bemnifosbuvir and Ruzasvir for HCV. Available online: https://ateapharma.com/hepatitis-c/bemnifosbuvir-ruzasvir/. Last accessed 09/23/2024.

Appendix G

Fiscal Year 2024 Annual Review of Targeted Immunomodulator Agents and 30-Day Notice 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)

Oklahoma Health Care Authority
October 2024

Current Prior Authorization Criteria

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

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
			avacopan (Tavneos®)**
			baricitinib (Olumiant®)€
			belimumab (Benlysta®)**
			canakinumab (Ilaris®)¥
			deucravacitinib (Sotyktu™)
			etanercept-szzs (Erelzi®)±
			etanercept-ykro (Eticovo®)±
			guselkumab (Tremfya®)
			ixekizumab (Taltz®)
			rilonacept (Arcalyst®)**
			risankizumab-rzaa (Skyrizi®)
			ritlecitinib (Litfulo™)€
			secukinumab (Cosentyx®)
			spesolimab-sbzo (Spevigo®)**
			tildrakizumab-asmn (Ilumya®)
			tocilizumab (Actemra®)π
			tocilizumab-bavi (Tofidence™)±
			upadacitinib (Rinvoq®)#
			ustekinumab (Stelara®)
			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.
ß Unique criteria applies for a diagnosis of Behçet's disease (BD).
¥Unique criteria applies for a diagnosis of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor-associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), familial Mediterranean fever (FMF), systemic juvenile idiopathic arthritis (SJIA), adult-onset Still's disease (AOSD), or gout flare.
~Unique criteria applies for a diagnosis of pemphigus vulgaris (PV). Unique criteria applies for a diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).
πUnique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS), and systemic sclerosis-associated interstitial lung disease (SSc-ILD).
¤Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.
#Unique criteria applies for 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).
**Unique criteria applies to this medication for approval.

Targeted Immunomodulator Agents Tier-2 Approval Criteria:

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

Targeted Immunomodulator Agents Tier-3 Approval Criteria:

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

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

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. A recent trial (within the last 360 days) of 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), 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 Humira® (adalimumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Actemra® (Tocilizumab) Approval Criteria [Chimeric Antigen Receptor (CAR) T Cell-Induced Cytokine Release Syndrome (CRS) Diagnosis]:

1. An FDA approved diagnosis of CAR T cell-induced CRS.

Actemra® (Tocilizumab) 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. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

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

1. An FDA approved diagnosis SSc-ILD; and
2. Member must be 18 years of age or older; and
3. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care

practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
4. Approvals will be for subcutaneous administration using the FDA approved dosing of 162mg once weekly.

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

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

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

1. An FDA approved indication of maintenance of remission of DIRA verified by genetic testing; and
2. Member must weigh ≥10kg; and

3. Member must not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra concomitantly with Arcalyst®; and
4. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis must be provided; and
5. Arcalyst® will be used for maintenance of remission following treatment with Kineret® (anakinra); and
6. A patient-specific, clinically significant reason the member cannot continue to utilize Kineret® (anakinra) instead of switching to Arcalyst® must be provided; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for adults and pediatric members weighing ≥10kg is 4.4mg/kg up to a maximum of 320mg, delivered as 1 or 2 injections (2mL/injection) once weekly; and
9. Approvals will be for the duration of 1 year.

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

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

c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member's recent weight in kilograms):
    i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
    ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and

8. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by decreased recurrence of pericarditis or improvement in signs and symptoms of recurrent pericarditis (e.g., C-reactive protein, pericarditic chest pain, pericardial effusion). Subsequent approvals will be granted for the duration of 1 year.

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

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

Benlysta® (Belimumab) Approval Criteria:

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

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

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

1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
2. For Cibinqo®, member must be 12 years of age or older; and
3. For Rinvoq®, member must be 12 years of age or older; and
4. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Member must have a documented 16-week trial with Adbry® (tralokinumab-ldrm) or Dupixent® (dupilumab) that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. Requested medication must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
7. For Cibinqo®, prescriber must verify the member will not use antiplatelet therapies (e.g., clopidogrel, prasugrel, ticagrelor) concurrently with Cibinqo®, except for low-dose aspirin, during the first 3 months of treatment; and
8. Cibinqo® and Rinvoq® will not be approved for use in combination with other Janus kinas (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
9. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
10. For Rinvoq®, the maximum approvable dose for AD is 30mg once daily.

Entyvio® (Vedolizumab) Approval Criteria:

1. An FDA approved diagnosis:
    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® sub-Q administration, member must have received at least 2 initial IV doses of Entyvio®; and
6. A quantity limit of 300mg every 8 weeks will apply for the IV formulation and 108mg every 2 weeks will apply for the sub-Q formulation. Approvals will be granted for titration quantities required for initial dosing; and
7. Initial approvals will be for the duration of 14 weeks as Entyvio® should be discontinued in patients who do not show evidence of therapeutic benefit by week 14.

Erelzi® (Etanercept-szza) and Eticovo® (Etanercept-ykro) Approval Criteria:

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

Humira® (Adalimumab) 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.

Humira® (Adalimumab) Approval Criteria [Noninfectious Intermediate and Posterior Uveitis or Panuveitis Diagnosis]:

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

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

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

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

1. An FDA approved indication of CAPS verified by genetic testing [which includes Familial Cold Auto-Inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)] in adult and pediatric members 4 years of age and older; and
2. Member must not be using a tumor necrosis factor (TNF) blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and

3. Ilaris® should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
4. The following dosing requirements must be met:
    a. Dosing should not be more often than once every 8 weeks; and
    b. Weight-based dosing (the member's recent weight must be provided):
        i. Body weight >40kg: 150mg; or
        ii. Body weight 15kg to 40kg: 2mg/kg (if inadequate response, dose may be increased to 3mg/kg); and
5. Approvals will be for the duration of 1 year.

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

1. An FDA approved indication for the treatment of gout flare; and
2. Member must have had ≥3 gout flares in the previous year; and
3. Member must meet 1 of the following:
    a. Inadequate response or intolerance to recent trials of oral colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroids (oral, intraarticular, and/or intramuscular) used for the treatment of previous gout flare(s); or
    b. Colchicine, NSAIDs, and corticosteroids are contraindicated for the member (specific information regarding contraindication must be submitted); and
4. A patient-specific, clinically significant reason why the member cannot use Kineret® (anakinra) must be provided; and
5. Approvals will be for (1) 150mg dose at a time. Subsequent approvals will require documentation that the member responded well to previous treatment with Ilaris®; and
6. Approvals will not be granted more often than once every 12 weeks.

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

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

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

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

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 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 provide documentation of patient-specific, clinically significant information (e.g., impacting member's mental health or ability to function in day-to-day living, reason why no treatment or cosmetic solutions are not appropriate) to demonstrate the medical necessity of this medication for this member; and
10. Member must have documented trials within the last 6 months that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance to all alternatives):
    a. Medium potency to very-high potency Tier-1 topical corticosteroid used for at least 12 weeks; or
    b. Oral corticosteroid used for at least 6 weeks; or
    c. Cyclosporine; or
    d. Methotrexate; or
    e. Contact immunotherapy (e.g., diphenylcyclopropenone, squaric acid dibutyl ester); and

11. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
12. Prescriber must verify female members are not breastfeeding; and
13. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the pregnancy registry; and
14. Initial approvals will be for a duration of 24 weeks of treatment; and
15. Reauthorization may be considered if the prescriber documents the member is responding well to treatment as indicated by a reduction in the member's SALT score (current SALT score must be provided).

Lupkynis® (Voclosporin) Approval Criteria:

1. An FDA approved indication for the treatment of adults with active lupus nephritis (LN) in combination with a background immunosuppressive therapy regimen; and
    a. Lupkynis® must be used in combination with mycophenolate mofetil and low dose oral corticosteroids; and
2. Member must be 18 years of age or older; and
3. Lupkynis® must be prescribed by a nephrologist, rheumatologist, or other specialist with expertise in the treatment of LN; and
4. Member's current urine protein-to-creatinine ratio (UPCR) must be provided and must be ≥1.5mg/mg; and
5. Member's current estimated glomerular filtration rate (eGFR) must be provided and must be >45mL/min/1.73m^2 prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor renal function regularly during treatment with Lupkynis® and modify the dose as needed in accordance with the package labeling; and
6. Member's current blood pressure (BP) must be ≤165/105mmHg prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor BP regularly during treatment with Lupkynis® and agree to discontinue treatment if BP is >165/105mmHg or member experiences a hypertensive emergency; and
7. Member must not be taking strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) concomitantly with Lupkynis®; and
8. Prescriber must verify member has been counseled on proper administration of Lupkynis® including taking it on an empty stomach every 12 hours; and
9. Lupkynis® will not be approved in combination with biologic therapies or cyclophosphamide; and
10. A quantity limit of 180 capsules per 30 days will apply; and

11. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in the member's UPCR. If the member does not experience therapeutic benefit by 6 months, discontinuation of Lupkynis® should be considered; 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.

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

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

Otezla® (Apremilast) Approval Criteria [Behçet's Disease (BD) Diagnosis]:

1. An FDA approved indication for the treatment of oral ulcers associated with BD; and
2. Member must have had oral ulcers at least 3 times in the last 12 month period; and
3. Member must have had a 2 week trial of the following that resulted in inadequate efficacy or intolerable adverse effects (or be contraindicated for the member):
    a. Topical corticosteroids (applied topically to the mouth); and
    b. Colchicine; and
4. Quantity limits according to package labeling will apply.

Rituxan® (Rituximab) Approval Criteria [Granulomatosis with Polyangiitis (GPA, Wegener's Granulomatosis) or Microscopic Polyangiitis (MPA) Diagnosis]:

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

Rituxan® (Rituximab) Approval Criteria [Pemphigus Vulgaris (PV) Diagnosis]:

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

Saphnelo® (Anifrolumab-fnia) Approval Criteria:

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

Siliq® (Brodalumab) Approval Criteria:

1. Member must meet Tier-3 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:

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:
    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 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®.

Tavneos® (Avacopan) Approval Criteria:

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

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) 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.

Xeljanz® (Tofacitinib Oral Solution) Approval Criteria:

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

Utilization of Targeted Immunomodulator Agents: Fiscal Year 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	2,986	18,882	$150,560,112.87	$7,973.74	$263.19	152,968	572,056
2023 Total	**2,986**	**18,882**	**$150,560,112.87**	**$7,973.74**	**$263.19**	**152,968**	**572,056**
Fiscal Year 2024							
FFS	3,312	17,993	$148,317,164.90	$8,243.05	$271.22	149,310	546,861
Aetna	512	1,058	$8,485,828.04	$8,020.63	$274.01	8,256	30,969
Humana	577	1,301	$11,951,509.14	$9,186.40	$306.10	12,074	39,045
OCH	500	984	$8,043,101.45	$8,173.88	$274.41	8,242	29,311
2024 Total	**3,612**	**21,336**	**$176,797,603.53**	**$8,286.35**	**$273.60**	**177,883**	**646,186**
% Change	**21.00%**	**13.00%**	**17.40%**	**3.90%**	**4.00%**	**16.30%**	**13.00%**
Change	**626**	**2,454**	**$26,237,490.66**	**$312.61**	**$10.41**	**24,915**	**74,130**

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	733	3,289	$12,719,361.88	$3,867.24	4.49
2023 Total	**733**	**3,289**	**$12,719,361.88**	**$3,867.24**	**4.49**
Fiscal Year 2024					
FFS	878	4,207	$14,533,260.69	$3,454.54	4.79
Aetna	38	69	$186,110.60	$2,697.26	1.82
Humana	8	10	$40,250.42	$4,025.04	1.25
OCH	73	139	$395,673.02	$2,846.57	1.9
2024 Total	**906**	**4,425**	**$15,155,294.73**	**$3,424.93**	**4.88**
% Change	**23.60%**	**34.54%**	**19.15%**	**-11.44%**	**8.69%**
Change	**173**	**1,136**	**$2,435,932.85**	**-$442.31**	**0.39**

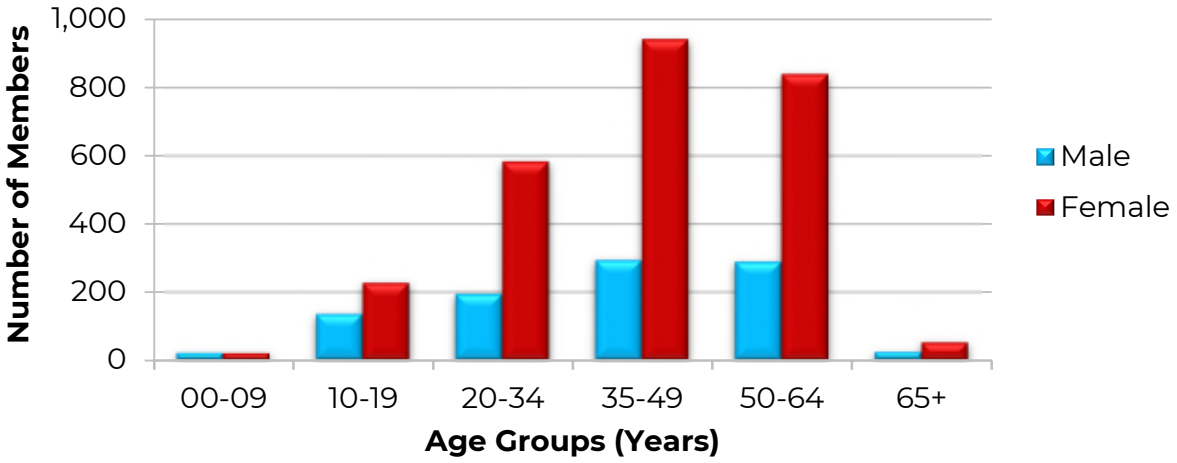
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data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

- Aggregate drug rebates collected during calendar year 2023 for Targeted Immunomodulator Agents totaled $132,057,089.31.[Δ] Rebates

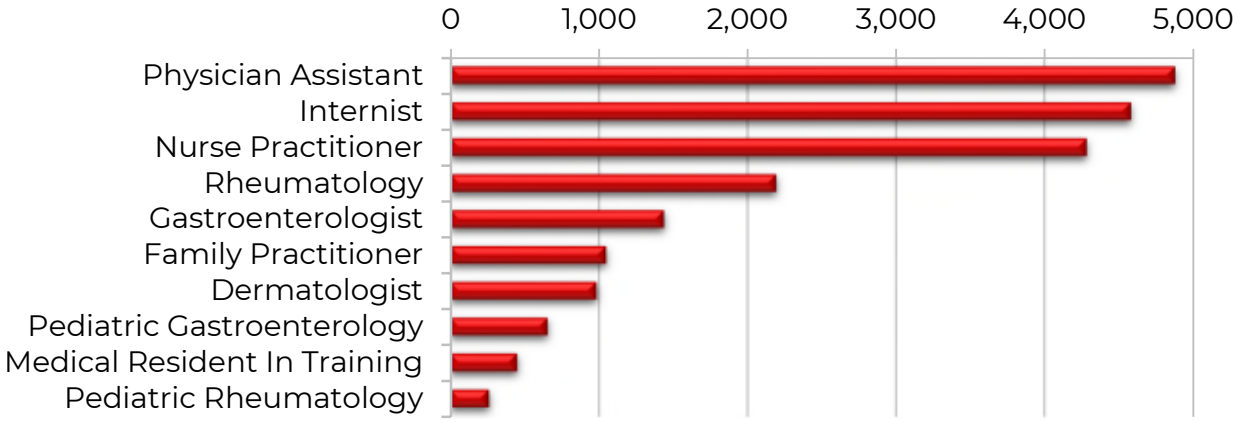
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

are collected after reimbursement for the medication and are not reflected in this report. Please note, calendar year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2024 (7/1/2023 to 6/30/2024) are still being collected at this time. The costs included in this report do not reflect net costs.

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



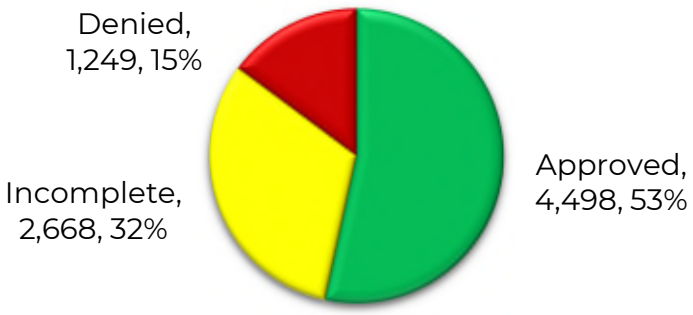
Top Prescriber Specialties of Targeted Immunomodulator Agents by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Targeted Immunomodulator Agents

There were 8,415 prior authorization requests submitted for targeted immunomodulator agents during fiscal year 2024. Computer edits are in place to detect lower tiered medications in a member's claims history and generate automated prior authorizations where possible. The following charts 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	3,499	50%	2,618	37%	938	13%	**7,055**
Aetna	380	69%	50	9%	123	22%	**553**
Humana	283	74%	0	0%	102	26%	**385**
OCH	336	80%	0	0%	86	20%	**422**
Total	**4,498**	**53%**	**2,668**	**32%**	**1,249**	**15%**	**8,415**

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

Anticipated Patent Expiration(s):

- Xeljanz® (tofacitinib oral solution and tablet): December 2025
- Olumiant® (baricitinib tablet): November 2032
- Sotyktu™ (deucravacitinib tablet): November 2033
- Xeljanz® XR [tofacitinib extended-release (ER) tablet]: March 2034
- Otezla® (apremilast tablet): November 2034
- Litfulo™ (ritlecitinib capsule): December 2034
- Velsipity™ (etrasimod tablet): June 2036
- Rinvoq® LQ (upadacitinib oral solution): October 2036
- Lupkynis® (voclosporin capsule): December 2037
- Rinvoq® (upadacitinib tablet): March 2038
- Leqselvi™ (deuruxolitinib tablet): May 2041
- Tavneos® (avacopan capsule): May 2041

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

- **October 2023:** The FDA approved Velsipity™ (etrasimod) for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

- **October 2023:** The FDA approved Bimzelx® (bimekizumab-bkzx) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
- **October 2023:** The FDA approved Enbrel® (etanercept) for an age expansion for pediatric patients 2 years of age or older with psoriatic arthritis (PsA). Previously, Enbrel® was only FDA approved in adults for this indication.
- **October 2023:** The FDA approved Zymfentra™ (infliximab-dyyb) for the maintenance treatment of adults with moderately to severely active Crohn's disease (CD) or UC following treatment with an infliximab product administered intravenously (IV). Zymfentra™ is the first subcutaneous (sub-Q) formulation of infliximab and is available as a 120mg/mL single-dose prefilled pen or syringe. The recommended maintenance dosing in CD or UC is 120mg sub-Q once every 2 weeks starting at week 10 and thereafter. Patients must first complete an induction regimen with an IV infliximab product prior to switching to Zymfentra™. For patients who are already responding to a maintenance regimen of an IV infliximab product, the first sub-Q dose of Zymfentra™ may be administered in place of the next scheduled IV dose and every 2 weeks thereafter.
- **October 2023:** The FDA approved Omvoh™ (mirikizumab-mrkz) for the treatment of moderately to severely active UC in adults.
- **October 2023:** The FDA approved Orencia® (abatacept) for an age expansion for pediatric patients 2 years of age and older with PsA. Previously, Orencia® was only FDA approved in adults for this indication.
- **October 2023:** The FDA approved Wezlana™ (ustekinumab-auub) as an interchangeable biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **October 2023:** The FDA approved Cosentyx® (secukinumab) for a new indication for the treatment of adults with moderate to severe hidradenitis suppurativa.
- **November 2023:** The FDA approved an unbranded formulation of Humira® (adalimumab) through a supplemental Biologics License Application (sBLA).
- **February 2024:** The FDA approved Simlandi® (adalimumab-ryvk) as a new interchangeable biosimilar to Humira® (adalimumab) for the treatment of 9 different Humira® indications.
- **March 2024:** The FDA approved Tyenne® (tocilizumab-aazg) as a biosimilar to Actemra® (tocilizumab) for the treatment of 4 different Actemra® indications.
- **March 2024:** The FDA approved Spevigo® (spesolimab-sbzo) for an age expansion and expanded indication for the treatment of generalized pustular psoriasis (GPP) in adult and pediatric patients 12 years of age and older weighing at least 40kg. Additionally, the FDA approved a new

sub-Q formulation of Spevigo®, available as a 150mg/mL single-dose prefilled syringe, intended for ongoing maintenance treatment of GPP when the patient is not experiencing a GPP flare. The recommended sub-Q dosing is a loading dose of 600mg [(4) 150mg injections] followed by 300mg [(2) 150mg injections] 4 weeks later and every 4 weeks thereafter. Previously, Spevigo® was only FDA approved for the treatment of GPP flares in adults and was only available as an IV formulation used during treatment of a GPP flare.

- **April 2024:** The FDA approved Selarsdi™ (ustekinumab-aekn) as a biosimilar to Stelara® (ustekinumab) for the treatment of 4 different Stelara® indications.
- **April 2024:** The FDA approved the sub-Q formulation of Entyvio® (vedolizumab) for a new indication for the maintenance treatment of moderate to severely active CD after at least 2 IV doses of vedolizumab. The sub-Q formulation is available as a 108mg/0.68mL prefilled syringe or pen and the recommended dosing is 108mg every 2 weeks.
- **April 2024:** The FDA approved Otezla® (apremilast) for an age expansion for pediatric patients 6 years of age and older weighing at least 20kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Additionally, the FDA approved a new 20mg strength of Otezla® for use in pediatric patients who weigh 20kg to less than 50kg. Previously, Otezla® was only FDA approved in adults for this indication.
- **April 2024:** The FDA approved Rinvoq® (upadacitinib) for an age expansion for pediatric patients 2 years of age and older with active PsA who have had an inadequate response or intolerance to 1 or more tumor necrosis factor (TNF) blockers. Additionally, the FDA approved a new indication for Rinvoq® for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to 1 or more TNF blockers. Along with these approvals, Rinvoq® LQ (upadacitinib oral solution) was approved for use in patients with these indications. Rinvoq® LQ is available as a 1mg/mL oral solution in a 180mL bottle.
- **April 2024:** The FDA approved Lupkynis® (voclosporin) for an updated label to include new efficacy and safety data supporting a longer duration of treatment beyond 1 year. Previously, the FDA approved labeling for Lupkynis® stated that the safety and efficacy of the medication had not been established beyond 1 year.
- **May 2024:** The FDA approved Benlysta® (belimumab) for an age expansion for the sub-Q formulation down 5 years of age for the treatment of systemic lupus erythematosus (SLE) or active lupus nephritis in patients who are receiving standard therapy. Previously, only the IV formulation of Benlysta® was FDA approved for use in pediatric patients.

- **June 2024:** The FDA approved Kevzara® (sarilumab) for a new indication for the treatment of active pJIA in patients who weigh 63kg or more.
- **June 2024:** The FDA approved Skyrizi® (risankizumab-rzaa) for a new indication for the treatment of moderately to severely active UC in adults.
- **June 2024:** The FDA approved Pyzchiva® (ustekinumab-ttwe) as a biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **July 2024:** The FDA approved Leqselvi™ (deuruxolitinib) for the treatment of adults with severe alopecia areata.
- **September 2024:** The FDA approved Tremfya® (guselkumab) for a new indication for the treatment of adults with moderately to severely active UC. Additionally, the FDA approved new strengths and formulations of Tremfya® for use in patients with UC, including a 200mg/20mL single-dose vial for IV infusion and a 200mg/2mL single-dose prefilled pen or syringe.
- **September 2024:** The FDA approved Cimzia® (certolizumab pegol) for a new indication for the treatment of pediatric patients 2 years of age and older with active pJIA.
- **September 2024:** The FDA approved Bimzelx® (bimekizumab-bkzx) for 3 new indications: treatment of adults with active PsA, treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and treatment of adults with active ankylosing spondylitis.
- **September 2024:** The FDA approved Otulfi™ (ustekinumab-aauz) as a biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.

Bimzelx® (Bimekizumab-bkzx) Product Summary[28]

Therapeutic Class: Humanized interleukin (IL)-17A and F antagonist

Indication(s):
- Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- Treatment of adults with active PsA
- Treatment of adults with active nr-axSpA with objective signs of inflammation
- Treatment of adults with active ankylosing spondylitis

How Supplied: 160mg/mL as a single-dose prefilled syringe or single-dose prefilled autoinjector

Dosing and Administration:

- Plaque Psoriasis:
  - 320mg [(2) 160mg injections] by subcutaneous (sub-Q) administration at weeks 0, 4, 8, 12, and 16, followed by 320mg every 8 weeks thereafter
  - For patients weighing ≥120kg, a dose of 320mg every 4 weeks should be considered after week 16
- PsA, Nr-axSpA, and Ankylosing Spondylitis:
  - 160mg by sub-Q administration every 4 weeks
  - Patients with PsA with coexisting moderate to severe plaque psoriasis should use the recommended dosage and administration for plaque psoriasis.

Efficacy: The efficacy of Bimzelz® was based primarily on 2 Phase 3, placebo-controlled studies (Trial-Ps-1 and Trial-Ps-2) for the plaque psoriasis indication, 2 Phase 3, placebo-controlled studies (Trial PsA-1 and Trial PsA-2) for the PsA indication, 1 Phase 3, placebo-controlled study (Trial nr-axSpA) for the nr-axSpA indication, and 1 Phase 3, placebo-controlled study (Trial AS-1) for the ankylosing spondylitis indication. These studies all enrolled adult patients 18 years of age or older.

- **Plaque Psoriasis Indication:**
  - Key Inclusion Criteria:
    - Psoriasis Area and Severity Index (PASI) score ≥12
    - Body surface area (BSA) involvement ≥10%
    - Investigator's Global Assessment (IGA) score ≥3 ("moderate")
  - Primary Endpoint(s):
    - Proportion of patients with an IGA score of 0 ("clear") or 1 ("almost clear") and at least a 2-grade improvement from baseline at week 16
    - Proportion of patients who achieve at least 90% reduction from baseline in PASI score (PASI 90) at week 16
  - Results:
    - IGA score of 0 or 1:
      - Trial-Ps-1: Achieved by 84% of patients who received bimekizumab vs. 5% of patients who received placebo [treatment difference: 79%; 95% confidence interval (CI): 73%, 85%]
      - Trial-Ps-2: Achieved by 93% of patients who received bimekizumab vs. 1% of patients who received placebo (treatment difference: 91%; 95% CI: 88%, 95%)
    - PASI 90:
      - Trial-Ps-1: Achieved by 85% of patients who received bimekizumab vs. 5% of patients who received placebo (treatment difference: 80%; 95% CI: 74%, 86%)

        - Trial-Ps-2: Achieved by 91% of patients who received bimekizumab vs. 1% of patients who received placebo (treatment difference: 90%; 95% CI: 86%, 93%)
- **PsA Indication:**
    - Key Inclusion Criteria:
        - Active PsA with baseline tender joint count ≥3 and swollen joint count ≥3
        - Trial PsA-1: No current or prior exposure to any biologics for the treatment of PsA or plaque psoriasis
        - Trial PsA-2: History of inadequate response or intolerance to treatment with 1 or 2 TNFα inhibitors
    - Primary Endpoint(s):
        - Proportion of patients achieving an American College of Rheumatology 50% (ACR50) response at week 16
    - Results:
        - ACR50 response:
            - Trial PsA-1: Achieved by 43.9% of patients who received bimekizumab vs. 10% of patients who received placebo (treatment difference: 33.9%; 95% CI: 28%, 39.7%)
            - Trial PsA-2: Achieved by 43.4% of patients who received bimekizumab vs. 6.8% of patients who received placebo (treatment difference: 36.7%; 95% CI: 29.4%, 44%)
- **Nr-axSpA Indication:**
    - Key Inclusion Criteria:
        - Active disease defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score ≥4 and spinal pain ≥4 on a 0-10 numerical rating scale (NRS)
        - Objective signs of inflammation with elevated C-reactive protein (CRP) and/or evidence of sacroiliitis on magnetic resonance imaging (MRI)
        - No definitive radiographic evidence of structural damage in the sacroiliac joints
        - History of failure to respond to 2 different nonsteroid anti-inflammatory drugs (NSAIDs) or intolerance or a contraindication to NSAID therapy
    - Primary Endpoint(s):
        - Proportion of patients achieving at least a 40% improvement in Assessment of Spondyloarthritis International Society score (ASAS40) at week 16
    - Results:
        - ASAS40:
            - Trial nr-axSpA-1: Achieved by 47.7% of patients who received bimekizumab vs. 21.4% of patients who

received placebo (treatment difference: 26.2%; 95% CI: 15%, 37.5%)

- **Ankylosing Spondylitis Indication:**
  - Key Inclusion Criteria:
    - Documented radiologic (x-ray) evidence fulfilling the modified New York (mNY) criteria for ankylosing spondylitis
    - Moderate to severe active disease defined by BASDAI score ≥4 and spinal pain ≥4 on a 0-10 NRS
    - History of failure to respond to 2 different NSAIDs or intolerance or a contraindication to NSAID therapy
  - Primary Endpoint(s):
    - Proportion of patients achieving ASAS40 at week 16
  - Results:
    - ASAS40:
      - Trial AS-1: Achieved by 44.8% of patients who received bimekizumab vs. 22.5% of patients who received placebo (treatment difference: 22.3%; 95% CI: 12.1%, 32.4%)

Cost: The Wholesale Acquisition Cost (WAC) of Bimzelx® is $7,552.80 per milliliter, resulting in a cost of $15,105.60 per 320mg dose or $7,552.80 per 160mg dose. For a member with plaque psoriasis weighing <120kg, this would result in an estimated cost of $135,950.40 for the first year of treatment. For a member with plaque psoriasis weighing ≥120kg using 320mg every 4 weeks, this would result in an estimated cost of $196,372.80 per year. For a member with PsA, nr-axSpA, or ankylosing spondylitis, the estimated cost would be $7,552.80 per 28 days or $98,186.40 per year based on recommended dosing.

Leqselvi™ (Deuruxolitinib) Product Summary[29]

Therapeutic Class: Janus kinase (JAK) inhibitor

Indication(s): Treatment of severe alopecia areata in adults

- **Limitation(s) of Use:** Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

How Supplied: 8mg oral tablet

Dosing and Administration: 8mg orally twice daily

Efficacy: The efficacy of Leqselvi™ was based primarily on 2 Phase 3, placebo-controlled studies (AA-1 and AA-2).

- Key Inclusion Criteria:
  - 18 years of age or older
  - At least 50% scalp hair loss, as defined by a Severity of Alopecia Tool (SALT) score ≥50

        - Current alopecia areata episode lasting at least 6 months and not exceeding 10 years
    - Primary Endpoint(s):
        - Proportion of patients achieving at least 80% scalp hair coverage (a SALT score ≤20) at week 24
    - Results:
        - SALT score ≤20:
            - AA-1: Achieved by 29% of patients who received deuruxolitinib vs. 1% of patients who received placebo (treatment difference: 28%; 95% CI: 23%, 33%)
            - AA-2: Achieved by 32% of patients who received deuruxolitinib vs. 1% of patients who received placebo (treatment difference: 31%; 95% CI: 25%, 37%)

Cost: The Wholesale Acquisition Cost (WAC) of Leqselvi™ is not yet available.

Omvoh™ (Mirikizumab-mrkz) Product Summary[30]

Therapeutic Class: IL-23 antagonist

Indication(s): Treatment of moderately-to-severely active UC in adults

How Supplied:
- 300mg/15mL solution in a single-dose vial for intravenous (IV) infusion
- 100mg/mL solution in a single-dose prefilled pen or syringe for sub-Q injection

Dosing and Administration:
- Induction Dosing: 300mg by IV infusion over at least 30 minutes at weeks 0, 4, and 8
- Maintenance Dosing: 200mg [(2) 100mg injections] sub-Q at week 12 and every 4 weeks thereafter

Efficacy: The efficacy of Omvoh™ was based primarily on 2 Phase 3, placebo-controlled studies (UC-1 and UC-2). UC-1 was a 12-week IV induction study and UC-2 was a 40-week sub-Q maintenance study.
- Key Inclusion Criteria:
    - 18 years of age or older
    - Moderately to severely active UC
    - Inadequate response, loss of response, or intolerance to any of the following: corticosteroids, 6-mercaptopurine, azathioprine, biologic therapy (TNF blocker, vedolizumab), or tofacitinib
- Primary Endpoint(s):
    - Clinical remission, defined as a modified Mayo score (mMS) stool frequency subscore of 0 or 1, rectal bleeding score of 0, and

centrally read endoscopy subscore of 0 or 1 (excluding friability) at week 12 (for UC-1) or week 40 (for UC-2)

- Results:
  - Clinical remission:
    - UC-1: Achieved by 24% of patients who received mirikizumab vs. 15% of patients who received placebo (treatment difference: 10%; 95% CI: 5%, 15%)
    - UC-2: Achieved by 51% of patients who received mirikizumab vs. 27% of patients who received placebo (treatment difference: 22%; 95% CI: 14%, 31%)

Cost: The Specialty Pharmaceutical Acquisition Cost (SPAC) of Omvoh™ is $694.86 per milliliter for the IV formulation and $3,474.30 per milliliter for the sub-Q formulation. This results in a cost of $10,422.90 per dose for the IV formulation and $6,948.60 per dose for the sub-Q formulation. This would result in an estimated cost of $100,754.70 for the first year of treatment.

Velsipity™ (Etrasimod) Product Summary[31]

Therapeutic Class: Sphingosine 1-phosphate (S1P) receptor modulator

Indication(s): Treatment of moderately-to-severely active UC in adults

How Supplied: 2mg oral tablet

Dosing and Administration: 2mg orally once daily

Efficacy: The efficacy of Velsipity™ was based primarily on 2 Phase 3, placebo-controlled studies (UC-1 and UC-2).

- Key Inclusion Criteria:
  - 16 years of age or older
  - Moderately to severely active UC
  - Inadequate response, loss of response, or intolerance to 1 or more of the following: oral aminosalicylates, corticosteroids, thiopurines, JAK inhibitors, biologic therapies (e.g., TNF blocker, anti-integrin, anti-IL 12/23).
- Primary Endpoint(s):
  - Clinical remission, defined as a mMS stool frequency subscore of 0 or 1, rectal bleeding score of 0, and centrally read endoscopy subscore of ≤1 (excluding friability) at weeks 12 and 52 (for UC-1) or at week 12 (for UC-2)
- Results:
  - Clinical remission at week 12:
    - UC-1: Achieved by 27% of patients who received etrasimod vs. 7% of patients who received placebo (treatment difference: 20%; 95% CI: 13%, 27%)

        - UC-2: Achieved by 26% of patients who received etrasimod vs. 15% of patients who received placebo (treatment difference: 11%; 95% CI: 3%, 20%)
    - Clinical remission at week 52:
        - UC-1: Achieved by 32% of patients who received etrasimod vs. 7% of patients who received placebo (treatment difference: 26%; 95% CI: 19%, 33%)

Cost: The WAC of Velsipity™ is $205.48 per tablet, resulting in an estimated cost of $6,164.40 per 30 days and $73,972.80 per year based on recommended dosing.

Recommendations

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

1. 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.

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.
[ß] 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:
   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) (GPP diagnosis should be verifiable in the member's diagnosis history); and
2. Prescriber must verify at least 1 of the following:
    a. Member has experienced >1 flare (relapsing GPP); or
    b. Member has symptoms persisting for >3 months (persistent GPP); 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.

Utilization Details of Targeted Immunomodulator Agents: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 PRODUCTS						
ADALIMUMAB PRODUCTS						
HUMIRA PEN INJ 40MG/0.4ML	6,266	1,255	$49,321,118.60	$7,871.23	4.99	33.25%
HUMIRA INJ 40MG/0.4ML	529	148	$4,229,539.61	$7,995.35	3.57	2.85%
HUMIRA PEN INJ 80MG/0.8ML	527	105	$7,299,026.68	$13,850.15	5.02	4.92%
HUMIRA PEN INJ 40MG/0.8ML	358	101	$3,327,050.71	$9,293.44	3.54	2.24%
HUMIRA KIT 40MG/0.8ML	197	48	$1,541,241.81	$7,823.56	4.1	1.04%
HUMIRA INJ 20MG/0.2ML	160	29	$1,083,300.06	$6,770.63	5.52	0.73%
HUMIRA PEN KIT CD/UC/HS 80MG/0.8ML	130	130	$2,662,792.40	$20,483.02	1	1.80%
HUMIRA PEN KIT PS/UV 80MG/0.8ML & 40MG/0.4ML	112	110	$1,533,841.23	$13,695.01	1.02	1.03%
HUMIRA INJ 10MG/0.1ML	19	5	$131,746.57	$6,934.03	3.8	0.09%
HUMIRA PEN KIT PED UC 80MG/0.8ML	4	4	$110,807.80	$27,701.95	1	0.07%
HUMIRA PED INJ CROHNS 80MG/0.8ML & 40MG/0.4ML	3	3	$31,186.11	$10,395.37	1	0.02%
HUMIRA PED INJ CROHNS 80MG/0.8ML	1	1	$20,779.35	$20,779.35	1	0.01%
SUBTOTAL	**8,306**	**1,939**	**$71,292,430.93**	**$8,583.24**	**4.28**	**48.07%**
ETANERCEPT PRODUCTS						
ENBREL SRCLK INJ 50MG/ML	2,836	642	$19,872,559.44	$7,007.25	4.42	13.40%
ENBREL INJ 50MG/ML	349	94	$2,336,951.00	$6,696.13	3.71	1.58%
ENBREL INJ 25/0.5ML	94	16	$360,466.85	$3,834.75	5.88	0.24%
ENBREL MINI INJ 50MG/ML	83	19	$485,747.22	$5,852.38	4.37	0.33%
ENBREL INJ 25MG	57	15	$322,280.83	$5,654.05	3.8	0.22%
SUBTOTAL	**3,419**	**786**	**$23,378,005.34**	**$6,837.67**	**4.35**	**15.76%**
APREMILAST PRODUCTS						
OTEZLA TAB 30MG	827	208	$3,669,357.32	$4,436.95	3.98	2.47%
OTEZLA TAB 10/20/30MG	95	84	$445,619.66	$4,690.73	1.13	0.30%
SUBTOTAL	**922**	**292**	**$4,114,976.98**	**$4,463.10**	**3.16**	**2.77%**
ANAKINRA PRODUCTS						
KINERET INJ 100MG/0.67ML	42	7	$292,470.34	$6,963.58	6	0.20%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**42**	**7**	**$292,470.34**	**$6,963.58**	**6**	**0.20%**
INFLIXIMAB PRODUCTS						
INFLECTRA INJ 100MG	15	8	$10,783.32	$718.89	1.88	0.01%
SUBTOTAL	**15**	**8**	**$10,783.32**	**$718.89**	**1.88**	**0.01%**
TIER-2 SUBTOTAL	**12,704**	**2,383***	**$99,088,666.91**	**$7,799.80**	**5.33**	**66.81%**
TIER-3 PRODUCTS						
ABATACEPT PRODUCTS						
ORENCIA CLICKJECT INJ 125MG/ML	267	60	$1,395,834.65	$5,227.85	4.45	0.94%
ORENCIA INJ 125MG/ML	130	27	$692,719.79	$5,328.61	4.81	0.47%
ORENCIA INJ 250MG	22	3	$59,948.89	$2,724.95	7.33	0.04%
ORENCIA INJ 87.5MG/0.7ML	8	2	$19,867.41	$2,483.43	4	0.01%
SUBTOTAL	**427**	**92**	**$2,168,370.74**	**$5,078.15**	**4.64**	**1.46%**
TOFACITINIB PRODUCTS						
XELJANZ TAB 5MG	186	34	$965,508.44	$5,190.91	5.47	0.65%
XELJANZ XR TAB 11MG	79	22	$424,209.13	$5,369.74	3.59	0.29%
XELJANZ TAB 10MG	30	6	$162,765.28	$5,425.51	5	0.11%
XELJANZ SOL 1MG/ML	8	4	$37,108.48	$4,638.56	2	0.03%
SUBTOTAL	**303**	**66**	**$1,589,591.33**	**$5,246.18**	**4.59**	**1.07%**
CERTOLIZUMAB PRODUCTS						
CIMZIA PREFL KIT 200MG/ML	172	37	$1,146,308.43	$6,664.58	4.65	0.77%
CIMZIA START KIT 200MG/ML	9	9	$145,673.94	$16,185.99	1	0.10%
SUBTOTAL	**181**	**46**	**$1,291,982.37**	**$7,138.02**	**3.93**	**0.87%**
GOLIMUMAB PRODUCTS						
SIMPONI INJ 50MG/0.5ML AUTO	77	19	$437,385.88	$5,680.34	4.05	0.29%
SIMPONI INJ 50MG/0.5ML SYR	27	3	$161,047.95	$5,964.74	9	0.11%
SIMPONI INJ 100MG/ML AUTO	5	1	$27,571.72	$5,514.34	5	0.02%
SUBTOTAL	**109**	**23**	**$626,005.55**	**$5,743.17**	**4.74**	**0.42%**
INFLIXIMAB PRODUCTS						
REMICADE INJ 100MG	76	13	$419,646.57	$5,521.67	5.85	0.28%
RENFLEXIS INJ 100MG	16	5	$30,977.58	$1,936.10	3.2	0.02%
AVSOLA INJ 100MG	9	1	$40,578.69	$4,508.74	9	0.03%
SUBTOTAL	**101**	**19**	**$491,202.84**	**$4,863.39**	**5.32**	**0.33%**
SARILUMAB PRODUCTS						
KEVZARA INJ 200MG/1.14ML AUTO	50	10	$167,113.66	$3,342.27	5	0.11%
KEVZARA INJ 200MG/1.14ML SYR	5	1	$20,523.45	$4,104.69	5	0.01%
SUBTOTAL	**55**	**11**	**$187,637.11**	**$3,411.58**	**5**	**0.13%**
VEDOLIZUMAB PRODUCTS						
ENTYVIO INJ 300MG	15	4	$100,799.45	$6,719.96	3.75	0.07%
ENTYVIO INJ 108MG/0.68ML	2	1	$12,494.70	$6,247.35	2	0.01%
SUBTOTAL	**17**	**5**	**$113,294.15**	**$6,664.36**	**3.4**	**0.08%**
BRODALUMAB PRODUCTS						
SILIQ INJ 210MG/1.5ML	2	1	$15,682.91	$7,841.46	2	0.01%
SUBTOTAL	**2**	**1**	**$15,682.91**	**$7,841.46**	**2**	**0.01%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-3 SUBTOTAL	**1,195**	**243***	**$6,483,767.00**	**$5,425.75**	**4.92**	**4.37%**
SPECIAL PA PRODUCTS						
UPADACITINIB PRODUCTS						
RINVOQ TAB 15MG ER	619	128	$3,733,437.09	$6,031.40	4.84	2.52%
RINVOQ TAB 30MG ER	137	30	$825,136.66	$6,022.90	4.57	0.56%
RINVOQ TAB 45MG ER	59	21	$685,434.33	$11,617.53	2.81	0.46%
SUBTOTAL	**815**	**179**	**$5,244,008.08**	**$6,434.37**	**4.55**	**3.54%**
SECUKINUMAB PRODUCTS						
COSENTYX PEN INJ 300MG DOSE	388	72	$3,168,060.59	$8,165.10	5.39	2.14%
COSENTYX PEN INJ 150MG/ML	68	20	$553,174.70	$8,134.92	3.4	0.37%
COSENTYX UNO INJ 300MG/2ML	54	19	$825,154.92	$15,280.65	2.84	0.56%
COSENTYX INJ 300MG DOSE	49	13	$435,085.68	$8,879.30	3.77	0.29%
COSENTYX INJ 150MG/ML	23	6	$206,377.67	$8,972.94	3.83	0.14%
COSENTYX INJ 75MG/0.5ML	8	2	$29,242.42	$3,655.30	4	0.02%
SUBTOTAL	**590**	**132**	**$5,217,095.98**	**$8,842.54**	**4.47**	**3.52%**
IXEKIZUMAB PRODUCTS						
TALTZ INJ 80MG/ML AUTO	509	90	$4,255,354.36	$8,360.22	5.66	2.87%
TALTZ INJ 80MG/ML SYR	72	12	$478,450.03	$6,645.14	6	0.32%
SUBTOTAL	**581**	**102**	**$4,733,804.39**	**$8,147.68**	**5.7**	**3.19%**
BELIMUMAB PRODUCTS						
BENLYSTA INJ 200MG/ML AUTO	519	105	$2,349,575.31	$4,527.12	4.94	1.58%
BENLYSTA INJ 200MG/ML SYR	23	7	$107,639.73	$4,679.99	3.29	0.07%
SUBTOTAL	**542**	**112**	**$2,457,215.04**	**$4,533.61**	**4.84**	**1.66%**
USTEKINUMAB PRODUCTS						
STELARA INJ 90MG/ML SYR	359	86	$9,157,333.77	$25,507.89	4.17	6.17%
STELARA INJ 45MG/0.5ML SYR	60	18	$806,738.58	$13,445.64	3.33	0.54%
STELARA INJ 45MG/0.5ML VIAL	15	5	$269,318.73	$17,954.58	3	0.18%
SUBTOTAL	**434**	**109**	**$10,233,391.08**	**$23,579.24**	**3.98**	**6.90%**
RISANKIZUMAB PRODUCTS						
SKYRIZI PEN INJ 150MG/ML	232	85	$4,548,159.73	$19,604.14	2.73	3.07%
SKYRIZI INJ 360MG/2.4ML	168	50	$3,369,156.31	$20,054.50	3.36	2.27%
SKYRIZI INJ 150MG/ML	14	5	$277,333.64	$19,809.55	2.8	0.19%
SKYRIZI SOL 60MG/ML	4	2	$36,898.24	$9,224.56	2	0.02%
SUBTOTAL	**418**	**142**	**$8,231,547.92**	**$19,692.70**	**2.94**	**5.55%**
TOCILIZUMAB PRODUCTS						
ACTEMRA INJ ACTPEN 162MG/0.9ML	193	41	$781,021.31	$4,046.74	4.71	0.53%
ACTEMRA INJ 162MG/0.9ML	78	14	$326,754.43	$4,189.16	5.57	0.22%
ACTEMRA INJ 400MG/20ML	2	2	$5,334.46	$2,667.23	1	0.00%
SUBTOTAL	**273**	**57**	**$1,113,110.20**	**$4,077.33**	**4.79**	**0.75%**
GUSELKUMAB PRODUCTS						
TREMFYA INJ 100MG/ML PEN	199	56	$2,598,603.71	$13,058.31	3.55	1.75%
TREMFYA INJ 100MG/ML SYR	19	7	$255,180.06	$13,430.53	2.71	0.17%
SUBTOTAL	**218**	**63**	**$2,853,783.77**	**$13,090.75**	**3.46**	**1.92%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CANAKINUMAB PRODUCTS						
ILARIS INJ 150MG/ML	79	16	$1,561,516.50	$19,766.03	4.94	1.05%
SUBTOTAL	**79**	**16**	**$1,561,516.50**	**$19,766.03**	**4.94**	**1.05%**
BARICITINIB PRODUCTS						
OLUMIANT TAB 2MG	29	3	$94,214.16	$3,248.76	9.67	0.06%
OLUMIANT TAB 1MG	7	1	$32,205.66	$4,600.81	7	0.02%
SUBTOTAL	**36**	**4**	**$126,419.82**	**$3,511.66**	**9**	**0.09%**
DEUCRAVACITINIB PRODUCTS						
SOTYKTU TAB 6MG	33	7	$209,626.83	$6,352.33	4.71	0.14%
SUBTOTAL	**33**	**7**	**$209,626.83**	**$6,352.33**	**4.71**	**0.14%**
AVACOPAN PRODUCTS						
TAVNEOS CAP 10MG	28	7	$421,248.69	$15,044.60	4	0.28%
SUBTOTAL	**28**	**7**	**$421,248.69**	**$15,044.60**	**4**	**0.28%**
RITLECITINIB PRODUCTS						
LITFULO CAP 50MG	28	4	$82,751.90	$2,955.43	7	0.06%
SUBTOTAL	**28**	**4**	**$82,751.90**	**$2,955.43**	**7**	**0.06%**
BIMEKIZUMAB PRODUCTS						
BIMZELX INJ 160MG/ML	8	3	$115,283.28	$14,410.41	2.67	0.08%
SUBTOTAL	**8**	**3**	**$115,283.28**	**$14,410.41**	**2.67**	**0.08%**
VOCLOSPORIN PRODUCTS						
LUPKYNIS CAP 7.9MG	7	1	$65,281.87	$9,325.98	7	0.04%
SUBTOTAL	**7**	**1**	**$65,281.87**	**$9,325.98**	**7**	**0.04%**
RILONACEPT PRODUCTS						
ARCALYST INJ 220MG	3	1	$64,307.73	$21,435.91	3	0.04%
SUBTOTAL	**3**	**1**	**$64,307.73**	**$21,435.91**	**3**	**0.04%**
TILDRAKIZUMAB PRODUCTS						
ILUMYA SOL 100MG/ML	1	1	$14,337.91	$14,337.91	1	0.01%
SUBTOTAL	**1**	**1**	**$14,337.91**	**$14,337.91**	**1**	**0.01%**
SPECIAL PA SUBTOTAL	**4,094**	**858***	**$42,744,730.99**	**$10,440.82**	**4.77**	**28.82%**
TOTAL	**17,993**	**3,312***	**$148,317,164.90**	**$8,243.05**	**5.43**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; CAP = capsule; CD = Crohn's disease; ER = extended-release; HS = hidradenitis suppurativa; INJ = injection; PED = pediatric; PREFL = prefilled; PS = psoriasis; SOL = solution; SRCLK = SureClick; SYR = syringe; TAB = tablet; UC = ulcerative colitis; UV = uveitis
Fiscal Year 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-2 PRODUCTS						
ADALIMUMAB PRODUCTS						
HUMIRA PEN INJ 40MG/0.4ML	365	172	$2,720,523.75	$7,453.49	2.12	32.06%
HUMIRA PEN INJ 40MG/0.8ML	28	14	$215,832.60	$7,708.31	2	2.54%
HUMIRA INJ 40MG/0.4ML	27	14	$215,787.93	$7,992.15	1.93	2.54%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HUMIRA PEN INJ 80MG/0.8ML	24	10	$350,126.12	$14,588.59	2.4	4.13%
HUMIRA INJ 20MG/0.2ML	9	3	$60,924.83	$6,769.43	3	0.72%
HUMIRA PEN KIT PS/UV 80MG/0.8ML & 40MG/0.4ML	8	8	$107,647.86	$13,455.98	1	1.27%
HUMIRA KIT 40MG/0.8ML	6	3	$53,908.31	$8,984.72	2	0.64%
HUMIRA PEN KIT CD/UC/HS 80MG/0.8ML	4	4	$81,402.90	$20,350.73	1	0.96%
HUMIRA INJ 10MG/0.1ML	2	1	$13,868.06	$6,934.03	2	0.16%
SUBTOTAL	**473**	**229**	**$3,820,022.36**	**$8,076.16**	**2.07**	**45.02%**
ETANERCEPT PRODUCTS						
ENBREL SRCLK INJ 50MG/ML	181	91	$1,305,918.72	$7,215.02	1.99	15.39%
ENBREL INJ 50MG/ML	29	15	$216,237.59	$7,456.47	1.93	2.55%
ENBREL INJ 25MG/0.5ML	7	3	$25,277.73	$3,611.10	2.33	0.30%
ENBREL INJ 25MG	3	1	$22,239.69	$7,413.23	3	0.26%
ENBREL MINI INJ 50MG/ML	3	1	$21,633.19	$7,211.06	3	0.25%
SUBTOTAL	**223**	**111**	**$1,591,306.92**	**$7,135.91**	**2.01**	**18.75%**
APREMILAST PRODUCTS						
OTEZLA TAB 30MG	45	23	$204,437.53	$4,543.06	1.96	2.41%
OTEZLA TAB 10/20/30MG	5	5	$23,644.99	$4,729.00	1	0.28%
SUBTOTAL	**50**	**28**	**$228,082.52**	**$4,561.65**	**1.79**	**2.69%**
INFLIXIMAB PRODUCTS						
ZYMFENTRA INJ 120MG/ML	1	1	$4,460.37	$4,460.37	1	0.05%
INFLECTRA INJ 100MG	1	1	$455.09	$455.09	1	0.01%
SUBTOTAL	**2**	**2**	**$4,915.46**	**$2,457.73**	**1**	**0.06%**
TIER-2 SUBTOTAL	**748**	**357***	**$5,644,327.26**	**$7,545.89**	**2.1**	**66.51%**
TIER-3 PRODUCTS						
ABATACEPT PRODUCTS						
ORENCIA CLICKJECT INJ 125MG/ML	17	6	$94,229.06	$5,542.89	2.83	1.11%
ORENCIA INJ 125MG/ML	4	2	$22,174.70	$5,543.68	2	0.26%
ORENCIA INJ 250MG	3	1	$6,460.23	$2,153.41	3	0.08%
SUBTOTAL	**24**	**9**	**$122,863.99**	**$5,119.33**	**2.67**	**1.45%**
TOFACITINIB PRODUCTS						
XELJANZ TAB 5MG	10	4	$50,671.77	$5,067.18	2.5	0.60%
XELJANZ XR TAB 11MG	8	6	$45,042.21	$5,630.28	1.33	0.53%
SUBTOTAL	**18**	**10**	**$95,713.98**	**$5,317.44**	**1.8**	**1.13%**
CERTOLIZUMAB PRODUCTS						
CIMZIA PREFL KIT 200MG/ML	13	7	$116,549.81	$8,965.37	1.86	1.37%
CIMZIA START KIT 200MG/ML	2	2	$33,359.96	$16,679.98	1	0.39%
SUBTOTAL	**15**	**9**	**$149,909.77**	**$9,993.98**	**1.67**	**1.77%**
GOLIMUMAB PRODUCTS						
SIMPONI INJ 100MG/ML AUTO	3	1	$21,086.64	$7,028.88	3	0.25%
SIMPONI INJ 50MG/0.5ML AUTO	3	2	$17,846.34	$5,948.78	1.5	0.21%
SUBTOTAL	**6**	**3**	**$38,932.98**	**$6,488.83**	**2**	**0.46%**
INFLIXIMAB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
REMICADE INJ 100MG	3	2	$3,834.75	$1,278.25	1.5	0.05%
SUBTOTAL	**3**	**2**	**$3,834.75**	**$1,278.25**	**1.5**	**0.05%**
SARILUMAB PRODUCTS						
KEVZARA INJ 200MG/1.14ML	2	1	$8,589.69	$4,294.85	2	0.10%
SUBTOTAL	**2**	**1**	**$8,589.69**	**$4,294.85**	**2**	0.10%
VEDOLIZUMAB PRODUCTS						
ENTYVIO INJ 300MG	1	1	$6,567.31	$6,567.31	1	0.08%
SUBTOTAL	**1**	**1**	**$6,567.31**	**$6,567.31**	**1**	**0.08%**
TIER-3 SUBTOTAL	**69**	**34***	**$426,412.47**	**$6,179.89**	**2.03**	**5.02%**
SPECIAL PA PRODUCTS						
BELIMUMAB PRODUCTS						
BENLYSTA INJ 200MG/ML AUTO	52	23	$252,403.32	$4,853.91	2.26	2.97%
BENLYSTA INJ 200MG/ML SYR	4	1	$19,415.64	$4,853.91	4	0.23%
SUBTOTAL	**56**	**24**	**$271,818.96**	**$4,853.91**	**2.33**	**3.20%**
UPADACITINIB PRODUCTS						
RINVOQ TAB 30MG ER	25	11	$155,956.74	$6,238.27	2.27	1.84%
RINVOQ TAB 15MG ER	22	14	$137,688.71	$6,258.58	1.57	1.62%
RINVOQ TAB 45MG ER	5	3	$59,726.05	$11,945.21	1.67	0.70%
SUBTOTAL	**52**	**28**	**$353,371.50**	**$6,795.61**	**1.86**	**4.16%**
IXEKIZUMAB PRODUCTS						
TALTZ INJ 80MG/ML AUTO	28	14	$217,314.46	$7,761.23	2	2.56%
TALTZ INJ 80MG/ML SYR	5	3	$34,635.65	$6,927.13	1.67	0.41%
SUBTOTAL	**33**	**17**	**$251,950.11**	**$7,634.85**	**1.94**	**2.97%**
RISANKIZUMAB PRODUCTS						
SKYRIZI PEN INJ 150MG/ML	15	14	$303,959.31	$20,263.95	1.07	3.58%
SKYRIZI INJ 360MG/2.4ML	9	8	$189,258.93	$21,028.77	1.13	2.23%
SKYRIZI SOL 60MG/ML	1	1	$9,013.21	$9,013.21	1	0.11%
SUBTOTAL	**25**	**23**	**$502,231.45**	**$20,089.26**	**1.09**	**5.92%**
SECUKINUMAB PRODUCTS						
COSENTYX PEN INJ 300MG DOSE	13	7	$100,473.59	$7,728.74	1.86	1.18%
COSENTYX PEN INJ 150MG/ML	8	4	$124,831.30	$15,603.91	2	1.47%
COSENTYX INJ 300MG DOSE	2	2	$22,249.70	$11,124.85	1	0.26%
COSENTYX INJ 150MG/ML	1	1	$7,420.37	$7,420.37	1	0.09%
SUBTOTAL	**24**	**14**	**$254,974.96**	**$10,623.96**	**1.71**	**3.00%**
USTEKINUMAB PRODUCTS						
STELARA INJ 90MG/ML	15	9	$403,714.70	$26,914.31	1.67	4.76%
STELARA INJ 45MG/0.5ML SYR	2	2	$26,755.09	$13,377.55	1	0.32%
SUBTOTAL	**17**	**11**	**$430,469.79**	**$25,321.75**	**1.55**	**5.07%**
GUSELKUMAB PRODUCTS						
TREMFYA INJ 100MG/ML	10	8	$135,054.80	$13,505.48	1.25	1.59%
SUBTOTAL	**10**	**8**	**$135,054.80**	**$13,505.48**	**1.25**	**1.59%**
TOCILIZUMAB PRODUCTS						
ACTEMRA INJ ACTPEN 162MG/0.9ML	7	4	$30,624.93	$4,374.99	1.75	0.36%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**7**	**4**	**$30,624.93**	**$4,374.99**	**1.75**	**0.36%**
ADALIMUMAB PRODUCTS						
HADLIMA INJ 40/0.4ML	2	1	$2,098.82	$1,049.41	2	0.02%
HYRIMOZ INJ 40/0.4ML	1	1	$6,587.90	$6,587.90	1	0.08%
ADALIMU-ADAZ INJ 40/0.4ML	1	1	$2,642.01	$2,642.01	1	0.03%
HADLIMA PUSH INJ 40/0.4ML	1	1	$1,049.41	$1,049.41	1	0.01%
SUBTOTAL	**5**	**4**	**$12,378.14**	**$2,475.63**	**1.25**	**0.15%**
CANAKINUMAB PRODUCTS						
ILARIS INJ 150MG/ML	4	2	$109,076.62	$27,269.16	2	1.29%
SUBTOTAL	**4**	**2**	**$109,076.62**	**$27,269.16**	**2**	**1.29%**
RITLECITINIB PRODUCTS						
LITFULO CAP 50MG	3	1	$11,341.92	$3,780.64	3	0.13%
SUBTOTAL	**3**	**1**	**$11,341.92**	**$3,780.64**	**3**	**0.13%**
DEUCRAVACITINIB PRODUCTS						
SOTYKTU TAB 6MG	3	1	$19,636.95	$6,545.65	3	0.23%
SUBTOTAL	**3**	**1**	**$19,636.95**	**$6,545.65**	**3**	**0.23%**
AVACOPAN PRODUCTS						
TAVNEOS CAP 10MG	2	1	$32,158.18	$16,079.09	2	0.38%
SUBTOTAL	**2**	**1**	**$32,158.18**	**$16,079.09**	**2**	**0.38%**
SPECIAL PA SUBTOTAL	**241**	**138**	**$2,415,088.31**	**$10,021.11**	**1.75**	**28.46%**
TOTAL	**1,058**	**512***	**$8,485,828.04**	**$8,020.63**	**2.07**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; CAP = capsule; CD = Crohn's disease; ER = extended-release; HS = hidradenitis suppurativa; INJ = injection; PED = pediatric; PREFL = prefilled; PS = psoriasis; SOL = solution; SRCLK = SureClick; SYR = syringe; TAB = tablet; UC = ulcerative colitis; UV = uveitis
Fiscal Year 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-2 PRODUCTS						
ADALIMUMAB PRODUCTS						
HUMIRA PEN INJ 40MG/0.4ML	444	181	$3,612,738.56	$8,136.80	2.45	30.23%
HUMIRA PEN INJ 80MG/0.8ML	51	20	$727,309.09	$14,260.96	2.55	6.09%
HUMIRA INJ 40MG/0.4ML	37	17	$283,264.40	$7,655.79	2.18	2.37%
HUMIRA PEN INJ 40MG/0.8ML	25	13	$215,808.96	$8,632.36	1.92	1.81%
HUMIRA KIT 40MG/0.8ML	14	7	$94,392.70	$6,742.34	2	0.79%
HUMIRA INJ 20MG/0.2ML	13	5	$88,290.59	$6,791.58	2.6	0.74%
HUMIRA PEN KIT CD/UC/HS 80MG/0.8ML	12	11	$243,071.54	$20,255.96	1.09	2.03%
HUMIRA PEN KIT PS/UV 80MG/0.8ML & 40MG/0.4ML	6	6	$80,850.38	$13,475.06	1	0.68%
SUBTOTAL	**602**	**260**	**$5,345,726.22**	**$8,879.94**	**2.32**	**44.73%**
ETANERCEPT PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ENBREL SRCLK INJ 50MG/ML	130	66	$1,061,201.24	$8,163.09	1.97	8.88%
ENBREL INJ 50MG/ML	20	11	$144,113.88	$7,205.69	1.82	1.21%
ENBREL MINI INJ 50MG/ML	15	6	$129,222.73	$8,614.85	2.5	1.08%
ENBREL INJ 25MG	3	1	$11,136.96	$3,712.32	3	0.09%
ENBREL INJ 25/0.5ML	3	1	$10,835.41	$3,611.80	3	0.09%
SUBTOTAL	**171**	**85**	**$1,356,510.22**	**$7,932.81**	**2.01**	**11.35%**
APREMILAST PRODUCTS						
OTEZLA TAB 30MG	64	32	$307,663.32	$4,807.24	2	2.57%
OTEZLA TAB 10/20/30MG	4	4	$19,110.18	$4,777.55	1	0.16%
SUBTOTAL	**68**	**36**	**$326,773.50**	**$4,805.49**	**1.89**	**2.73%**
INFLIXIMAB PRODUCTS						
INFLECTRA INJ 100MG	7	4	$21,786.54	$3,112.36	1.75	0.18%
SUBTOTAL	**7**	**4**	**$21,786.54**	**$3,112.36**	**1.75**	**0.18%**
ANAKINRA PRODUCTS						
KINERET INJ 100MG/0.67ML	4	3	$17,963.67	$4,490.92	1.33	0.15%
SUBTOTAL	**4**	**3**	**$17,963.67**	**$4,490.92**	**1.33**	**0.15%**
TIER-2 SUBTOTAL	**852**	**366***	**$7,068,760.15**	**$8,296.67**	**2.33**	**59.15%**
TIER-3 PRODUCTS						
ABATACEPT PRODUCTS						
ORENCIA CLICKJECT INJ 125MG/ML	22	11	$162,580.39	$7,390.02	2	1.36%
ORENCIA INJ 125MG/ML	6	2	$41,381.58	$6,896.93	3	0.35%
ORENCIA INJ 87.5MG/0.7ML	2	1	$3,021.62	$1,510.81	2	0.03%
SUBTOTAL	**30**	**14**	**$206,983.59**	**$6,899.45**	**2.14**	**1.73%**
TOFACITINIB PRODUCTS						
XELJANZ TAB 5MG	11	5	$61,903.79	$5,627.62	2.2	0.52%
XELJANZ TAB 10MG	6	3	$31,588.03	$5,264.67	2	0.26%
XELJANZ XR TAB 11MG	4	4	$22,521.22	$5,630.31	1	0.19%
SUBTOTAL	**21**	**12**	**$116,013.04**	**$5,524.43**	**1.75**	**0.97%**
CERTOLIZUMAB PRODUCTS						
CIMZIA PREFL KIT 200MG/ML	18	6	$124,782.67	$6,932.37	3	1.04%
SUBTOTAL	**18**	**6**	**$124,782.67**	**$6,932.37**	**3**	**1.04%**
SARILUMAB PRODUCTS						
KEVZARA INJ 200MG/1.14ML	13	5	$68,151.13	$5,242.39	2.6	0.57%
SUBTOTAL	**13**	**5**	**$68,151.13**	**$5,242.39**	**2.6**	**0.57%**
GOLIMUMAB PRODUCTS						
SIMPONI INJ 50MG/0.5ML AUTO	9	4	$53,546.22	$5,949.58	2.25	0.45%
SUBTOTAL	**9**	**4**	**$53,546.22**	**$5,949.58**	**2.25**	**0.45%**
BRODALUMAB PRODUCTS						
SILIQ INJ 210MG/1.5ML	4	2	$40,750.48	$10,187.62	2	0.34%
SUBTOTAL	**4**	**2**	**$40,750.48**	**$10,187.62**	**2**	**0.34%**
INFLIXIMAB PRODUCTS						
AVSOLA INJ 100MG	3	1	$13,550.91	$4,516.97	3	0.11%
SUBTOTAL	**3**	**1**	**$13,550.91**	**$4,516.97**	**3**	**0.11%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VEDOLIZUMAB PRODUCTS						
ENTYVIO INJ 300MG	1	1	$6,568.94	$6,568.94	1	0.05%
SUBTOTAL	**1**	**1**	**$6,568.94**	**$6,568.94**	**1**	**0.05%**
TIER-3 SUBTOTAL	**99**	**45***	**$630,346.98**	**$6,367.14**	**2.2**	**5.27%**
SPECIAL PA PRODUCTS						
UPADACITINIB PRODUCTS						
RINVOQ TAB 15MG ER	57	25	$430,190.55	$7,547.20	2.28	3.60%
RINVOQ TAB 30MG ER	19	7	$128,359.95	$6,755.79	2.71	1.07%
RINVOQ TAB 45MG ER	5	4	$59,371.05	$11,874.21	1.25	0.50%
SUBTOTAL	**81**	**36**	**$617,921.55**	**$7,628.66**	**2.25**	**5.17%**
IXEKIZUMAB PRODUCTS						
TALTZ INJ 80MG/ML AUTO	43	19	$384,608.14	$8,944.38	2.26	3.22%
TALTZ INJ 80MG/ML SYR	3	2	$20,781.39	$6,927.13	1.5	0.17%
SUBTOTAL	**46**	**21**	**$405,389.53**	**$8,812.82**	**2.19**	**3.39%**
BELIMUMAB PRODUCTS						
BENLYSTA INJ 200MG/ML AUTO	46	19	$266,805.31	$5,800.12	2.42	2.23%
SUBTOTAL	**46**	**19**	**$266,805.31**	**$5,800.12**	**2.42**	**2.23%**
SECUKINUMAB PRODUCTS						
COSENTYX UNO INJ 300MG/2ML	14	10	$177,596.92	$12,685.49	1.4	1.49%
COSENTYX PEN INJ 150MG/ML	14	6	$192,634.37	$13,759.60	2.33	1.61%
COSENTYX PEN INJ 300MG DOSE	11	6	$118,273.20	$10,752.11	1.83	0.99%
COSENTYX INJ 300MG DOSE	4	2	$29,681.48	$7,420.37	2	0.25%
COSENTYX INJ 150MG/ML	2	1	$14,840.74	$7,420.37	2	0.12%
SUBTOTAL	**45**	**25**	**$533,026.71**	**$11,845.04**	**1.8**	**4.46%**
USTEKINUMAB PRODUCTS						
STELARA INJ 90MG/ML SYR	28	16	$873,369.58	$31,191.77	1.75	7.31%
STELARA INJ 45MG/0.5ML VIAL	5	4	$69,664.20	$13,932.84	1.25	0.58%
STELARA INJ 45MG/0.5ML SYR	5	4	$67,046.95	$13,409.39	1.25	0.56%
SUBTOTAL	**38**	**24**	**$1,010,080.73**	**$26,581.07**	**1.58**	**8.45%**
RISANKIZUMAB PRODUCTS						
SKYRIZI PEN INJ 150MG/ML	17	13	$374,795.19	$22,046.78	1.31	3.14%
SKYRIZI INJ 360MG/2.4ML	13	9	$282,294.53	$21,714.96	1.44	2.36%
SKYRIZI INJ 150MG/ML	1	1	$20,525.86	$20,525.86	1	0.17%
SKYRIZI SOL 60MG/ML	1	1	$9,013.21	$9,013.21	1	0.08%
SUBTOTAL	**32**	**24**	**$686,628.79**	**$21,457.15**	**1.33**	**5.75%**
TOCILIZUMAB PRODUCTS						
ACTEMRA INJ ACTPEN 162MG/0.9ML	15	7	$67,582.40	$4,505.49	2.14	0.57%
ACTEMRA INJ 162MG/0.9ML	3	2	$9,432.71	$3,144.24	1.5	0.08%
SUBTOTAL	**18**	**9**	**$77,015.11**	**$4,278.62**	**2**	**0.64%**
CANAKINUMAB PRODUCTS						
ILARIS INJ 150MG/ML	16	6	$370,876.49	$23,179.78	2.67	3.10%
SUBTOTAL	**16**	**6**	**$370,876.49**	**$23,179.78**	**2.67**	**3.10%**
GUSELKUMAB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TREMFYA INJ 100MG/ML	12	9	$181,855.00	$15,154.58	1.33	1.52%
SUBTOTAL	**12**	**9**	**$181,855.00**	**$15,154.58**	**1.33**	**1.52%**
ADALIMUMAB PRODUCTS						
ADALIMUMAB-ADAZ INJ 40MG/0.4ML	5	3	$7,948.85	$1,589.77	1.67	0.07%
HYRIMOZ INJ 40MG/0.4ML	2	1	$13,175.80	$6,587.90	2	0.11%
ADALIMUMAB-ADAZ INJ 40MG/0.4ML	1	1	$1,326.71	$1,326.71	1	0.01%
SUBTOTAL	**8**	**5**	**$22,451.36**	**$2,806.42**	**1.6**	**0.19%**
DEUCRAVACITINIB PRODUCTS						
SOTYKTU TAB 6MG	3	1	$19,636.95	$6,545.65	3	0.16%
SUBTOTAL	**3**	**1**	**$19,636.95**	**$6,545.65**	**3**	**0.16%**
BIMEKIZUMAB PRODUCTS						
BIMZELX INJ 160MG/ML	2	2	$28,822.82	$14,411.41	1	0.24%
SUBTOTAL	**2**	**2**	**$28,822.82**	**$14,411.41**	**1**	**0.24%**
TILDRAKIZUMAB PRODUCTS						
ILUMYA SOL 100MG/ML	2	1	$28,111.02	$14,055.51	2	0.24%
SUBTOTAL	**2**	**1**	**$28,111.02**	**$14,055.51**	**2**	**0.24%**
RITLECITINIB PRODUCTS						
LITFULO CAP 50MG	1	1	$3,780.64	$3,780.64	1	0.03%
SUBTOTAL	**1**	**1**	**$3,780.64**	**$3,780.64**	**1**	**0.03%**
SPECIAL PA SUBTOTAL	**350**	**175***	**$4,252,402.01**	**$12,149.72**	**2**	**35.58%**
TOTAL	**1,301**	**577***	**$11,951,509.14**	**$9,186.40**	**2.25**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; CAP = capsule; CD = Crohn's disease; ER = extended-release; HS = hidradenitis suppurativa; INJ = injection; PED = pediatric; PREFL = prefilled; PS = psoriasis; SOL = solution; SRCLK = SureClick; SYR = syringe; TAB = tablet; UC = ulcerative colitis; UV = uveitis
Fiscal Year 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-2 PRODUCTS						
ADALIMUMAB PRODUCTS						
HUMIRA PEN INJ 40MG/0.4ML	358	176	$2,755,482.16	$7,696.88	2.03	34.26%
HUMIRA INJ 40MG/0.4ML	33	15	$263,005.32	$7,969.86	2.2	3.27%
HUMIRA PEN INJ 40MG/0.8ML	26	13	$195,587.83	$7,522.61	2	2.43%
HUMIRA PEN INJ 80/0.8ML	23	11	$309,806.99	$13,469.87	2.09	3.85%
HUMIRA KIT 40MG/0.8ML	13	6	$101,113.45	$7,777.96	2.17	1.26%
HUMIRA INJ 20MG/0.2ML	13	6	$88,105.41	$6,777.34	2.17	1.10%
HUMIRA PEN KIT CD/UC/HS 80MG/0.8ML	6	6	$121,251.48	$20,208.58	1	1.51%
HUMIRA PEN KIT PS/UV 80MG/0.8ML & 40MG/0.4ML	5	5	$67,451.64	$13,490.33	1	0.84%
HUMIRA INJ 10MG/0.1ML	1	1	$6,934.03	$6,934.03	1	0.09%
SUBTOTAL	**478**	**239**	**$3,908,738.31**	**$8,177.28**	**2**	**48.60%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ETANERCEPT PRODUCTS						
ENBREL SRCLK INJ 50MG/ML	148	82	$1,125,327.98	$7,603.57	1.8	13.99%
ENBREL INJ 50MG/ML	15	10	$108,108.50	$7,207.23	1.5	1.34%
SUBTOTAL	**163**	**92**	**$1,233,436.48**	**$7,567.09**	**1.77**	**15.34%**
APREMILAST PRODUCTS						
OTEZLA TAB 30MG	41	22	$192,679.14	$4,699.49	1.86	2.40%
OTEZLA TAB 10/20/30MG	6	6	$28,520.45	$4,753.41	1	0.35%
SUBTOTAL	**47**	**28**	**$221,199.59**	**$4,706.37**	**1.68**	**2.75%**
INFLIXIMAB PRODUCTS						
ZYMFENTRA INJ 120MG/ML	3	1	$5,672.82	$1,890.94	3	0.07%
INFLECTRA INJ 100MG	1	1	$1,011.99	$1,011.99	1	0.01%
SUBTOTAL	**4**	**2**	**$6,684.81**	**$1,671.20**	**2**	**0.08%**
ANAKINRA PRODUCTS						
KINERET INJ 100MG/0.67ML	1	1	$5,524.65	$5,524.65	1	0.07%
SUBTOTAL	**1**	**1**	**$5,524.65**	**$5,524.65**	**1**	**0.07%**
TIER-2 SUBTOTAL	**693**	**341***	**$5,375,583.84**	**$7,756.98**	**2.03**	**66.83%**
TIER-3 PRODUCTS						
ABATACEPT PRODUCTS						
ORENCIA CLICKJECT INJ 125MG/ML	17	8	$94,249.32	$5,544.08	2.13	1.17%
ORENCIA INJ 125MG/ML	1	1	$5,544.37	$5,544.37	1	0.07%
SUBTOTAL	**18**	**9**	**$99,793.69**	**$5,544.09**	**2**	**1.24%**
TOFACITINIB PRODUCTS						
XELJANZ TAB 5MG	12	6	$67,545.38	$5,628.78	2	0.84%
XELJANZ XR TAB 11MG	1	1	$5,630.32	$5,630.32	1	0.07%
SUBTOTAL	**13**	**7**	**$73,175.70**	**$5,628.90**	**1.86**	**0.91%**
CERTOLIZUMAB PRODUCTS						
CIMZIA PREFL KIT 200MG/ML	12	5	$87,729.87	$7,310.82	2.4	1.09%
SUBTOTAL	**12**	**5**	**$87,729.87**	**$7,310.82**	**2.4**	**1.09%**
VEDOLIZUMAB PRODUCTS						
ENTYVIO INJ 300MG	3	2	$23,923.29	$7,974.43	1.5	0.30%
SUBTOTAL	**3**	**2**	**$23,923.29**	**$7,974.43**	**1.5**	**0.30%**
GOLIMUMAB PRODUCTS						
SIMPONI INJ 50MG/0.5ML AUTO	2	2	$11,897.56	$5,948.78	1	0.15%
SUBTOTAL	**2**	**2**	**$11,897.56**	**$5,948.78**	**1**	**0.15%**
INFLIXIMAB PRODUCTS						
REMICADE INJ 100MG	2	2	$11,644.42	$5,822.21	1	0.14%
SUBTOTAL	**2**	**2**	**$11,644.42**	**$5,822.21**	**1**	**0.14%**
SARILUMAB PRODUCTS						
KEVZARA INJ 200MG/1.14ML	1	1	$4,354.53	$4,354.53	1	0.05%
SUBTOTAL	**1**	**1**	**$4,354.53**	**$4,354.53**	**1**	**0.05%**
TIER-3 SUBTOTAL	**51**	**28***	**$312,519.06**	**$6,127.82**	**1.82**	**3.89%**
SPECIAL PA PRODUCTS						
UPADACITINIB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RINVOQ TAB 15MG ER	24	14	$150,224.22	$6,259.34	1.71	1.87%
RINVOQ TAB 30MG ER	12	7	$74,673.86	$6,222.82	1.71	0.93%
RINVOQ TAB 45MG ER	5	4	$59,016.05	$11,803.21	1.25	0.73%
SUBTOTAL	**41**	**25**	**$283,914.13**	**$6,924.73**	**1.64**	**3.53%**
IXEKIZUMAB PRODUCTS						
TALTZ INJ 80MG/ML AUTO	31	14	$252,999.31	$8,161.27	2.21	3.15%
TALTZ INJ 80MG/ML SYR	9	4	$62,344.17	$6,927.13	2.25	0.78%
SUBTOTAL	**40**	**18**	**$315,343.48**	**$7,883.59**	**2.22**	**3.92%**
BELIMUMAB PRODUCTS						
BENLYSTA INJ 200MG/ML AUTO	38	18	$184,448.58	$4,853.91	2.11	2.29%
BENLYSTA INJ 200MG/ML SYR	1	1	$4,853.91	$4,853.91	1	0.06%
SUBTOTAL	**39**	**19**	**$189,302.49**	**$4,853.91**	**2.05**	**2.35%**
SECUKINUMAB PRODUCTS						
COSENTYX PEN INJ 300MG DOSE	15	8	$114,864.14	$7,657.61	1.88	1.43%
COSENTYX UNO INJ 300MG/2ML	5	3	$88,964.57	$17,792.91	1.67	1.11%
COSENTYX INJ 150MG/ML	4	3	$44,499.40	$11,124.85	1.33	0.55%
COSENTYX PEN INJ 150MG/ML	3	2	$22,059.06	$7,353.02	1.5	0.27%
COSENTYX INJ 75MG/0.5ML	2	1	$18,545.22	$9,272.61	2	0.23%
SUBTOTAL	**29**	**17**	**$288,932.39**	**$9,963.19**	**1.71**	**3.59%**
RISANKIZUMAB PRODUCTS						
SKYRIZI PEN INJ 150MG/ML	13	13	$263,550.58	$20,273.12	1	3.28%
SKYRIZI INJ 360MG/2.4ML	7	5	$147,201.39	$21,028.77	1.4	1.83%
SUBTOTAL	**20**	**18**	**$410,751.97**	**$20,537.60**	**1.11**	**5.11%**
TOCILIZUMAB PRODUCTS						
ACTEMRA INJ ACTPEN 162MG/0.9ML	16	9	$44,825.34	$2,801.58	1.78	0.56%
ACTEMRA INJ 162MG/0.9ML	2	1	$9,421.30	$4,710.65	2	0.12%
SUBTOTAL	**18**	**10**	**$54,246.64**	**$3,013.70**	**1.8**	**0.67%**
USTEKINUMAB PRODUCTS						
STELARA INJ 90MG/ML SYR	12	7	$322,894.96	$26,907.91	1.71	4.01%
STELARA INJ 45MG/0.5ML SYR	2	2	$26,818.78	$13,409.39	1	0.33%
STELARA INJ 45MG/0.5ML VIAL	1	1	$13,932.84	$13,932.84	1	0.17%
STELARA INJ 5MG/ML VIAL	1	1	$4,932.82	$4,932.82	1	0.06%
SUBTOTAL	**16**	**11**	**$368,579.40**	**$23,036.21**	**1.45**	**4.58%**
GUSELKUMAB PRODUCTS						
TREMFYA INJ 100MG/ML PEN	8	6	$108,043.84	$13,505.48	1.33	1.34%
TREMFYA INJ 100MG/ML SYR	1	1	$13,884.21	$13,884.21	1	0.17%
SUBTOTAL	**9**	**7**	**$121,928.05**	**$13,547.56**	**1.29**	**1.52%**
CANAKINUMAB PRODUCTS						
ILARIS INJ 150MG/ML	8	4	$167,099.77	$20,887.47	2	2.08%
SUBTOTAL	**8**	**4**	**$167,099.77**	**$20,887.47**	**2**	**2.08%**
ADALIMUMAB PRODUCTS						
ADALIMUMAB-ADAZ INJ 40MG/0.4ML	3	3	$3,980.13	$1,326.71	1	0.05%
HADLIMA PUSH INJ 40MG/0.4ML	3	2	$3,115.72	$1,038.57	1.5	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**6**	**5**	**$7,095.85**	**$1,182.64**	**1.2**	**0.09%**
AVACOPAN PRODUCTS						
TAVNEOS CAP 10MG	4	3	$64,316.36	$16,079.09	1.33	0.80%
SUBTOTAL	**4**	**3**	**$64,316.36**	**$16,079.09**	**1.33**	**0.80%**
BIMEKIZUMAB PRODUCTS						
BIMZELX INJ 160MG/ML	3	1	$43,234.23	$14,411.41	3	0.54%
SUBTOTAL	**3**	**1**	**$43,234.23**	**$14,411.41**	**3**	**0.54%**
RITLETICINIB PRODUCTS						
LITFULO CAP 50MG	3	2	$11,341.92	$3,780.64	1.5	0.14%
SUBTOTAL	**3**	**2**	**$11,341.92**	**$3,780.64**	**1.5**	**0.14%**
VOCLOSPORIN PRODUCTS						
LUPKYNIS CAP 7.9MG	2	1	$19,614.82	$9,807.41	2	0.24%
SUBTOTAL	**2**	**1**	**$19,614.82**	**$9,807.41**	**2**	**0.24%**
DEUCRAVACITINIB PRODUCTS						
SOTYKTU TAB 6MG	1	1	$6,545.65	$6,545.65	1	0.08%
SUBTOTAL	**1**	**1**	**$6,545.65**	**$6,545.65**	**1**	**0.08%**
BARICITINIB PRODUCTS						
OLUMIANT TAB 1MG	1	1	$2,751.40	$2,751.40	1	0.03%
SUBTOTAL	**1**	**1**	**$2,751.40**	**$2,751.40**	**1**	**0.03%**
SPECIAL PA SUBTOTAL	**240**	**138***	**$2,354,998.55**	**$9,812.49**	**1.74**	**29.28%**
TOTAL	**984**	**500***	**$8,043,101.45**	**$8,173.88**	**1.97**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; CAP = capsule; CD = Crohn's disease; ER = extended-release; HS = hidradenitis suppurativa; INJ = injection; PED = pediatric; PREFL = prefilled; PS = psoriasis; SOL = solution; SRCLK = SureClick; SYR = syringe; TAB = tablet; UC = ulcerative colitis; UV = uveitis
Fiscal Year 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
BENLYSTA IV INJ (J0490)	1,019	155	$3,944,623.27	$3,871.07	6.57
RITUXAN INJ (J9312)	595	157	$2,835,770.09	$4,766.00	3.79
RENFLEXIS INJ (Q5104)	387	78	$646,987.55	$1,671.80	4.96
SIMPONI ARIA INJ (J1602)	367	98	$777,020.06	$2,117.22	3.74
SAPHNELO INJ (J0491)	355	84	$1,792,453.36	$5,049.16	4.23
REMICADE INJ (J1745)	331	78	$559,703.69	$1,690.95	4.24
ACTEMRA INJ (J3262)	260	47	$675,900.19	$2,599.62	5.53
ENTYVIO INJ (J3380)	238	56	$1,575,132.00	$6,618.20	4.25
ORENCIA INJ (J0129)	221	44	$820,480.25	$3,712.58	5.02
INFLECTRA INJ (Q5103)	131	40	$102,205.05	$780.19	3.28
AVSOLA INJ (Q5121)	103	15	$88,855.60	$862.68	6.87
TRUXIMA INJ (Q5115)	86	26	$148,938.62	$1,731.84	3.31
CIMZIA INJ (J0717)	48	12	$93,880.00	$1,955.83	4
SKYRIZI IV INJ (J2327)	37	18	$337,689.00	$9,126.73	2.06
RIABNI INJ (Q5123)	13	4	$18,744.36	$1,441.87	3.25
STELARA SQ INJ (J3357)	5	4	$67,353.30	$13,470.66	1.25
STELARA IV INJ (J3358)	5	5	$21,308.30	$4,261.66	1
RUXIENCE INJ (Q5119)	5	3	$7,566.50	$1,513.30	1.67
ILARIS INJ (J0638)	1	1	$18,649.50	$18,649.50	1
TOTAL	**4,207⁺**	**878***	**$14,533,260.69**	**$3,454.54**	**4.79**

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

Aetna Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BENLYSTA IV INJ (J0490)	19	10	$47,932.60	$2,522.77	1.9
SAPHNELO INJ (J0491)	14	9	$66,846.00	$4,774.71	1.56
RENFLEXIS INJ (Q5104)	7	3	$11,860.80	$1,694.40	2.33
SIMPONI ARIA INJ (J1602)	7	4	$7,056.40	$1,008.06	1.75
ACTEMRA INJ (J3262)	5	2	$13,046.40	$2,609.28	2.5
AVSOLA INJ (Q5121)	5	2	$2,924.40	$584.88	2.5
RIABNI INJ (Q5123)	4	1	$0.00	$0.00	4
RITUXAN INJ (J9312)	2	2	$15,774.00	$7,887.00	1
ENTYVIO INJ (J3380)	2	2	$13,173.00	$6,586.50	1
ORENCIA INJ (J0129)	2	2	$7,497.00	$3,748.50	1
REMICADE INJ (J1745)	2	1	$0.00	$0.00	2
TOTAL	**69⁺**	**38***	**$186,110.60**	**$2,697.26**	**1.82**

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
INFLECTRA INJ (Q5103)	4	3	$2,634.00	$658.50	1.33
RITUXAN INJ (J9312)	3	3	$23,760.00	$7,920.00	1
ACTEMRA INJ (J3262)	2	1	$0.02	$0.01	2
STELARA SQ INJ (J3357)	1	1	$13,856.40	$13,856.40	1
TOTAL	**10⁺**	**8***	**$40,250.42**	**$4,025.04**	**1.25**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; SQ = subcutaneous
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
BENLYSTA IV INJ (J0490)	35	15	$106,793.40	$3,051.24	2.33
SIMPONI ARIA INJ (J1602)	20	11	$31,116.60	$1,555.83	1.82
ORENCIA INJ (J0129)	12	6	$50,337.00	$4,194.75	2
INFLECTRA INJ (Q5103)	12	6	$5,549.40	$462.45	2
RENFLEXIS INJ (Q5104)	10	5	$11,648.00	$1,164.80	2
RITUXAN INJ (J9312)	9	7	$56,007.60	$6,223.07	1.29
REMICADE INJ (J1745)	9	7	$17,080.88	$1,897.88	1.29
SAPHNELO INJ (J0491)	8	5	$41,136.00	$5,142.00	1.6
ACTEMRA INJ (J3262)	8	3	$15,891.24	$1,986.41	2.67
AVSOLA INJ (Q5121)	8	3	$3,168.10	$396.01	2.67
SKYRIZI IV INJ (J2327)	4	2	$36,000.00	$9,000.00	2
ENTYVIO INJ (J3380)	3	3	$19,728.00	$6,576.00	1
RUXIENCE INJ (Q5119)	1	1	$1,216.80	$1,216.80	1
TOTAL	**139⁺**	**73***	**$395,673.02**	**$2,846.57**	**1.9**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection; IV = intravenous
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 Hyperoxaluria Medications and 30-day Notice to Prior Authorize Rivfloza® (Nedosiran)

Oklahoma Health Care Authority
October 2024

Current Prior Authorization Criteria

Oxlumo® (Lumasiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels. Diagnosis of PH1 must be confirmed by:
    a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene (results of genetic testing must be submitted); or
    b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and
2. Oxlumo® must be prescribed by a nephrologist, geneticist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a nephrologist, geneticist, 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. 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. 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.

Utilization of Hyperoxaluria Medications: Fiscal Year 2024

There was no SoonerCare utilization of hyperoxaluria medications during fiscal year 2024 (07/01/2023 to 06/30/2024).

Prior Authorization of Hyperoxaluria Medications: Fiscal Year 2024

There were no prior authorization requests submitted for hyperoxaluria medications during fiscal year 2024.

Market News and Updates[1]

Anticipated Patent Expiration(s):

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

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

- **October 2023:** The FDA approved Rivfloza® (nedosiran), a once monthly subcutaneous (sub-Q) injection, to lower urinary oxalate levels in adults and children 9 years of age and older with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.

Rivfloza® (Nedosiran) Product Summary[2,3]

Therapeutic Class: Lactate dehydrogenase A (LDHA)-directed small interfering ribonucleic acid (siRNA)

Indication(s): To lower urinary oxalate levels in children 9 years of age and older and adults with PH1 and relatively preserved kidney function [e.g., estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2]

How Supplied: Rivfloza® is a 160mg/mL solution available as follows:

- 80mg (0.5mL) single dose vial (SDV)
- 128mg (0.8mL) single dose prefilled syringe
- 160mg (1mL) single dose prefilled syringe

Dosing and Administration: Administered as a sub-Q injection to the abdomen or upper thigh once monthly, with dosing based on age and actual body weight:

Age	Weight	Dosing Regimen
9 to 11 years of age	<50kg	3.3mg/kg, not to exceed 128mg, once monthly (0.5mL SDV)
	≥50kg	160mg once monthly (1mL prefilled syringe)
12 years of age and older	<50kg	128mg once monthly (0.8mL prefilled syringe)
	≥50kg	160mg once monthly (1mL prefilled syringe)

- SDVs are intended for use under the supervision of a health care professional. Caregivers for pediatric patients may administer vials after proper training or if a health care professional determines it is appropriate.
- In pediatric patients 9 to 11 years of age who weigh ≥50kg, a health care professional or caregiver may inject Rivfloza® using the 1mL prefilled syringe.

Efficacy: The safety and efficacy of Rivfloza® were studied in a multicenter, randomized, double-blind, placebo-controlled trial over a 6-month treatment period.

- Key Inclusion Criteria:
  - 6 years of age or older with PH1 or primary hyperoxaluria type 2 (PH2) and an eGFR ≥30mL/min/1.73m^2
  - 24-hour urinary oxalate excretion ≥0.7mmol/1.73m^2 collected during screening period
- Key Exclusion Criteria:
  - Prior renal or hepatic transplant
  - Plasma oxalate >30micromol/L
  - Documented evidence of clinical manifestation of systemic oxalosis
  - Currently on dialysis or anticipated requirement for dialysis during study period
  - Use of an RNA interference (RNAi) drug during the last 6 months
- Primary Endpoint(s):
  - The area under curve (AUC) from days 90 to 180 of the percent change from baseline in 24-hour urinary oxalate excretion
- Results:
  - Mean percent change from baseline in 24-hour urinary oxalate excretion was 35% in the nedosiran group and 12% in the placebo group
  - Too few patients with PH2 were enrolled to evaluate efficacy in the PH2 population

Cost Comparison:

Product	Cost Per mL	Cost Per Dose	Cost Per Year
Rivfloza® (nedosiran 160mg/mL)	**$62,880**	**$62,880***	**$754,560***
Oxlumo® (lumasiran 94.5mg/0.5mL)	$116,698	$175,047	$700,188⁺

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 160mg once monthly.
⁺Cost is based on the FDA approved maintenance dose of 3mg/kg every 3 months for a member weighing 80kg.

Recommendations

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.

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Appendix I

Fiscal Year 2024 Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution)

Oklahoma Health Care Authority
October 2024

Current Prior Authorization Criteria

Adakveo® (Crizanlizumab-tmca) Approval Criteria:

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

Aranesp® (Darbepoetin Alfa) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of anemia due to chemotherapy in members with non-myeloid malignancies; or
    b. Treatment of anemia associated with chronic renal failure; and
        i. For the diagnosis of anemia associated with chronic renal failure: member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

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. 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 a duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Enjaymo® (Sutimlimab-jome) Approval Criteria:

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

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

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

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

3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

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; 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

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.

Pyrukynd® (Mitapivat) Approval Criteria:

1. An FDA approved indication of hemolytic anemia in adults with pyruvate kinase (PK) deficiency confirmed by the following:
    a. Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, with at least 1 missense variant; and
        i. Hemoglobin (Hgb) ≤10g/dL; or
        ii. Member has received ≥6 red blood cell (RBC) transfusions in the past year; and
2. Pyrukynd® must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
3. Member must not have moderate or severe hepatic impairment; and
4. If Pyrukynd® is to be discontinued, prescriber must verify dose will be tapered gradually according to package labeling and member will be monitored for signs of acute hemolysis and worsening anemia; and

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

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

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

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

1. An FDA approved indication of 1 of the following:
    a. Treatment of adult members with very low-to-intermediate risk MDS with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with anemia failing an erythropoiesis stimulating agent (ESA) and requiring ≥2 red blood cell (RBC) units over 8 weeks; or
    b. Treatment of adult members with very low-to-intermediate risk MDS with anemia who are ESA-naive and who required ≥2 RBS units within the last 8 weeks; and
2. For MDS-RS or MDS/MPN-RS-T:
    a. Member must have had an inadequate response to prior treatment with an ESA, be intolerant of ESAs, or have a serum erythropoietin level >200U/L; and
    b. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
    c. Prescriber must verify the member does not have deletion 5q (del 5q); and
3. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
4. Reblozyl® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in treatment of MDS (or an advanced care practitioner with a supervising physician who is a hematologist, oncologist, or specialist with expertise in treating MDS); and
5. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
6. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and
7. A recent (within the last 3 months) weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 6months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Siklos® (Hydroxyurea Tablets) Approval Criteria:

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

Zynteglo™ (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must be 4 years of age or older; and
3. Member must weigh ≥6kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
    a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
    b. ≥8 transfusions of packed RBCs per year in the last 2 years; and
5. Zynteglo™ must be prescribed by a hematologist 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 have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; 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 Zynteglo™); 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 Zynteglo™ 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 6months after administration of Zynteglo™; 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 Zynteglo™; and
14. 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
15. 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
16. 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
17. Approvals will be for 1 dose per member per lifetime.

Utilization of Anemia Medications: Fiscal Year 2024

Comparison of Fiscal Years: Erythropoietin Stimulating Agents (ESAs) Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	11	115	$51,747.98	$449.98	$44.61	177	1,160
2023 Total	**11**	**115**	**$51,747.98**	**$449.98**	**$44.61**	**177**	**1,160**
Fiscal Year 2024							
FFS	14	94	$56,875.17	$605.06	$47.48	107	1,198
Aetna	2	4	$3,625.12	$906.28	$51.79	3	70
Humana	1	1	$4,287.41	$4,287.41	$153.12	4	28
Centene	4	19	$8,086.08	$425.58	$32.47	52	249
2024 Total	**18**	**118**	**$72,873.78**	**$617.57**	**$47.17**	**166**	**1,545**
% Change	**63.60%**	**2.60%**	**40.80%**	**37.20%**	**5.70%**	**-6.20%**	**33.20%**
Change	**7**	**3**	**$21,125.80**	**$167.59**	**$2.56**	**-11**	**385**

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 calendar year 2023 for ESA medications totaled $32,514.27.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, calendar year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2024 are still being collected at this time. The costs included in this report do not reflect net costs

Comparison of Fiscal Years: ESAs Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	32	111	$79,588.14	$717.01	3.47
2023 Total	**32**	**111**	**$79,588.14**	**$717.01**	**3.47**
Fiscal Year 2024					
FFS	42	150	$76,887.64	$512.58	3.57
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	**42**	**150**	**$76,887.64**	**$512.58**	**3.57**
% Change	**31.25%**	**35.14%**	**-3.39%**	**-28.15%**	**2.88%**
Change	**10**	**39**	**-$2,700.50**	**-$204.53**	**0.1**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 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.

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

Comparison of Fiscal Years: Sickle Cell Disease (SCD) and Beta Thalassemia Medications Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	233	1,187	$1,395,594.16	$1,175.73	$35.46	81,725	39,353
2023 Total	**233**	**1,187**	**$1,395,594.16**	**$1,175.73**	**$35.46**	**81,725**	**39,353**
Fiscal Year 2024+							
FFS	219	1,028	$1,880,218.59	$1,175.73	$35.46	81,725	39,353
Aetna	22	43	$25,461.11	$592.12	$19.66	3,202	1,295
Humana	30	59	$150,603.01	$2,552.59	$86.11	3,392	1,749
OCH	26	50	$2,666.15	$53.32	$1.87	3,589	1,425
2024 Total	**229**	**1,180**	**$2,058,948.86**	**$1,744.87**	**$52.63**	**81,050**	**39,119**
% Change	**-1.70%**	**-0.60%**	**47.50%**	**48.40%**	**48.40%**	**-0.80%**	**-0.60%**
Change	**-4**	**-7**	**$663,354.70**	**$569.14**	**$17.17**	**-675**	**-234**

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 pharmacy claims for beta thalassemia medications during fiscal year 2023 and 2024.

- Aggregate drug rebates collected during calendar year 2023 for SCD medications totaled $445,362.86.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, calendar year 2023 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2024 are still being collected at this time. The costs included in this report do not reflect net costs.

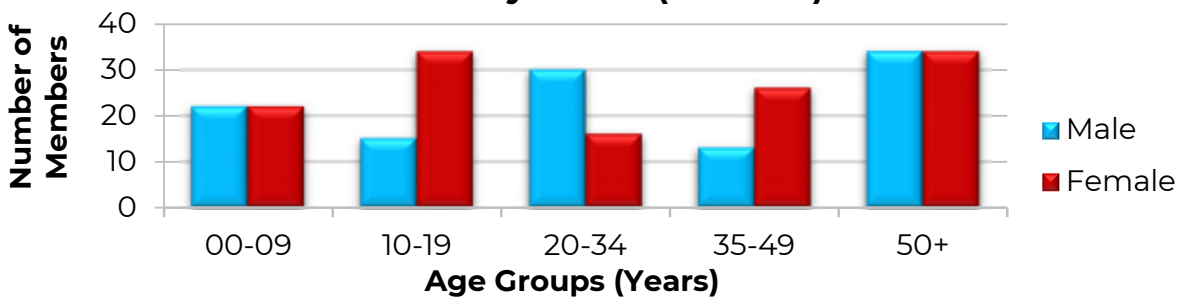
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Comparison of Fiscal Years: SCD and Beta Thalassemia Medications Medical Claims (All Plans)

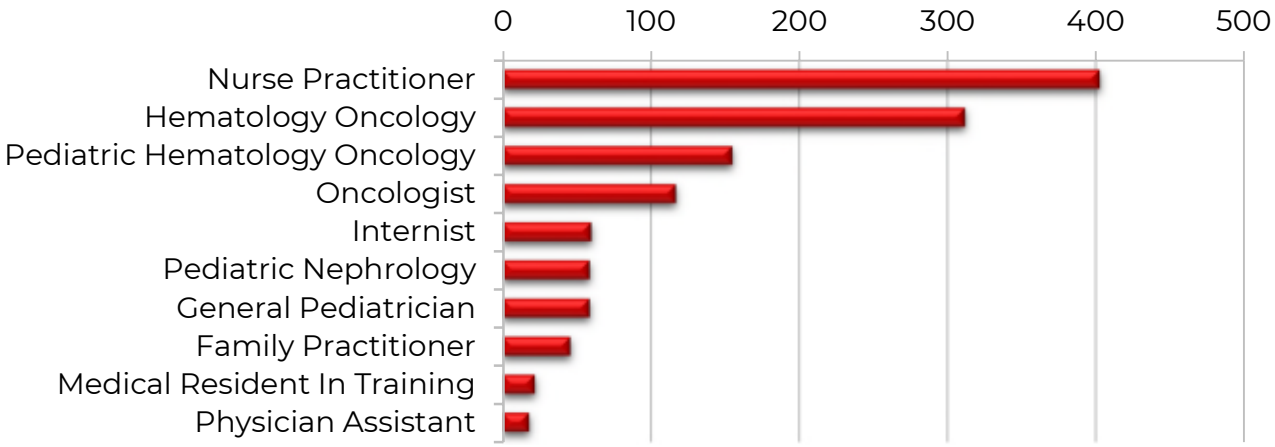
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	24	170	$1,618,357.04	$9,519.75	7.08
2023 Total	**24**	**170**	**$1,618,357.04**	**$9,519.75**	**7.08**
Fiscal Year 2024					
FFS	19	175	$1,545,583.60	$8,831.91	9.21
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	2	3	$20,336.00	$6,778.67	1.5
2024 Total	**20**	**178**	**$1,565,919.60**	**$8,797.30**	**8.90**
% Change	**-16.67%**	**4.71%**	**-3.24%**	**-7.59%**	**25.71%**
Change	**-4**	**8**	**-$52,437.44**	**-$722.45**	**1.82**

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 Anemia Medications: Pharmacy Claims (All Plans)



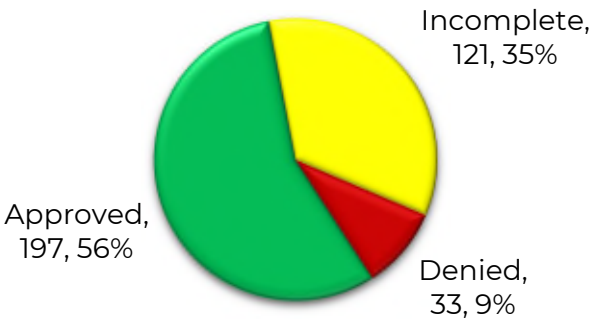
Top Prescriber Specialties of Anemia Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anemia Medications

There were 351 prior authorization requests submitted for anemia medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Plan Type	Approved		Incomplete		Denied		Total
	Number	%	Number	%	Number	%	
FFS	186	56%	121	36%	27	8%	**334**
Aetna	0	0%	0	0%	0	0%	**0**
Humana	10	67%	0	0%	5	33%	**15**
OCH	1	50%	0	0%	1	50%	**2**
Total	**197**	**56%**	**121**	**34%**	**33**	**9%**	**351**

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]

Anticipated Patent Expiration(s):

- Vafseo® (vadadustat tablets): March 2036
- Oxbryta® (voxelotor tablets for oral suspension): December 2036
- Oxbryta® (voxelotor tablets): October 2037
- Jesduvroq™ (daprodustat tablets): March 2038
- Pyrukynd® (mitapivat tablets) July 2041

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

- **December 2023:** The FDA approved Casgevy™ (exagamglogene autotemcel) and Lyfgenia® (lovotibeglogene autotemcel) for the treatment of sickle cell disease (SCD) in patients 12 years of age or older. The 2 approvals represent the first cell-based gene therapies for the treatment of SCD. Casgevy™ is the first FDA approved therapy that will utilize the CRISPR/Cas9 technology. Lyfgenia® uses a lentiviral vector

(LVV) for genetic modification. Both products are made from the patients' own stem cells, which are modified and given back as a one-time, single-dose infusion as part of a hematopoietic stem cell transplant (HSCT).

- **January 2024:** The FDA approved a new indication for Casgevy™ to treat patients 12 years of age and older with transfusion-dependent beta thalassemia (TDT). This approval follows the first FDA approved gene therapy for TDT, Zynteglo™ (betibeglogene autotemcel), which was FDA approved in August 2022.
- **March 2024:** Akebia Therapeutics announced the FDA approval of Vafseo® (vadadustat) oral tablets for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been on dialysis for at least 3 months.
- **April 2024:** The FDA approved Xromi® (hydroxyurea) oral solution to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients 6 months to younger than 2 years of age with sickle cell anemia with recurrent moderate to severe painful crises. Xromi® will be available in a 100mg/mL oral solution.
- **July 2024:** Ani Pharmaceuticals announced the FDA approval and launch of L-glutamine oral powder, a generic version of Endari®. L-glutamine was approved through an Abbreviated New Drug Application (ANDA).

News:

- **January 2024:** Upon the approval of Casgevy™, Vertex announced that they were working with experienced hospitals to become authorized treatment centers (ATCs) throughout the U.S. for the administration of Casgevy™. So far, 9 ATCs have been activated in the U.S. to offer Casgevy™ to eligible patients.
- **August 2024:** Bluebird bio announced that more than 70 qualified treatment centers (QTCs) have been activated for the administration of Zynteglo™ and Lyfgenia®.
- **September 2024:** Pfizer announced the voluntary withdrawal of all lots of Oxbryta® (voxelotor) from the market and the discontinuation all active voxelotor clinical trials and expanded access programs worldwide. The decision is based on the clinical data that now indicates the overall benefits of Oxbryta® no longer outweigh the risks in the SCD population, as the data suggests an imbalance in vaso-occlusive crises (VOCs) and fatal events.

Pipeline:

- **Obexelimab:** Obexelimab is an investigational bifunctional monoclonal antibody that works by inhibiting a broad B cell population that is being studied for various autoimmune diseases including warm

Autoimmune Hemolytic Anemia (wAIHA). wAIHA is an autoimmune disorder that causes hemolysis at body temperature. An open-label safety and dose confirmation Phase 2 trial is currently enrolling.

- **Pyrukynd® (Mitapivat):** Pyrukynd® is a pyruvate kinase activator that was approved by the FDA in 2022 for the treatment of hemolytic anemia with pyruvate kinase deficiency (PKD) in adults. Currently Pyrukynd® is being studied in multiple trials including a Phase 3 trial for pediatric patients with PKD, a Phase 3 trial for adults with non-transfusion-dependent alpha or beta thalassemia, and a Phase 3 trial for patients 16 years of age or older with SCD.
- **RP-L102:** RP-L102 is an investigational gene therapy that is being studied for Fanconi anemia. Fanconi anemia is a rare genetic disorder that is caused by a mutation in the *FANCA* gene and is characterized by bone marrow failure, cancer predisposition, and congenital malformations. RP-L102 uses a patient's hematopoietic stem cells (HSCs) that have been genetically modified with a LVV to contain a functional copy of the *FANCA* gene. The FDA accepted an Investigational New Drug (IND) application and RP-L102 has been granted Orphan Drug, Fast Track, and Regenerative Medicine Advanced Therapy (RMAT) designations based on the positive efficacy and safety results of an ongoing Phase 1/2 trial.

Casgevy™ (Exagamglogene Autotemcel) Product Summary[18]

Therapeutic Class: Autologous genome-edited HSC-based gene therapy

Indication(s): Treatment of patients 12 years of age or older with:

- SCD with recurrent VOCs; or
- TDT

How Supplied: A cell suspension for intravenous (IV) infusion

- Casgevy™ is supplied in 1 or more vials containing a frozen suspension of genome edited autologous CD34+ cells

Dosing and Administration:

- Patients are required to undergo HSC mobilization followed by apheresis to obtain CD34+ cells for Casgevy™ manufacturing.
- Dosing of Casgevy™ is based on body weight and the minimum recommended dose is 3×10^6 CD34+ cells/kg.
- Full myeloablative conditioning must be administered between 48 hours and 7 days before infusion of Casgevy™.
- Prophylaxis for seizures should be considered prior to initiating myeloablative conditioning.

- Patient's identity should be verified to match the unique patient identification information on the product labels and Lot Information Sheet prior to thaw and infusion.
- Casgevy™ should not be sampled, altered, or irradiated.
- Each vial of Casgevy™ should be administered via IV infusion within 20 minutes of thawing.

Mechanism of Action: After Casgevy™ infusion, the edited CD34+ cells engraft in the bone marrow and differentiate to erythroid lineage cells with reduced *BCL11A* gene expression. Reduced *BCL11A* gene expression results in an increase in γ-globin expression and fetal hemoglobin (HbF) protein production in erythroid cells.

Efficacy: The safety and efficacy of Casgevy™ were evaluated in single-arm, open-label, multi-center trials for each indication in patients 12 to 35 years of age. All eligible patients underwent mobilization and apheresis to collect CD34+ stem cells for the manufacturing of Casgevy™ followed by myeloablative conditioning and infusion of Casgevy™.

- **SCD Indication:**
  - Key Inclusion Criteria:
    - History of ≥2 protocol-defined severe VOC events during each of the 2 years prior to screening defined as: acute pain event requiring a visit to a medical facility and administration of pain medications or red blood cell (RBC) transfusions, acute chest syndrome, priapism lasting >2 hours and requiring a visit to a medical facility, or splenic sequestration
  - Key Exclusion Criteria:
    - Available 10/10 human leukocyte antigen (HLA)-matched related HSC donor
    - More than 10 unplanned hospitalizations or emergency department (ED) visits related to chronic pain rather than SCD-related acute pain crises in the year before screening
  - Intervention(s):
    - At the time of the interim analysis, a total of 63 patients enrolled in the trial, of which 58 (92%) patients started mobilization. A total of 44 (76%) patients received Casgevy™ infusion and formed the full analysis set (FAS).
  - Primary Endpoint(s):
    - Freedom from severe VOC episodes ≥12 consecutive months during the 24-month follow-up period (VF12)
    - Freedom from hospitalization for severe VOCs ≥12 consecutive months within the 24-month evaluation period (HF12)

- Results:
    - The VF12 response rate was 29 of 31 patients [93.5%; 98% one-sided confidence interval (CI): 77.9%, 100.0%]. The 29 VF12 responders did not experience protocol-defined severe VOCs during the evaluation period with a median duration of 22.2 months at the time of the interim analysis.
    - One VF12 responder, after initially achieving a VF12 response, experienced an acute pain episode meeting the definition of a severe VOC at month 22.8 requiring a 5-day hospitalization; this patient was reported to have a parvovirus B19 infection at the time.
    - Of the 31 patients evaluable for VF12 response, 1 patient was not evaluable for HF12 response; the remaining 30 patients (100%; 98% one-sided CI: 87.8%, 100.0%) achieved the endpoint of HF12.
    - There were no reported cases of graft failure or graft rejection

- **TDT Indication:**
    - Key Inclusion Criteria:
        - History of requiring ≥100mL/kg/year or 10units/year of RBC transfusions 2 years prior to enrollment
    - Key Exclusion Criteria:
        - Available 10/10 HLA-matched related donor
        - Prior allogeneic HSCT
    - Intervention(s):
        - At the time of the interim analysis, a total of 59 patients enrolled in the trial, of which 59 (100%) started mobilization. A total of 52 (88%) patients received Casgevy™ infusion and formed the FAS.
        - 35 patients from the FAS (67%) had adequate follow-up to allow evaluation of the primary efficacy endpoint and formed the primary efficacy set (PES).
    - Primary Endpoint(s):
        - Proportion of patients achieving transfusion independence for ≥12 consecutive months (TI12)
    - Results:
        - The TI12 responder rate was 32 of 35 patients (91.4%; 98.3% one-sided CI: 75.7%, 100%).
        - All patients who achieved TI12 remained transfusion-independent, with a median duration of transfusion-independence of 20.8 months and normal mean weighted average total Hb levels.
        - The median time to last RBC transfusion for patients who achieved TI12 was 30 days following Casgevy™ infusion.

- Three patients did not achieve TI12. These patients had reductions in annualized RBC transfusion volume. requirements of 79.8%, 83.9% and 97.9%, and reductions in annualized transfusion frequency of 78.6%, 67.4% and 94.6%, respectively, compared to baseline requirements.
- There were no reported cases of graft failure or graft rejection.

Cost: The Wholesale Acquistion Cost (WAC) of Casgevy™ is $2.2 million per 1-time treatment, regardless of indication.

Lyfgenia® (Lovotibeglogene Autotemcel) Product Summary[19]

Therapeutic Class: Autologous HSC-based gene therapy

Indication(s): Treatment of SCD and a history of vaso-occlusive events (VOEs) in patients 12 years of age or older

- **Limitation(s) of Use:** Following treatment with Lyfgenia®, patients with α-thalassemia trait (-α3.7/-α3.7) may experience anemia with erythroid dysplasia that may require chronic RBC transfusions. Lyfgenia® has not been studied in patients with more than 2 α-globin gene deletions

How Supplied: A cell suspension for IV infusion

- A single dose of Lyfgenia® contains a minimum of 3 x10^6 CD34+ cells/kg of body weight, in 1-4 infusion bags

Dosing and Administration:

- Patients are required to undergo HSC mobilization followed by apheresis to obtain CD34+ cells for Lyfgenia® manufacturing.
- Dosing of Lyfgenia® is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight. The minimum recommended dose is 3×10^6 CD34+ cells/kg.
- Myeloablative conditioning must be administered before infusion of Lyfgenia®. Following myeloablative conditioning, a minimum of 48 hours of washout before Lyfgenia® infusion should be allowed.
- Patient's identity should be verified to match the unique patient identification information on the Lyfgenia® infusion bag(s) prior to infusion.
- Lyfgenia® should not be sampled, altered, irradiated or refrozen.
- Lyfgenia® should be administered within 4 hours after thawing.

Mechanism of Action: Lyfgenia® adds functional copies of a modified β^A-globin gene into patients' HSCs through transduction of autologous CD34+ cells with BB305 LVV. After Lyfgenia® infusion, the transduced CD34+ HSCs engraft in the bone marrow and differentiate to produce red blood cells

containing biologically active β^A-T87Q-globin that will combine with α-globin to produce functional Hb containing adult hemoglobin (HbA).

Efficacy: The safety and efficacy of Lyfgenia® were evaluated in single-arm, 24-month, open-label, multi-center Phase 1/2 trial in patients 12 to 50 years of age.

- Key Inclusion Criteria:
  - Diagnosis of SCD with either βS/βS or βS/β0 or βS/β+ genotype
  - ≥4 severe VOEs in the 24 months prior to informed consent
  - Hydroxyurea failure or intolerance
- Key Exclusion Criteria:
  - Prior recipient of an allogeneic transplant or gene therapy
  - Unable to receive RBC transfusion
  - Availability of a willing, matched HLA–identical sibling hematopoietic cell donor
  - Presence of 2 α-globin gene deletions
- Intervention(s):
  - 43 patients underwent apheresis after mobilization with plerixafor, of which 36 patients received myeloablative busulfan conditioning.
  - 7 patients did not proceed to conditioning; 2 patients discontinued due to apheresis-related issues, and 5 discontinued at patient and/or physician discretion.
  - 36 patients received the IV infusion of Lyfgenia® with a median dose of $6.4x10^6$ CD34+ cells/kg (48 hours after the last dose of busulfan).
- Primary Endpoint(s):
  - VOE complete resolution between 6 months and 18 months after infusion
  - Severe VOE complete resolution between 6 months and 18 months after infusion
- Results:
  - VOE complete resolution was seen in 28 of 32 patients (88.2%; 95% CI: 71, 97)
  - Severe VOE complete resolution was seen in 30 of 32 patients (94%; 95% CI: 79, 99)
  - No patients experienced graft failure or graft rejection
  - A median of 2 mobilization cycles were required in order to obtain an adequate cell count from apheresis.
  - All 36 patients infused in HGB-206 Group C were evaluated for globin response (GR). In Group C, 31 of 36 patients (86%) achieved GR. All patients maintained GR once it was achieved.

Cost: The WAC of Lyfgenia® is $3.1 million per 1-time treatment.

Vafseo® (Vadadustat) Product Summary[20]

Therapeutic Class: Hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor

Indication(s): Treatment of anemia due to CKD in adults who have been receiving dialysis for at least 3 months

- **Limitation(s) of Use:**
  - Not shown to improve quality of life, fatigue, or patient well-being
  - Not indicated for use:
    - As a substitute for transfusion in patients requiring immediate correction of anemia
    - In patients with anemia due to CKD not on dialysis

How Supplied: 150mg, 300mg, and 450mg tablets

Dosing and Administration:

- Recommended starting dose is 300mg orally once daily, with or without food
- The maximum recommended dose is 600mg once daily.
- Hemoglobin (Hb) levels should be monitored when initiating or adjusting dose and then monthly.
- The dose should be increased no more frequently than once every 4 weeks. Decreases in dose can occur more frequently.
- The dose should be adjusted in increments of 150mg to achieve or maintain Hb levels of 10g/dL to 11g/dL.
- Refer to the full *Prescribing Information* for the recommended starting dose, titration, and monitoring recommendations

Efficacy: The safety and efficacy of Vafseo® were studied in 2 Phase 3 randomized noninferiority open-label trials, INNO$_2$VATE-1 and INNO$_2$VATE-2. For INNO$_2$VATE-1 patients were included that had initiated dialysis <16 weeks prior to trial participation and were ESA-naïve, had limited ESA use, or were maintained on an ESA. For INNO$_2$VATE-2 patients were included who were on chronic maintenance dialysis for >12 weeks and who converted from prior ESA therapy.

- <u>Key Inclusion Criteria:</u>
  - 18 years of age or older
  - Serum ferritin ≥100ng/mL and transferrin saturations ≥20%
  - Hb concentration between 8 and <11g/dL
- <u>Key Exclusion Criteria:</u>
  - Anemia due to causes other than CKD
  - Received RBC transfusion within 8 weeks prior to randomization
  - Uncontrolled hypertension or recent cardiovascular (CV) event

- Intervention(s):
  - Patients were randomized 1:1 to 1 of the following for 52 weeks:
    - Vafseo® 300mg once daily; and
      - Vafseo® was titrated in increments of 160mg up to 600mg to achieve the target Hb range of 10-11g/dL.
    - Darbepoetin alfa as per the *Prescribing Information*
- Primary Endpoint(s):
  - Efficacy: Mean change in Hb levels from baseline to weeks 24-36
    - A key secondary endpoint was the mean change in Hb levels from baseline to weeks 40-52.
  - Safety: Median time to the first major adverse CV event (MACE)
- Results:
  - Vafseo® was found to be noninferior in both trials to darbepoetin alfa with a treatment difference of -0.3 (95% CI: -0.5, -0.1) and -0.2 (95% CI: -0.2, -0.1) at weeks 24-36, and for weeks 40-52, the treatment difference was -0.1 (95% CI: -0.3, -0.2) and -0.2 (95% CI: -0.3, -0.1).

Cost Comparison: HIF PH Inhibitor Products

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
Vafseo® (vadadustat) 300mg tablet	**$42.60**	**$2,556.00***	**$30,672.00***
Jesduvroq® (daprodustat) 8mg tablet	$31.28	$2,815.20⁺	$33,782.40⁺

Costs do not reflect rebated prices or net costs.
Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Vafseo® cost is based on the maximum FDA approved dose of 600mg once daily.
⁺Jesduvroq® cost is based on the maximum FDA approved dose of 24mg once daily.

Recommendations

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

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 planned 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~~

10. ~~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~~

11. ~~The following quantity limits will apply:~~
    a. ~~(3) 500mg tablets per day; and~~
    b. ~~(5) 300mg tablets for oral suspension per day; and~~

12. ~~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.~~

Utilization Details of Anemia Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYUREA PRODUCTS						
HYDROXYUREA CAP 500MG	802	198	$17,220.20	$21.47	4.05	0.89%
DROXIA CAP 300MG	29	10	$1,489.03	$51.35	2.9	0.08%
DROXIA CAP 400MG	22	10	$1,263.31	$57.42	2.2	0.07%
DROXIA CAP 200MG	10	5	$473.19	$47.32	2	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYUREA POW	9	4	$699.49	$77.72	2.25	0.04%
SIKLOS TAB 1,000MG	3	1	$4,191.13	$1,397.04	3	0.22%
SUBTOTAL	**875**	**228**	**$25,336.35**	**$28.96**	**3.84**	**1.31%**
VOXELOTOR PRODUCTS						
OXBRYTA TAB 500MG	75	12	$867,344.06	$11,564.59	6.25	44.78%
OXBRYTA TAB SUSP 300MG	66	8	$848,887.96	$12,861.9	8.25	43.82%
OXBRYTA TAB 300MG	12	2	$138,650.22	$11,554.19	6	7.16%
SUBTOTAL	**153**	**22**	**$1,854,882.24**	**$12,123.41**	**6.95**	**95.76%**
EPOETIN ALFA PRODUCTS						
EPOGEN INJ 20,000/ML	42	7	$10,565.19	$251.55	6	0.55%
PROCRIT INJ 20,000/ML	38	2	$21,279.08	$559.98	19	1.10%
PROCRIT INJ 40,000/ML	1	1	$4,287.41	$4,287.41	1	0.22%
EPOGEN INJ 4,000/ML	1	1	$537.97	$537.97	1	0.03%
PROCRIT INJ 10,000/ML	1	1	$1,080.41	$1,080.41	1	0.06%
PROCRIT INJ 4,000/ML	1	1	$435.01	$435.01	1	0.02%
SUBTOTAL	**84**	**13**	**$38,185.07**	**$454.58**	**6.46**	**1.97%**
DARBOPOETIN ALFA PRODUCTS						
ARANESP INJ 60MCG	8	1	$14,952.08	$1,869.01	8	0.77%
ARANESP INJ 60MCG	2	1	$3,738.02	$1,869.01	2	0.19%
SUBTOTAL	**10**	**2**	**$18,690.10**	**$1,869.01**	**5**	**0.96%**
TOTAL	**1,122**	**233***	**$1,937,093.76**	**$1,726.47**	**4.82**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; POW = powder; SUSP = suspension; TAB = tablet
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
HYDROXYUREA PRODUCTS						
HYDROXYUREA CAP 500MG	36	19	$897.65	$24.93	1.89	3.09%
DROXIA CAP 300MG	2	1	$115.34	$57.67	2	0.40%
DROXIA CAP 200MG	1	1	$33.26	$33.26	1	0.11%
DROXIA CAP 400MG	1	1	$28.50	$28.50	1	0.10%
HYDROXYUREA POW	1	1	$135.14	$135.14	1	0.46%
SUBTOTAL	**41**	**23**	**$1,209.89**	**$29.51**	**1.78**	**4.16%**
VOXELOTOR PRODUCTS						
OXBRYTA TAB 500MG	2	1	$24,251.22	$12,125.61	2	83.38%
SUBTOTAL	**2**	**1**	**$24,251.22**	**$12,125.61**	**2**	**83.38%**
DARBOPOETIN ALFA PRODUCTS						
ARANESP INJ 60MCG	2	1	$3,585.32	$1,792.66	2	12.33%
SUBTOTAL	**2**	**1**	**$3,585.32**	**$1,792.66**	**2**	**12.33%**
EPOETIN ALFA PRODUCTS						
EPOGEN INJ 20,000/ML	2	1	$39.80	$19.90	2	0.14%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**2**	**1**	**$39.80**	**$19.90**	**2**	**0.14%**
TOTAL	**47**	**24***	**$29,086.23**	**$618.86**	**1.96**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; POW = powder; SUSP = suspension; TAB = tablet
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
HYDROXYUREA PRODUCTS						
HYDROXYUREA CAP 500MG	42	26	$866.38	$20.63	1.62	0.56%
DROXIA CAP 400MG	2	1	$69.47	$34.74	2	0.04%
DROXIA CAP 300MG	1	1	$33.27	$33.27	1	0.02%
HYDROXYUREA POW	1	1	$77.10	$77.10	1	0.05%
SUBTOTAL	**46**	**29**	**$1,046.22**	**$22.74**	**1.59**	**0.68%**
VOXELOTOR PRODUCTS						
OXBRYTA TAB SUSP 300MG	9	3	$101,054.35	$11,228.26	3	65.24
OXBRYTA TAB 300MG	3	1	$36,376.83	$12,125.61	3	23.49
OXBRYTA TAB 500MG	1	1	$12,125.61	$12,125.61	1	7.83%
SUBTOTAL	**13**	**5**	**$149,556.79**	**$11,504.37**	**2.6**	**96.56**
EPOETIN ALFA PRODUCTS						
PROCRIT INJ 40,000/ML	1	1	$4,287.41	$4,287.41	1	2.77%
SUBTOTAL	**1**	**1**	**$4,287.41**	**$4,287.41**	**1**	**2.77%**
TOTAL	**60**	**30***	**$154,890.42**	**$2,581.51**	**2.00**	**100%**

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

Oklahoma Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYUREA PRODUCTS						
HYDROXYUREA CAP 500MG	31	19	$536.36	$17.30	1.63	4.99%
HYDROXYUREA POW	7	2	$252.03	$36.00	3.5	2.34%
DROXIA CAP 400MG	5	3	$244.59	$48.92	1.67	2.27%
DROXIA CAP 200MG	3	1	$100.73	$33.58	3	0.94%
DROXIA CAP 300MG	3	1	$100.60	$33.53	3	0.94%
SUBTOTAL	**49**	**26**	**$1,234.31**	**$25.19**	**1.88**	**11.48%**
EPOETIN ALFA PRODUCTS						
EPOGEN INJ 20,000/ML	13	1	$3,398.01	$261.39	13	31.60%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RETACRIT INJ 10,000/ML	2	1	$2,637.60	$1,318.80	2	24.53%
PROCRIT INJ 10,000/ML	2	1	$1,610.67	$805.34	2	14.98%
PROCRIT INJ 2,000/ML	2	1	$439.80	$219.90	2	4.09%
SUBTOTAL	**19**	**4**	**$8,086.08**	**$425.58**	**4.75**	**75.20%**
L-GLUTAMINE PRODUCTS						
ENDARI POW 5GM	1	1	$1,431.84	$1,431.84	1	13.32%
SUBTOTAL	**1**	**1**	**$1,431.84**	**$1,431.84**	**1**	**13.32%**
TOTAL	**69**	**30***	**$10,752.23**	**$155.83**	**2.3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; POW = powder; SUSP = suspension; TAB = tablet
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
ADAKVEO INJ J0791	119	16	$842,384.20	$7,078.86	7.44
ARANESP INJ J0881	91	22	$62,325.20	$684.89	4.14
PROCRIT INJ J0885	60	20	$14,562.44	$242.71	3
REBLOZYL INJ J0896	56	3	$703,199	$12,557.13	18.67
TOTAL	**326**	**61**	**$1,622,471.24**	**$4,976.91**	**5.34**

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

Oklahoma Complete Health Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ADAKVEO INJ J0791	3	2	$20,336.00	$6,778.67	1.5
TOTAL	**3**	**2**	**$20,336.00**	**$6,778.67**	**1.5**

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 Synagis® (Palivizumab)

Oklahoma Health Care Authority
October 2024

Current Prior Authorization Criteria[1]

Prior authorization is required for all members who receive palivizumab in an outpatient setting. Palivizumab is approved for members who meet the established prior authorization criteria, which is based on the American Academy of Pediatrics (AAP) 2014 guidelines for palivizumab prophylaxis.

Synagis® (Palivizumab) Approval Criteria:

A. Member Selection:
   1. Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:
      a. Born before 29 weeks, 0 days gestation; or
      b. Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or
      c. Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or
      d. May be considered for:
         i. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or
         ii. Infants who undergo cardiac transplantation during RSV season; or
         iii. Infants who are profoundly immunocompromised during RSV season; or
         iv. Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised; or
   2. Infants 12 to 24 months of age at the start of RSV season:
      a. Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) during the 6 months before the start of the RSV season; or

b. May be considered for:
    i. Infants who undergo cardiac transplantation during RSV season; or
    ii. Infants who are profoundly immunocompromised during RSV season; or
    iii. Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.

B. Product Selection: A patient-specific, clinically significant reason why the member cannot receive Beyfortus® (nirsevimab-alip), as recommended by the CDC, must be provided. Additionally, the prescriber must confirm the member has not already received Beyfortus® for the current RSV season. Concomitant use with Beyfortus® will not be approved.

C. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. Initial and subsequent approvals will be for the duration of 1 month until RSV season ends. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval. Members initially approved for palivizumab will require a patient-specific, clinically significant reason why the member still cannot receive Beyfortus® (nirsevimab-alip).

D. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. Doses are to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.

E. Dose-Pooling: To avoid unnecessary risk to the member, multiple members are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Utilization of Synagis® (Palivizumab): Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2023	254	840	$2,331,515.31	$2,775.61	$92.54	730	25,194
2024	57	136	$406,229.04	$2,986.98	$99.57	122	4,080
% Change	**-77.60%**	**-83.80%**	**-82.60%**	**7.60%**	**7.60%**	**-83.30%**	**-83.80%**
Change	**-197**	**-704**	**-$1,925,286.27**	**$211.37**	**$7.03**	**-608**	**-21,114**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: There was no SoonerSelect pharmacy utilization of Synagis® during fiscal year 2023 or 2024.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2023	1	3	$11,504.71	$3,834.90	3
2024	1	1	$3,568.50	$3,568.50	1
% Change	**0.00%**	**-66.67%**	**-68.98%**	**-6.95%**	**-66.67%**
Change	**0**	**-2**	**-$7,936.21**	**-$266.40**	**-2**

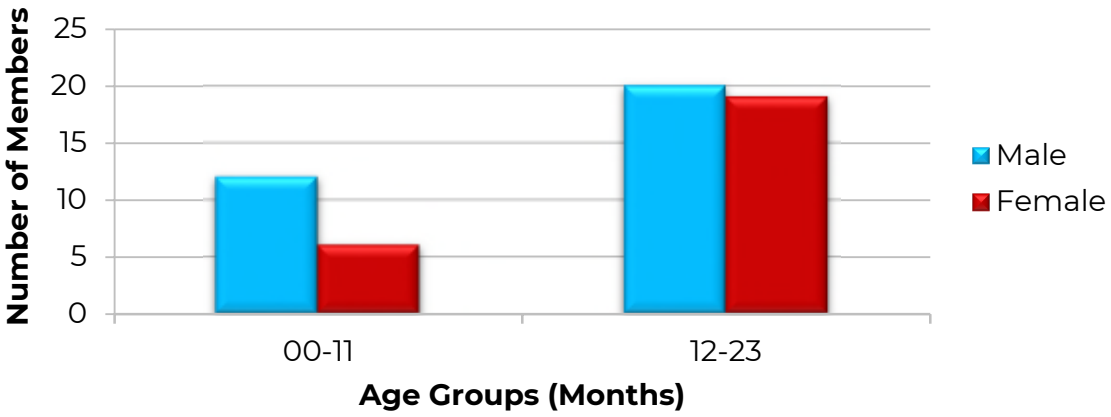
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
Please note: There was no SoonerSelect medical utilization of Synagis® during fiscal year 2023 or 2024.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Cost Per Vial

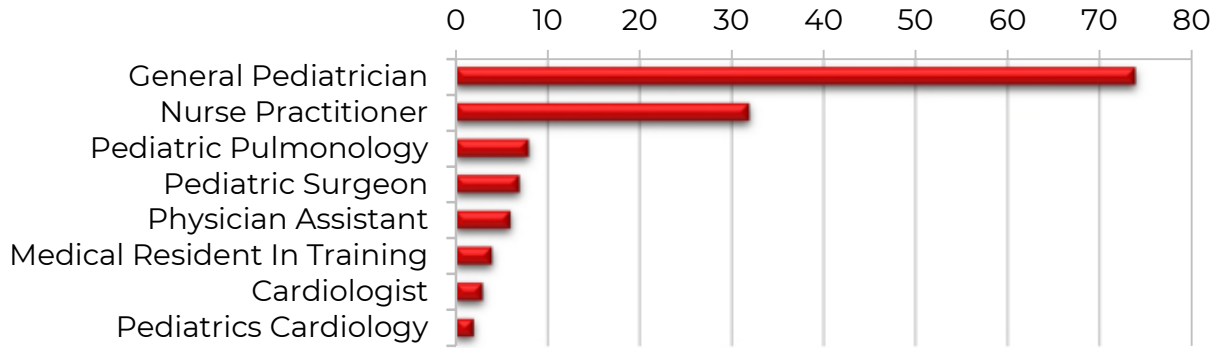
Vial Size	Cost Per Vial
Synagis® (palivizumab) 100mg/mL vial	$3,369.16
Synagis® (palivizumab) 50mg/0.5mL vial	$1,784.25

Costs do not reflect rebated prices or net costs.
Costs based on specialty pharmaceutical allowable cost (SPAC).

Demographics of Members Utilizing Synagis® (Palivizumab)



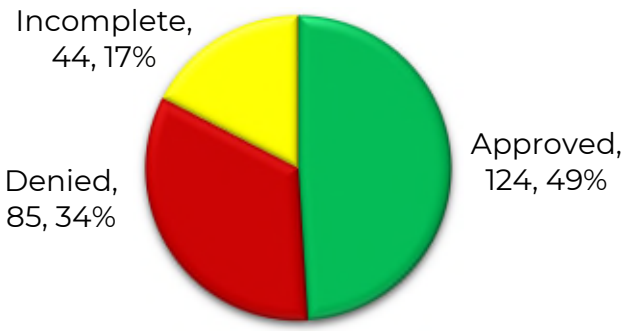
Top Prescriber Specialties of Synagis® (Palivizumab) by Number of Claims



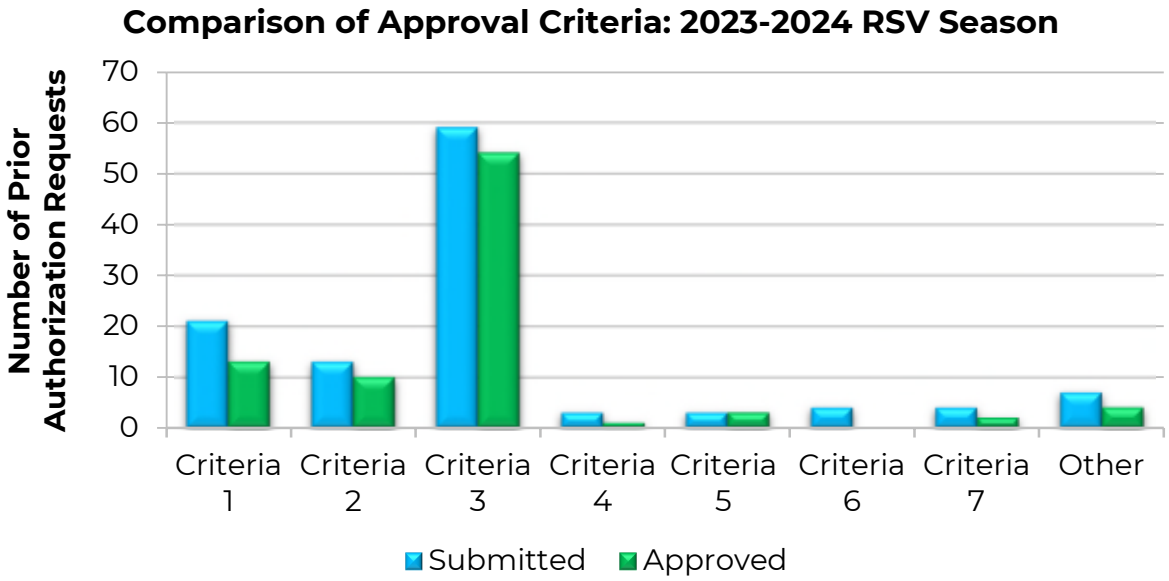
Prior Authorization of Synagis® (Palivizumab)

There were 253 palivizumab prior authorization requests submitted for 123 unique members during fiscal year 2024. This is a decrease in both submitted petitions and number of members requesting palivizumab compared to fiscal year 2023 when there were 876 palivizumab prior authorization requests submitted for 389 unique members. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions



The following graph shows the number of submissions and approvals for each prior authorization criteria. The graph is followed by a numbered list in which the list number corresponds to the criteria number in the graph. The most commonly requested and approved criteria selection during the 2023 to 2024 respiratory syncytial virus (RSV) season was criteria number 3: infants born before 29 weeks, 0 days gestation. Infants born before 32 weeks, 0 days gestation and who had chronic lung disease (CLD) of prematurity was the next most commonly requested and approved criteria selection (criteria number 1).



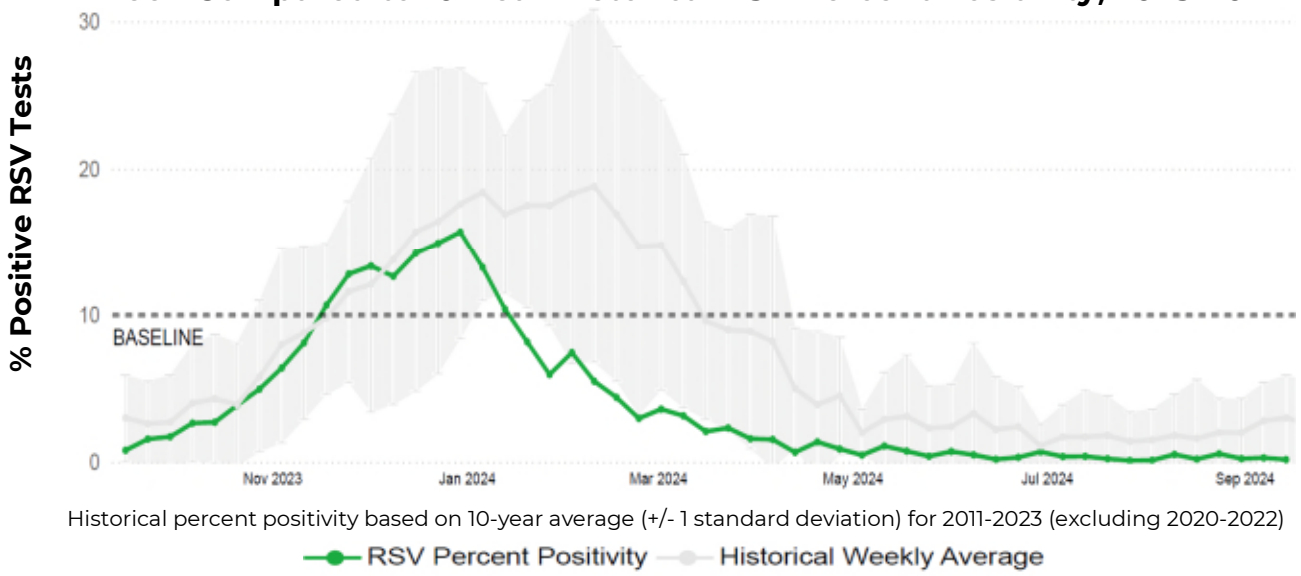
Criteria List:

1. Infants 0 to 24 months of age at the start of RSV season born before 32 weeks, 0 days gestation and have CLD of prematurity
2. Infants who have hemodynamically significant congenital heart disease and will require surgical procedures, or have moderate-to-severe pulmonary hypertension
3. Infants born before 29 weeks, 0 days gestation
4. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
5. Infants who undergo cardiac transplantation during RSV season
6. Infants who are profoundly immunocompromised during RSV season
7. Infants with cystic fibrosis with clinical evidence of CLD and/or are nutritionally compromised

RSV Season Comparison[2,3,4,5,6,7]

The following chart contains the weekly percentage of laboratory positive RSV tests in Oklahoma as reported by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System. The chart shows the percent positivity for the 2023-2024 RSV season compared to a 10-year historical average. RSV is determined to be in season once the percentage of positive tests is >10% for 2 consecutive weeks. Similarly, the season is determined to be at an end when the percentage of positive tests is <10% for 2 consecutive weeks.

OSDH: Percent of Positive RSV Tests Reported by Sentinel Providers by Week Compared to 10-Year Historical RSV Percent Positivity, 2023-2024



The OSDH currently reports RSV testing data as a mixture of antigen and polymerase chain reaction (PCR) testing. PCR testing is not separately reported by the OSDH to evaluate local trends specific to the state of Oklahoma. The *Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection* released by the AAP in 2014 states the following with regard to RSV seasonality:

> "During the 6 RSV seasons from July 2007 to January 2013, the median duration of the RSV season ranged from 13 to 23 weeks, with median peak activity from mid-December to early February, with the exception of Florida and Alaska. Within the 10 Health and Human Services Regions, in the few regions when the RSV season began in October, the season ended in March or early April. In regions where the RSV season began in November or December, the season ended by April or early May. Because 5 monthly doses of palivizumab at 15mg/kg per dose will provide more than 6 months of serum palivizumab concentrations above the desired serum concentration for most infants, administration of more than 5 monthly doses is not recommended within the continental United States."

When looking at the United States as a whole and comparing RSV seasons since 2019, the CDC's National Respiratory and Enteric Virus Surveillance System (NREVSS) shows that there was historically low RSV circulation during the 2020-2021 season, which was followed by atypical seasonality during the next 2 seasons. The 2021-2022 season began in late spring and lasted longer than pre-pandemic seasons. The 2022-2023 season began later in the year than the 2021-2022 season, but earlier than in pre-pandemic years, which was suggestive of a return toward pre-pandemic seasonality. The 2023-2024

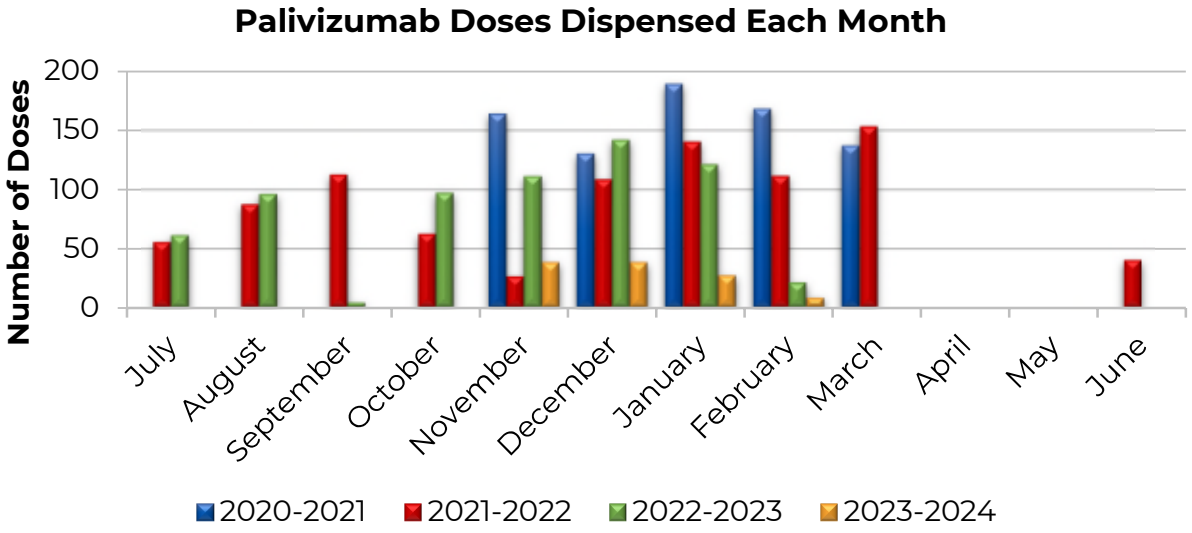
season aligned more closely with pre-pandemic RSV seasons, with an onset that occurred during the expected winter months.

CDC: Weekly Percent of Tests Positive for RSV Reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS), 2019-2024

Historically, in Oklahoma, RSV seasons were similar with a peak typically in December or January and a season end by late March. Beginning in 2020, the percentage of positive tests in Oklahoma did not exceed 10% during the typical RSV season months, likely due to nonpharmacological interventions (e.g., masking, social distancing, decreased travel) related to the COVID-19 pandemic. However, atypical RSV circulation was observed beginning in June 2021, coinciding with the relaxation of some COVID-19-related restrictions and interventions. As a result of the atypical RSV season onset and offset, the palivizumab approval criteria was updated by the Drug Utilization Review (DUR) Board in September 2021 to allow coverage based on RSV positivity in Oklahoma, rather than only during specific months. Currently, SoonerCare coverage of palivizumab is determined based on the percentage of positive tests, as reported by the OSDH. Additionally, the palivizumab approval criteria was updated by the DUR Board in September 2023 to require a patient-specific, clinically significant reason why the member cannot receive Beyfortus® (nirsevimab), as recommended by the CDC Advisory Committee on Immunization Practices (ACIP). During fiscal year 2024 (July 2023 through June 2024) in Oklahoma, the percentage of positive antigen and PCR detection tests exceeded the 10% threshold during portions of November 2023, December 2023, and January 2024.

The following bar graph shows the number of palivizumab doses reimbursed by SoonerCare for each month during the last 4 RSV seasons. The use of palivizumab outside the typical RSV season months (November through March) was allowed for the first time during fiscal year 2022 (shown in red) due to atypical RSV season onset and offset. During fiscal year 2023 (shown in green), although RSV circulation continued to be somewhat atypical, the overall number of doses dispensed decreased significantly compared to fiscal year 2022. During fiscal year 2024 (shown in gold), the number of doses

dispensed decreased significantly compared to previous years; however, the pattern of utilization aligned more closely with the typical RSV season months.



Market News and Updates[8]

News:

- **February 2024:** The American Academy of Pediatrics (AAP) released updated recommendations for the prevention of RSV disease in infants and children. Based on its efficacy, duration, and convenience, nirsevimab is preferred over palivizumab. If nirsevimab is not available or not feasible to administer, palivizumab should be administered to high-risk infants who are eligible to receive palivizumab based on previous AAP recommendations for palivizumab prophylaxis. The AAP continues to recommend the use of nirsevimab in patient populations that are consistent with the Advisory Committee on Immunization Practices (ACIP) recommendations.

Recommendations

The College of Pharmacy does not recommend any changes to the current Synagis® (palivizumab) approval criteria at this time.

Utilization Details of Synagis® (Palivizumab): Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PALIVIZUMAB PRODUCTS						
SYNAGIS INJ 100MG/ML	108	55	$355,950.56	$3,295.84	1.96	87.62%
SYNAGIS INJ 50MG/0.5ML	28	22	$50,278.48	$1,795.66	1.27	12.38%
TOTAL	**136**	**57***	**$406,229.04**	**$2,986.98**	**2.39**	**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

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PALIVIZUMAB INJ 50MG (90378)	1	1	$3,568.50	$3,568.50	1
TOTAL	**1†**	**1***	**$3,568.50**	**$3,568.50**	**1**

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

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[1] Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. RSV Policy Statement – Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics* 2014; 134(2):415–420. doi: 10.1542/peds.2014-1665.

[2] Oklahoma State Department of Health (OSDH). Viral View: RSV (Respiratory Syncytial Virus). Available online at: https://oklahoma.gov/health/health-education/acute-disease-service/viral-view/rsv.html. Last accessed 09/19/2024.

[3] OSDH. RSV Surveillance Report – Regional RSV Laboratory Testing Percent Positivity Compared to Baseline: Data as of Week Ending 09/14/2024. Available online at: https://healthokgov.app.box.com/s/fh1142w09g7atxoucxs3yej2sxghi75m. Issued 09/19/2024. Last accessed 09/19/2024.

[4] Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. RSV Technical Report – Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics* 2014; 134(2):e620–e638. doi: 10.1542/peds.2014-1666.

[5] Centers for Disease Control and Prevention (CDC). The National Respiratory and Enteric Virus Surveillance System (NREVSS): Interactive Dashboard. Available online at: https://www.cdc.gov/nrevss/php/dashboard/index.html. Last accessed 09/19/2024.

[6] Olsen SJ, Winn AK, Budd AP, et al. Changes in Influenza and Other Respiratory Virus Activity During the COVID-19 Pandemic – United States, 2020 – 2021. *MMWR Morb Mortal Wkly Rep* 2021; 70:1013–1019. doi: 10.15585/mmwr.mm7029a1.

[7] Hamid, S, Winn A, Parikh R, et al. Seasonality of Respiratory Syncytial Virus – United States, 2017–2023. *MMWR Morb Mortal Wkly Rep* 2023; 72:355–361. doi: 10.15585/mmwr.mm7214a1.

[8] American Academy of Pediatrics (AAP). AAP Recommendations for the Prevention of RSV Disease in Infants and Children. Available online at: https://publications.aap.org/redbook/resources/25379/. Issued 02/21/2024. Last accessed 09/19/2024.

Appendix K

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

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: September 26, 2024

FDA Approves Drug with New Mechanism of Action for Treatment of Schizophrenia

The FDA approved Cobenfy™ (xanomeline and trospium chloride) capsules for oral use for the treatment of schizophrenia in adults. It is the first antipsychotic drug approved to treat schizophrenia that targets cholinergic receptors as opposed to dopamine receptors, which has long been the standard of care.

Cobenfy™'s effectiveness for the treatment of schizophrenia in adults was evaluated in 2 studies with identical designs. Study 1 and Study 2 were 5-week, randomized, double-blind, placebo-controlled, multi-center studies in adults with a diagnosis of schizophrenia according to DSM-5 criteria. The primary efficacy measure was the change from baseline in the Positive and Negative Syndrome Scale (PANSS) total score at week 5. Each item is rated by a clinician on a seven-point scale. In both studies, the participants who received Cobenfy™ experienced a meaningful reduction in symptoms from baseline to Week 5 as measured by the PANSS Total Score compared to the placebo group.

The prescribing information includes warnings that Cobenfy™ can cause urinary retention, increased heart rate, decreased gastric movement, or angioedema of the face and lips. Cobenfy™ is not recommended for patients with mild hepatic impairment and should not be used in patients with known hepatic impairment. There is also a risk of liver damage. Patients should stop using Cobenfy™ if experiencing signs or symptoms of substantial liver disease (including yellowing of the skin or the white part of the eyes, dark urine and unexplained itching). Cobenfy™ is substantially excreted by the kidney and is not recommended in patients with moderate to severe renal impairment. Cobenfy™ should not be prescribed to patients with urinary retention, moderate or severe kidney or liver disease, gastric retention, untreated narrow-angle glaucoma, or a history of hypersensitivity to either Cobenfy™ or its components.

The most common side effects of Cobenfy™ are nausea, indigestion, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and gastroesophageal reflux disease.

The approval of Cobenfy™ was granted to Bristol-Myers Squibb Company.

FDA NEWS RELEASE

For Immediate Release: September 24, 2024

FDA Approves New Drug to Treat Niemann-Pick Disease, Type C

The FDA approved Aqneursa™ (levacetylleucine) for the treatment of neurological symptoms associated with Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing at least 15kg.

The safety and efficacy of Aqneursa™ for the treatment of NPC were evaluated in a randomized, double-blind, placebo-controlled, two-period, 24-week crossover study. The duration was 12 weeks for each treatment period. The study enrolled 60 patients. To be eligible for the study patients had to be 4 years of age or older with a confirmed diagnosis of NPC and at least mild disease-related neurological symptoms. Participants could

receive miglustat as background treatment in the study. The primary efficacy outcome was a modified version of the Scale for the Assessment and Rating of Ataxia (SARA), referred to as the functional SARA (fSARA). The fSARA consists of the gait, sitting, stance, and speech disturbance domains of the original SARA with modifications to the scoring responses. On average, participants treated with Aqneursa™ for 12 weeks showed a better outcome in the fSARA score compared to when they were treated with placebo.

The prescribing information contains a warning that Aqneursa™ may cause embryo-fetal harm if used during pregnancy. Females should inform their healthcare provider of a known or suspected pregnancy before taking Aqneursa™. The most common side effects are abdominal pain, difficulty swallowing, upper respiratory tract infections and vomiting. Aqneursa™ should be taken orally up to three times per day, with or without food. The recommended dose varies depending on the individual's body weight, as outlined in the prescribing information.

The FDA granted Aqneursa™ Priority Review, Fast Track, Orphan Drug and Rare Pediatric Disease designations for this application. The FDA granted approval of Aqneursa™ to IntraBio Inc.

FDA NEWS RELEASE

For Immediate Release: September 20, 2024

FDA Approves Nasal Spray Influenza Vaccine for Self- or Caregiver-Administration

The FDA approved FluMist® for self- or caregiver-administration. FluMist® is approved for the prevention of influenza disease caused by influenza virus subtypes A and B in individuals 2 through 49 years of age. FluMist® is sprayed into the nose and has been used safely and effectively for many years. It was initially approved by the FDA in 2003 for use in individuals 5 through 49 years of age, and in 2007, the FDA approved the use of FluMist® to include children 2 through 5 years of age. It is the first vaccine to prevent influenza that does not need to be administered by a health care provider.

FluMist® contains a weakened form of live influenza virus strains and is sprayed in the nose. A prescription is still required to receive FluMist®. There are now 2 approved options for receiving FluMist®. The vaccine may be administered by a health care provider in a health care setting (including a pharmacy), or it may be administered by the vaccine recipient or a caregiver who is 18 years of age or older.

The most commonly reported side effects of FluMist® are fever over 100°F in children 2 through 6 years of age, runny nose and nasal congestion in individuals 2 through 49 years of age, and a sore throat in adults 18 through 49 years of age. For those interested in self- or caregiver-administration, the vaccine manufacturer plans to make the vaccine available through a third-party online pharmacy. Those who choose this option will complete a screening and eligibility assessment when they order FluMist®. The third-party pharmacy determines eligibility based on the completed screening and, if it is determined that the intended vaccine recipient is eligible, the pharmacy writes the prescription and ships the vaccine to the address provided by the individual who placed the order. The vaccine can then be administered to the prescribed household member(s) at their convenience. A caregiver should administer FluMist® to individuals 2 through 17 years of age, as individuals in this age group should not self-administer the vaccine.

A study was conducted with vaccine recipients and caregivers to evaluate whether the instructions for use were appropriately designed so that recipients and caregivers could safely and effectively use the vaccine. Vaccine recipients and caregivers who administer FluMist® will be sent the vaccine, the Prescribing Information, Information for

Patients and their Caregivers and Instructions for Use. The Instructions for Use provides detailed instructions for storage, administration and disposal of FluMist®.

The FDA granted this approval of FluMist® (influenza vaccine live, intranasal) to MedImmune LLC.

FDA NEWS RELEASE

For Immediate Release: September 20, 2024

FDA Approves First Treatment for Niemann-Pick Disease, Type C

The FDA approved Miplyffa™ (arimoclomol), an oral medication for the treatment of Neimann-Pick disease, type C (NPC). Miplyffa™, in combination with the enzyme inhibitor miglustat, is approved to treat neurological symptoms associated with NPC in adults and children 2 years of age and older. Miplyffa™ is the first drug approved by the FDA to treat NPC.

NPC is a rare genetic disease that results in progressive neurological symptoms and organ dysfunction. It is caused by changes in either the *NPC1* or *NPC2* gene, affecting the necessary transport of cholesterol and other lipids within a cell. As a result, these cells do not function as they should, ultimately causing organ damage. On average, individuals affected by this devastating disease only live for about 13 years.

The safety and effectiveness of Miplyffa™ were evaluated in a randomized, double-blind, placebo-controlled 12-month trial in patients 2 to 19 years of age who had a molecularly confirmed diagnosis of NPC. Fifty patients were randomized 2:1 to treatment with weight-adjusted Miplyffa™ (31 to 124mg) or placebo orally 3 times per day. Among these 50 patients, 39 (78%) received miglustat as background treatment in the trial. Miplyffa™'s efficacy was demonstrated by the rescored 4-domain NPC Clinical Severity Scale (R4DNPCCSS) score in the patients who used miglustat as their background treatment. The R4DNPCCSS is a measure of NPC disease progression that looks at 4 items that patients with NPC, their caregivers, and physicians have identified as most relevant including ambulation, speech, swallow, and fine motor skills. Higher scores signify a greater severity of the disease. Compared to placebo, Miplyffa™ resulted in a slower disease progression as measured by the R4DNPCCSS score.

The prescribing information for Miplyffa™ contains a warning for hypersensitivity reactions including hives and angioedema. Individuals experiencing these adverse reactions should stop using the drug. Females who are pregnant or plan to become pregnant should not use Miplyffa™. The most common side effects of Miplyffa™ include upper respiratory tract infection, diarrhea, and decreased weight. Miplyffa™, along with miglustat, should be taken orally with or without food according to the recommended dose for the patient's body weight.

The FDA granted Miplyffa™ Priority Review, Orphan Drug, Rare Pediatric Disease, Fast Track, and Breakthrough Therapy designations for this application. The FDA granted approval of Miplyffa™ to Zevra Therapeutics.

Current Drug Shortages Index (as of September 25, 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***
Azac Bumetanide Injection itidine 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***
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***
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***
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***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***
Vitamin A Palmitate Injection	***Currently in Shortage***