OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
October 11, 2023
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – October 11, 2023

DATE: October 4, 2023

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 Pipeline Update – Appendix B

Action Item – Vote to Prior Authorize Rebyota® (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk) and Update the Approval Criteria for Zinplava™ (Bezlotoxumab) – Appendix C

Action Item – Vote to Prior Authorize Orserdu™ (Elacestrant) and Update the Approval Criteria for the Breast Cancer Medications – Appendix D

Action Item – Annual Review of Imcivree® (Setmelanotide) – Appendix E

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

Annual Review of Myeloproliferative Neoplasm Medications and 30-Day Notice to Prior Authorize Ojjaara (Momelotinib) – Appendix G

Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Jesduvroq™ (Daprodustat) – Appendix H

Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Idacio® (Adalimumab-aacf), Litfulo™ (Ritlecitinib), Tofidence™ (Tocilizumab-bavi), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh) – Appendix I

Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl) – Appendix J

Annual Review of Spinal Muscular Atrophy (SMA) Medications – Appendix K

30-Day Notice to Prior Authorize Veopoz™ (Pozelimab-bbfg) – Appendix L

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – October 11, 2023 @ 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. Adams

DUR Board Members:

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

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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: 160 823 0246
Passcode: 994690

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 13, 2023 DUR Board Meeting Minutes
   B. September 13, 2023 DUR Board Recommendations Memorandum
   C. Correspondence

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

4. **Update on Medication Coverage Authorization Unit/Fall Pipeline Update – See Appendix B**
   A. Pharmacy Help Desk Activity for September 2023
   B. Medication Coverage Activity for September 2023
   C. Fall Pipeline Update

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

5. **Action Item – Vote to Prior Authorize Rebyota® (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk) and Update the Approval Criteria for Zinplava™ (Bezlotoxumab) – See Appendix C**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

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

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

7. **Action Item – Annual Review of Imcivree® (Setmelanotide) – See Appendix E**
   A. Current Prior Authorization Criteria
   B. Utilization of Imcivree® (Setmelanotide)
   C. Prior Authorization of Imcivree® (Setmelanotide)
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of Imcivree® (Setmelanotide)

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

9. **Annual Review of Myeloproliferative Neoplasm Medications and 30-Day Notice to Prior Authorize Ojjaara (Momelotinib) – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Myeloproliferative Neoplasm Medications
   C. Prior Authorization of Myeloproliferative Neoplasm Medications
   D. Market News and Updates
   E. Ojjaara (Momelotinib) Product Summary
   F. College of Pharmacy Recommendations
   G. Utilization Details of Myeloproliferative Neoplasm Medications

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

10. **Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Jesduvroq™ (Daprodustat) – See Appendix H**
    A. Current Prior Authorization Criteria
    B. Utilization of Anemia Medications
    C. Prior Authorization of Anemia Medications
    D. Market News and Updates

E. Jesduvroq™ (Daprodustat) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Anemia Medications

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

11. Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Idacio® (Adalimumab-aacf), Litfulo™ (Ritlecitinib), Tofidence™ (Tocilizumab-bavi), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh) – See Appendix I

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. Moss, Dr. Muchmore, Chairman:

12. Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl) – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of Muscular Dystrophy Medications
C. Prior Authorization of Muscular Dystrophy Medications
D. Market News and Updates
E. Elevidys (Delandistrogene Moxeparvovec-rokl) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Muscular Dystrophy Medications

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

13. Annual Review of Spinal Muscular Atrophy (SMA) Medications – See Appendix K

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

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

14. 30-Day Notice to Prior Authorize Veopoz™ (Pozelimab-bbfg) – See Appendix L

A. Introduction
B. Veopoz™ (Pozelimab-bbfg) Product Summary
C. College of Pharmacy Recommendations

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

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

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

16. **Future Business* (Upcoming Product and Class Reviews)**
    A. Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications
    B. Atopic Dermatitis Medications
    C. Injectable and Vaginal Progesterone Products
    D. Multiple Myeloma Medications

    *Future product and class reviews subject to change.

17. **Adjournment**

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING SEPTEMBER 13, 2023

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

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Morgan Masterson, Pharm.D; Clinical Pharmacist		X
Mattie Morgan, Pharm.D.; Pharmacy Resident	X	
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Jo'Nel Reynolds, 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
Emily Borders, Pharm.D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.	X	
Victoria Jones, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, 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
David Bryan, J.D.; Deputy General Counsel	X	
Terry Cothran, D.Ph.; Pharmacy Director	X	
Josh Holloway, J.D.; Deputy General Counsel		X

Brandon Keppner; Chief Operating Officer		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:	
Tiffany Dickey, Aimmune	Robin Selsor, Aimmune
Eric Berthelot, Sobi	Alexandria Jarvais, Sobi
Ty Griffin, Ferring	Paul Monies, Oklahoma Watch
Melissa Abbott, Eisai	JJ Roth, Mirum Pharmaceuticals
Todd Ness, AbbVie	Shellie Keast, Mercer
Brent Parker, Merck	Kent Neeland, Sanofi Vaccines
H. David Williams, Luye Pharma	Evie Knisely, Novartis
David Prather, Novo Nordisk	Bob Atkins, Biogen
Lance Burcham, Sanofi	Ed Clasby, Medtronic
Nima Nabavi, Amgen	Fred McClellan, Ascendis
Peter Lee, OMES	Robert Greely, Biogen
Rhonda Clark, Indivior	Wendi Chandler
Aaron Austin, Takeda	Phillip Lohec, Viatris
Gina Heinen, Novo Nordisk	Bryan Dillon, Otsuka
Gary Parenteau, Dexcom	Amanda Nowakowski, ViiV Healthcare
Frank Alvarado, Johnson & Johnson	

PRESENT FOR PUBLIC COMMENT:	
Alexandria Jarvais, Sobi	Tiffany Dickey, Aimmune

AGENDA ITEM NO. 1: **CALL TO ORDER**
1A: ROLL CALL
Dr. Muchmore called the meeting to order at 4:00pm. Roll call by Dr. Adams established the presence of a quorum.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**
2A: AGENDA ITEM NO. 18 ALEXANDRIA JARVAIS
2B: AGENDA ITEM NO. 20 TIFFANY DICKEY
ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MEETING MINUTES**
3A: JULY 12, 2023 DUR MINUTES – VOTE
Materials included in agenda packet; presented by Dr. Muchmore
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **APPROVAL OF DUR BOARD INTERIM VICE CHAIR**
Dr. Patatanian was nominated for interim vice chair.
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 5: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/NONALCOHOLIC FATTY LIVER DISEASE (NAFLD) UPDATE**
5A: PHARMACY HELPDESK ACTIVITY FOR AUGUST 2023
5B: MEDICATION COVERAGE ACTIVITY FOR AUGUST 2023
5C: NAFLD UPDATE
Materials included in agenda packet; presented by Dr. Reynolds, Dr. Wilson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE LEQEMBI® (LECANEMAB-IRMB) AND UPDATE THE APPROVAL CRITERIA FOR THE ALZHEIMER'S DISEASE MEDICATIONS**
6A: MARKET NEWS AND UPDATES
6B: LEQEMBI® (LECANEMAB-IRMB) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE VYJUVEK™ (BEREMAGENE GEPERPAVEC-SVDT)**
7A: MARKET NEWS AND UPDATES
7B: VYJUVEK™ (BEREMAGENE GEPERPAVEC-SVDT) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Muñoz moved to approve; seconded by Dr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE KYZATREX™ (TESTOSTERONE UNDECANOATE CAPSULE) AND UPDATE THE APPROVAL CRITERIA FOR THE TESTOSTERONE PRODUCTS**
8A: MARKET NEWS AND UPDATES
8B: KZYATREX™ (TESTOSTERONE UNDECANOATE CAPSULE) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE BRIXADI™ (BUPRENORPHINE EXTENDED-RELEASE INJECTION), NALOCET® (OXYCODONE/ ACETAMINOPHEN TABLET), AND PROLATE™ (OXYCODONE/ACETAMINOPHEN ORAL SOLUTION AND TABLET) AND TO UPDATE THE APPROVAL CRITERIA FOR THE OPIOID ANALGESICS AND MEDICATION ASSISTED TREATMENT (MAT) MEDICATIONS**
9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Reynolds
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE TOPICAL CORTICOSTEROIDS**
10A: MARKET NEWS AND UPDATES

10B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Mr. Foster moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO UPDATE THE APPROVAL CRITERIA FOR THE INTRAVENOUS (IV) IRON PRODUCTS
11A: MARKET NEWS AND UPDATES
11B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: VOTE TO PRIOR AUTHORIZE XACDURO® (SULBACTAM/DURLOBACTAM) AND UPDATE THE APPROVAL CRITERIA FOR THE VARIOUS SYSTEMIC ANTIBIOTICS
12A: MARKET NEWS AND UPDATES
12B: XACDURO® (SULBACTAM/DURLOBACTAM) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: VOTE TO PRIOR AUTHORIZE CUVRIOR™ (TRIENTINE TETRAHYDROCHLORIDE)
13A: CUVRIOR™ (TRIENTINE TETRAHYDROCHLORIDE) PRODUCT SUMMARY
13B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Mr. Foster moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

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

AGENDA ITEM NO. 15: ANNUAL REVIEW OF OXLUMO® (LUMASIRAN)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF OXLUMO® (LUMASIRAN)
15C: PRIOR AUTHORIZATION OF OXLUMO® (LUMASIRAN)
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF OXLUMO® (LUMASIRAN)
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: ANNUAL REVIEW OF CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) MODULATORS

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

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

AGENDA ITEM NO. 17: ANNUAL REVIEW OF GATTEX® [TEDUGLUTIDE (RDNA ORIGIN)]

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF GATTEX® [TEDUGLUTIDE (RDNA ORIGIN)]
17C: PRIOR AUTHORIZATION OF GATTEX® [TEDUGLUTIDE (RDNA ORIGIN)]
17D: MARKET NEWS AND UPDATES
17E: COLLEGE OF PHARMACY RECOMMENDATIONS
17F: UTILIZATION DETAILS OF GATTEX® [TEDUGLUTIDE (RDNA ORIGIN)]

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

AGENDA ITEM NO. 18: ANNUAL REVIEW OF SYNAGIS® (PALIVIZUMAB)

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF SYNAGIS® (PALIVIZUMAB)
18C: PRIOR AUTHORIZATION OF SYNAGIS® (PALIVIZUMAB)
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF SYNAGIS® (PALIVIZUMAB)

Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 19: ANNUAL REVIEW OF BREAST CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ORSERDU™ (ELACESTRANT)

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF BREAST CANCER MEDICATIONS
19C: PRIOR AUTHORIZATION OF BREAST CANCER MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: ORSERDU™ (ELACESTRANT) PRODUCT SUMMARY
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF BREAST CANCER MEDICATIONS

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

AGENDA ITEM NO. 20: ANNUAL REVIEW OF ZINPLAVA™ (BEZLOTOXUMAB) AND 30-DAY NOTICE TO PRIOR AUTHORIZE REBYOTA® (FECAL MICROBIOTA, LIVE-JSLM) AND VOWST™ (FECAL MICROBIOTA SPORES, LIVE-BRPK)

20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF ZINPLAVA™ (BEZLOTOXUMAB)

20C: PRIOR AUTHORIZATION OF ZINPLAVA™ (BEZLOTOXUMAB)
20D: MARKET NEWS AND UPDATES
20E: PRODUCT SUMMARIES
20F: COLLEGE OF PHARMACY RECOMMENDATIONS
20G: UTILIZATION DETAILS OF ZINPLAVA™ (BEZLOTOXUMAB)
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER

AGENDA ITEM NO. 21: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Reynolds
ACTION: NONE REQUIRED

AGENDA ITEM NO. 22: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
22A: ANEMIA MEDICATIONS
22B: HEPATITIS C MEDICATIONS
22C: MUSCULAR DYSTROPHY MEDICATIONS
22D: 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. 23: ADJOURNMENT
The meeting was adjourned at 5:41pm.

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

Memorandum

Date: September 15, 2023

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 13, 2023

Recommendation 1: Nonalcoholic Fatty Liver Disease (NAFLD) Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Leqembi® (Lecanemab-irmb) 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 Leqembi™ (lecanemab-irmb) with the following criteria (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 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.

The College of Pharmacy also recommends updating the Aduhelm® (aducanumab-avwa) approval criteria based on net costs and to be consistent with the approval criteria for Leqembi™ (lecanemab-irmb) (changes shown in red):

Aduhelm® (Aducanumab-avwa) 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 24 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5; 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. Aduhelm® 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 325mg per day or less, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Aduhelm®; and
8. Member must not have had a stroke or 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 any pre-treatment localized superficial siderosis, ≥10 brain microhemorrhages, or a brain hemorrhage >1cm within 1 year of treatment initiation as safety with Aduhelm® has not been established in patients with these conditions; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Aduhelm® and prior to the 7th infusion (1st dose of 10mg/kg) and 12th infusion (6th dose of 10mg/kg); and
12. The prescriber must confirm that the member will be monitored for ARIA during the first 8 doses of treatment with Aduhelm®, particularly during titration, and also throughout treatment; 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 and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H); and
14. Aduhelm® 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. Aduhelm® 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. Aduhelm® must be administered by a health care provider; and~~
~~16. Aduhelm® must be shipped via cold chain supply shipping and stored in a refrigerator; and~~

17. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
18. A patient-specific, clinically significant reason why the member cannot use Leqembi™ (lecanemab-irmb) must be provided; and
19. Initial approvals will be for 6 months. Confirmation that MRI has been completed and is acceptable to the provider prior to 7th infusion is required for continuation; and
20. 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; and
21. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
22. The maximum dose approvable is 10mg/kg per 28 days; and
23. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Recommendation 3: Vote to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Vyjuvek™ (beremagene geperpavec-svdt) with the following criteria (shown in red)

Vyjuvek™ (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members 6 months of age and older with dystrophic epidermolysis bullosa (DEB); 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 administration 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. A maximum approval quantity of 1 carton (2.5mL) per week or 4 cartons (10mL) per 28 days will apply; 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.

Recommendation 4: Vote to Prior Authorize Kyzatrex™ (Testosterone Undecanoate Capsule) and Update the Approval Criteria for the Testosterone Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Testosterone Products Product Based Prior Authorization (PBPA) category based on new FDA approvals, product discontinuations, and net costs (changes shown in red in the following Tier chart and approval criteria):

1. The prior authorization and placement of Kyzatrex® (testosterone undecanoate) into the Special Prior Authorization (PA) Tier; and
2. Moving Vogelxo® (testosterone 1% topical gel pump) from Tier-1 to Tier-2; and
3. Moving Axiron® (testosterone topical solution) from Tier-2 to Tier-1; and
4. Removing methyltestosterone powder, Androxy® (fluoxymesterone oral tablet), and Striant® (testosterone buccal tablet) based on product discontinuations.

Testosterone Products		
Tier-1*	**Tier-2**	**Special PA**
~~**methyltestosterone powder**~~	testosterone enanthate sub-Q auto-injector (Xyosted®)	~~**fluoxymesterone oral tab (Androxy®)**~~

testosterone cypionate IM inj (Depo Testosterone®)	testosterone nasal gel (Natesto®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone patch (Androderm®)	~~**testosterone buccal tab (Striant®)**~~
testosterone topical gel 1% **packet, tube** (Testim®, Vogelxo®)	testosterone topical gel 1%, 1.62% packet (Androgel®)	testosterone pellets (Testopel®)
testosterone topical gel 1.62% pump (Androgel®) – **Brand Preferred**	**testosterone topical gel 1% pump (Vogelxo®)**	testosterone undecanoate oral cap (Jatenzo®, **Kyzatrex®,** Tlando®)
testosterone topical solution (Axiron®)	testosterone topical gel 2% pump (Fortesta®)	
	~~**testosterone topical solution (Axiron®)**~~	
	testosterone undecanoate IM inj (Aveed®)	

*Tier-1 products include generic injectable products and supplementally rebated topical products.
cap = capsule; IM = intramuscular; inj = injection; PA = prior authorization; sub-Q = subcutaneous; tab = tablet

Recommendation 5: Vote to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/Acetaminophen Tablet), and Prolate™ (Oxycodone/Acetaminophen Oral Solution and Tablet) and to 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 Nalocet® and Prolate® to Tier-3 of the Short-Acting Opioid Analgesics category based on net costs; and
2. Moving Nucynta® and Nucynta® ER 50mg to Tier-1 based on net costs; and
3. Moving Nucynta® ER 100mg, 150mg, 200mg, and 250mg to Tier-2 based on net costs and morphine milligram equivalent (MME); and
4. Removing Arymo™ ER, Lazanda®, MorphaBond™, Subsys®, Synalgos-DC®, Troxyca® ER, and Xartemis® XR 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®)	~~**oxycodone/APAP ER tab (Xartemis® XR)**~~

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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 only (Nucynta® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tapentadol ER tab 100mg, 150mg, 200mg, 250mg (Nucynta® ER)	hydromorphone ER tab (Exalgo®)	
	tramadol ER tab (Ultram ER®, Ryzolt®)	methadone tab and oral soln (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		~~**morphine ER tab (Arymo™ ER)**~~	
		~~**morphine ER tab (MorphaBond™)**~~	
		oxycodone ER cap (Xtampza® ER)	
		~~**oxycodone/ naltrexone ER cap (Troxyca® ER)**~~	
		~~**tapentadol ER tab (Nucynta® ER)**~~	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
codeine tab	~~**tapentadol IR tab (Nucynta®)**~~	hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	tramadol oral soln (Qdolo™)
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	celecoxib 56mg/tramadol 44mg (Seglentis®)
~~**dihydrocodeine/ ASA/caff cap (Synalgos-DC®)**~~		**oxycodone/APAP tab (Nalocet®)**	
hydrocodone/ APAP tab (Norco®)		**oxycodone/APAP tab and oral soln (Prolate®)**	
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)		oxycodone tab (Oxaydo®)	
hydromorphone tab (Dilaudid®)		oxycodone tab (RoxyBond™)	
morphine IR tab (MSIR®)			
oxycodone/APAP tab (Percocet®)			***Oncology Only:***
oxycodone/ASA tab (Percodan®)			fentanyl buccal film (Onsolis®)
oxycodone IR cap (Oxy IR®)			fentanyl buccal tab (Fentora®)
oxycodone IR tab (Roxicodone®)			~~**fentanyl nasal spray (Lazanda®)**~~
tapentadol IR (Nucynta®)			~~**fentanyl SL spray (Subsys®)**~~
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®, Fentora®, ~~Lazanda®,~~ and Onsolis®~~, and Subsys®~~ 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. Hydrocodone/Acetaminophen (APAP) Unique Strengths Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) must be provided.
4. 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.
5. 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.
6. Seglentis® (Celecoxib 56mg/Tramadol 44mg) 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.
7. Tramadol 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 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.

~~8. Xartemis® XR (Oxycodone/APAP ER Tablet) Approval Criteria:~~

~~a. An acute pain condition requiring around-the-clock opioid treatment; and~~

~~b. A patient-specific, clinically significant reason must be provided for all of the following:~~

~~i. Why the member cannot use any other opioid medication for treatment of acute pain; and~~

~~ii. Why the member requires a long-acting medication for an acute pain condition; and~~

~~iii. Why the member cannot use Oxycontin® (oxycodone ER) and over-the-counter (OTC) APAP individual products in place of this combination product; and~~

~~c. A quantity limit of 4 tablets per day will apply with a maximum approval duration of 10 days; and~~

~~d. The member must not exceed 3,250mg of APAP per day from all sources; and~~

~~e. Tier structure rules still apply.~~

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

1. The prior authorization of Brixadi™ with criteria similar to Sublocade®; and
2. Updating the approval criteria for Brixadi™ and Sublocade® to be consistent with clinical practice regarding concomitant treatment with transmucosal buprenorphine; and
3. Updating the approval criteria for Sublocade®, Suboxone®, Subutex®, and Zubsolv® to remove the Drug Enforcement Agency (DEA) X requirement based on the 2023 Consolidated Appropriations Act.

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

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder; and

~~2. Sublocade® must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and~~

3. For Sublocade®, member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; ~~and~~ or

4. For Brixadi™, member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
5. Concomitant treatment with opioids (including tramadol) will be denied; and
6. ~~Sublocade®~~ Medication should only be prepared and administered by a health care provider; and
7. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual tablets) must be provided; and
8. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
9. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
10. A quantity limit of 1 monthly dose ~~(300mg or 100mg)~~ per 28 days or 4 weekly doses per 28 days will apply.

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; and
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. ~~Buprenorphine products FDA approved for a diagnosis of opioid abuse/ dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and~~
4. Member must have an FDA approved diagnosis of opioid abuse/ dependence; and
5. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
6. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
7. 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 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 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 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 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 SL tablets per 30 days will apply.

Recommendation 6: Vote to Update the Approval Criteria for the Topical Corticosteroids

MOTION CARRIED by unanimous approval.

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

1. Ultra-High to High Potency:
   a. Move clobetasol propionate 0.05% foam (Olux®) from Tier-3 to Tier-1
   b. Move clobetasol propionate 0.05% shampoo (Clobex®) from Tier-3 to Tier-2
2. Medium-High to Medium Potency:
   a. Move triamcinolone acetonide 0.147mg/g spray (Kenalog®) from Tier-2 to Tier-3
3. Low Potency:
   a. Move hydrocortisone 2.5% solution (Texacort®) from Tier-2 to Tier-3

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®)	~~Sh,~~Spr
betamethasone dipropionate 0.05% (Diprosone®)	C,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G,L	clobetasol propionate 0.05% (~~Olux®,~~ Olux-E®, Tovet®)	F
clobetasol propionate 0.05% (Olux®)	**F**	clobetasol propionate 0.05% (Clobex®)	L**,Sh**	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

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
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	halobetasol propionate 0.01% (Bryhali®)	L
halobetasol propionate 0.05% (Ultravate®)	C,O	halcinonide 0.1% (Halog®)	C,O,So	halobetasol propionate 0.05%	F
		halobetasol propionate 0.05% (Ultravate®)	L		
		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	desoximetasone 0.05% (Topicort LP®)	C,O
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.12% (Luxiq®)	F	hydrocortisone valerate 0.2% (Westcort®)	C,O
fluticasone propionate 0.005% (Cutivate®)	O	betamethasone valerate 0.1% (Beta-Val®)	L	**triamcinolone acetonide 0.147mg/g (Kenalog®)**	**Spr**
fluticasone propionate 0.05% (Cutivate®)	C	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F		
mometasone furoate 0.1% (Elocon®)	C,L,O, So	clocortolone pivalate 0.1% (Cloderm®)	C		
triamcinolone acetonide 0.025%	O	fluocinolone acetonide 0.025% (Synalar®)	C,O		
triamcinolone acetonide 0.1%	C,L,O	fluocinonide emollient 0.05% (Lidex E®)	C		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
triamcinolone acetonide 0.5%	C,O	flurandrenolide 0.05%	C,L,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 0.147mg/g (Kenalog®)**~~	~~**Spr**~~		
		triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C	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
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	~~**hydrocortisone 2.5% (Texacort®)**~~	~~**So**~~	**hydrocortisone 2.5% (Texacort®)**	**So**
hydrocortisone acetate 2.5%	C,L,O	hydrocortisone/pramoxine 1%/1% (Pramosone®)	C,L		
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 7: Vote to Update the Approval Criteria for the Intravenous (IV) Iron Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Injectafer® (ferric carboxymaltose) approval criteria based on recent FDA approved indication for iron deficiency in patients with heart failure (new criteria and changes shown in red):

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 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; 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.

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 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.

Additionally, the College of Pharmacy recommends updating the Monoferric® (ferric derisomaltose) approval criteria based on net cost (changes shown in red):

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 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; and
5. A patient-specific, clinically significant reason why the member cannot utilize Feraheme® (ferumoxytol) and Injectafer® (ferric carboxymaltose) must be provided.

Recommendation 8: Vote to Prior Authorize Xacduro® (Sulbactam/Durlobactam) and Update the Approval Criteria for the Various Systemic Antibiotics

MOTION CARRIED by unanimous approval.

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

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; 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); or
4. For members with carbapenem-resistant *Acinetobacter baumannii* (CRAB), a patient-specific, clinically significant reason why the member cannot use 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).

Additionally, the College of Pharmacy recommends updating the current approval criteria for Fetroja® (cefiderocol), Kimyrsa™ (oritavancin), Recarbrio™

(imipenem/cilastatin/relebactam), Solosec® (secnidazole oral granules), and Zerbaxa® (ceftolozane/tazobactam) to be consistent with the FDA approved indications (changes shown in red):

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   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. ~~The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use 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
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Kimyrsa™ (Oritavancin) Approval Criteria:

1. An FDA approved indication for the treatment of acute bacterial skin and skin structure infection (ABSSSI) caused or suspected to be caused by susceptible isolates of designated gram-positive microorganisms; and
2. Member must be 18 years of age or older; and
3. ~~The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use Orbactiv® (oritavancin) 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).

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

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   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. The prescriber must verify that limited or no alternative treatment options are available; and~~

4. A patient-specific, clinically significant reason why the member cannot use 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, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 56 vials per 14 days will apply.

Solosec® (Secnidazole Oral Granules) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis or trichomoniasis; and
2. A patient-specific, clinically significant reason why the member cannot use metronidazole, tinidazole, or other cost effective therapeutic equivalent alternative(s) must be provided; and
3. A quantity limit of 1 packet per 30 days will apply.

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   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, 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).

Finally, the College of Pharmacy recommends removing the prior authorization of amoxicillin 500mg tablets based on net costs (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 500mg tablets~~
   - 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®)
   - Doxycycline monohydrate 150mg capsules and tablets
   - Doxycycline monohydrate DR 40mg capsules (Oracea®)
   - Minocycline ER capsules (Ximino®)
   - Minocycline ER tablets (Minolira™)
   - Minocycline ER tablets (Solodyn®)

Recommendation 9: Vote to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Cuvrior™ (trientine tetrahydrochloride) with the following criteria:

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 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 penicillamine, generic trientine hydrochloride, 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: Annual Review of Tepezza® (Teprotumumab-trbw)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the current Tepezza® (teprotumumab-trbw) approval criteria based on the FDA approved expanded indication (changes shown in red):

Tepezza® (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease in adult members 18 years of age and older; and
   ~~a. Member must be experiencing eye symptoms related to thyroid eye disease; and~~
   b. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza®, and for at least 6 months after the last dose of Tepezza®; and
4. Member must not have had prior surgical treatment for thyroid eye disease; and
   a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza® for members who have had prior surgical treatment for thyroid eye disease, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza®; and
5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of thyroid eye disease; and
   a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza® must be provided on the prior authorization request; and
6. Tepezza® must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza® must be administered by a health care professional. Prior authorization requests must indicate how Tepezza® will be administered; and
   a. Tepezza® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or

b. Tepezza® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza®; and

8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approvals will be for a maximum of 8 total infusions.

Recommendation 11: Annual Review of Oxlumo® (Lumasiran)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Oxlumo® (lumasiran) approval criteria based on the recent FDA approval and to be consistent with clinical practice (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, 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. ~~Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2 prior to starting Oxlumo® and must agree to monitor renal function regularly during treatment with Oxlumo®; and~~
4. Member must not have a history of liver transplant; and
5. ~~Member must not have evidence of systemic oxalosis; and~~
6. Prescriber must verify that Oxlumo® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion or plasma oxalate levels.

Recommendation 12: Annual Review of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for the CFTR modulators based on the recent FDA approved age expansions and to be more consistent with clinical practice (changes shown in red):

Kalydeco® (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to ivacaftor based on clinical and/*or in vitro* assay data; and
2. Documentation must be submitted with results of *CFTR* genetic testing; and
3. Member must be 1 ~~4~~ month~~s~~ of age or older; and
4. Members using Kalydeco® must be supervised by a pulmonary disease specialist; and
5. Prescriber must verify the member has been counseled on proper administration of Kalydeco® including taking with a fat-containing food; and
6. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Kalydeco®, every 3 months during the first year of treatment, and annually thereafter; and
7. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
8. Member must not be taking any of the following medications concomitantly with Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. For members 1 month to younger than 6 months of age:
    a. Member must not have any level of hepatic impairment; and
    b. Member must not be taking concomitant moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
10. A quantity limit of 2 tablets or 2 granule packets per day or 56 tablets or granule packets per 28 days will apply; and
11. An age restriction of 1 ~~4~~ month~~s~~ to 5 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
14. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
3. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
4. Member must be 12 months of age or older; and
5. Members using Orkambi® must be supervised by a pulmonary disease specialist; and
6. Prescriber must verify the member has been counseled on proper administration of Orkambi® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
9. Member must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
10. A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply or a quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
11. An age restriction of 12 months to 5 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
14. Subsequent approvals will be for the duration of 1 year.

Symdeko® (Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 6 years of age or older; and
4. Members using Symdeko® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and
6. Prescriber must verify the member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
9. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
10. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
11. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
12. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®; and
13. Subsequent approvals will be for the duration of 1 year.

Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 *F508del* mutation in the CF transmembrane conductance regulator *(CFTR)* gene or a mutation in the *CFTR* gene that is responsive based on *in vitro* data; and
2. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
3. Member must be 2 ~~6~~ years of age or older; and
4. Members using Trikafta® must be supervised by a pulmonary disease specialist; and
5. If the member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and
6. Prescriber must verify the member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Trikafta®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify the member does not have severe hepatic impairment; and
9. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
10. Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
11. ~~A quantity limit of 3 tablets per day or 84 tablets per 28 days will apply; and~~
12. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
    b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
13. For Trikafta® oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta® tablets cannot be used; and
14. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable.

For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

15. Initial approvals will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® or Symdeko® to Trikafta®; and
16. Subsequent approvals will be for the duration of 1 year.

Recommendation 13: Annual Review of Gattex® [Teduglutide (rDNA origin)]

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Gattex® [teduglutide (rDNA origin] approval criteria based on the FDA approved age expansion and label updates (changes shown in red):

Gattex® [Teduglutide (rDNA Origin)] Approval Criteria:

1. An FDA approved diagnosis of severe short bowel syndrome; and
2. Member must require parenteral support (PS) ~~parenteral nutrition (PN)~~ as indicated by the following:
    a. For adult members: Must require ~~PN~~ PS at least 3 times per week, every week, for the past 12 months; or
    b. For pediatric members: PS accounts for at least 30% of caloric and/or fluid/electrolyte needs; and
3. Documentation of all of the following:
    a. Prior use of supportive therapies (e.g., anti-motility agents, proton pump inhibitors, bile acid sequestrants, octreotide); and
    b. For adult members, colonoscopy within the previous 6 months, with removal of polyps if present; and
    c. For pediatric members, a fecal occult blood test within the previous 6 months; and
        i. If there is unexpected blood in the stool, a colonoscopy/ sigmoidoscopy was performed; and
    d. Gastro-intestinal malignancy has been ruled out; and
4. Approval will be for the duration of ~~3~~ 6 months, after which time, prescriber must verify benefit of medication by documented reduction of at least 20% in PS. Subsequent approvals will be for the duration of 1 year.

Recommendation 14: Annual Review of Synagis® (Palivizumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Synagis® (palivizumab) approval criteria based on the FDA approval of Beyfortus™ (nirsevimab-alip) and the Centers for Disease Control and Prevention (CDC) and American Academy of Pediatrics (AAP) recommendations (changes shown in red):

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 approvals will be for the duration of 3 months from the determined RSV season start date in Oklahoma.~~ Initial and subsequent approvals will be for the duration of 1 month until RSV season end. 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.

Recommendation 15: Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Orserdu™ (Elacestrant)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER 2023.

Recommendation 16: Annual Review of Zinplava™ (Bezlotoxumab) and 30-Day Notice to Prior Authorize Rebyota® (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN OCTOBER 2023.

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.

August 23, 2023

Re: September 13, 2023 Medicaid DUR Board; Ensuring Equitable Access to Leqembi®

Dear Board Members:

I am writing today on behalf of the Alzheimer's Association to ask that the Oklahoma Drug Utilization Review Board make a coverage decision that allows equitable access to Medicaid coverage for Leqembi® at the next meeting. The Alzheimer's Association asks the Board to recommend access to Leqembi that follows the *Lecanemab: Appropriate Use Recommendations*[1] developed by the Alzheimer's Disease and Related Disorders Therapeutics Work Group. Each day without access to the drug, the Alzheimer's Association estimates more than 2,000 individuals aged 65 or older transition from mild dementia due to Alzheimer's to a more advanced stage of the disease where they will no longer be eligible for Leqembi. Therefore, missing the opportunity to see improved outcomes or clinical benefits at the early stages of their disease progression.

As you are aware, lecanemab (Leqembi) received traditional approval from the FDA on July 6th, 2023 as a treatment for early stage Alzheimer's disease. Leqembi is the second in a new category of medications approved for the treatment of Alzheimer's disease that target the fundamental pathophysiology of the disease. This medication represents an important advancement in the ongoing fight to effectively treat Alzheimer's disease. On behalf of those living with Alzheimer's disease and their families, the Alzheimer's Association continues to call on regulating bodies to provide access to monoclonal antibodies targeting amyloid for the treatment of Alzheimer's disease, including Leqembi.

The Alzheimer's Association leads the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximizing quality care and support. As the leading voluntary health organization in Alzheimer's care, support and research, the Alzheimer's Association is dedicated to promoting care considerations that lead to improved patient outcomes and committed to ensuring that evidence-based practices for the diagnosis and care of Alzheimer's disease are available to all individuals living with Alzheimer's.

Currently more than 67,000 individuals in Oklahoma are living with Alzheimer's disease, and over 135,000 family members and friends are providing care to their loved ones. On behalf of those living with Alzheimer's disease and their families, the Alzheimer's Association asks that the Oklahoma Drug Utilization Review Board allow equitable access to Leqembi. As an FDA-approved treatment for people with early-stage Alzheimer's, access to coverage should be available to Oklahoma Medicaid beneficiaries living with this disease. Ensuring access to this new treatment may mean prolonging the earliest stages of this disease, prior to significant cognitive and functional decline.

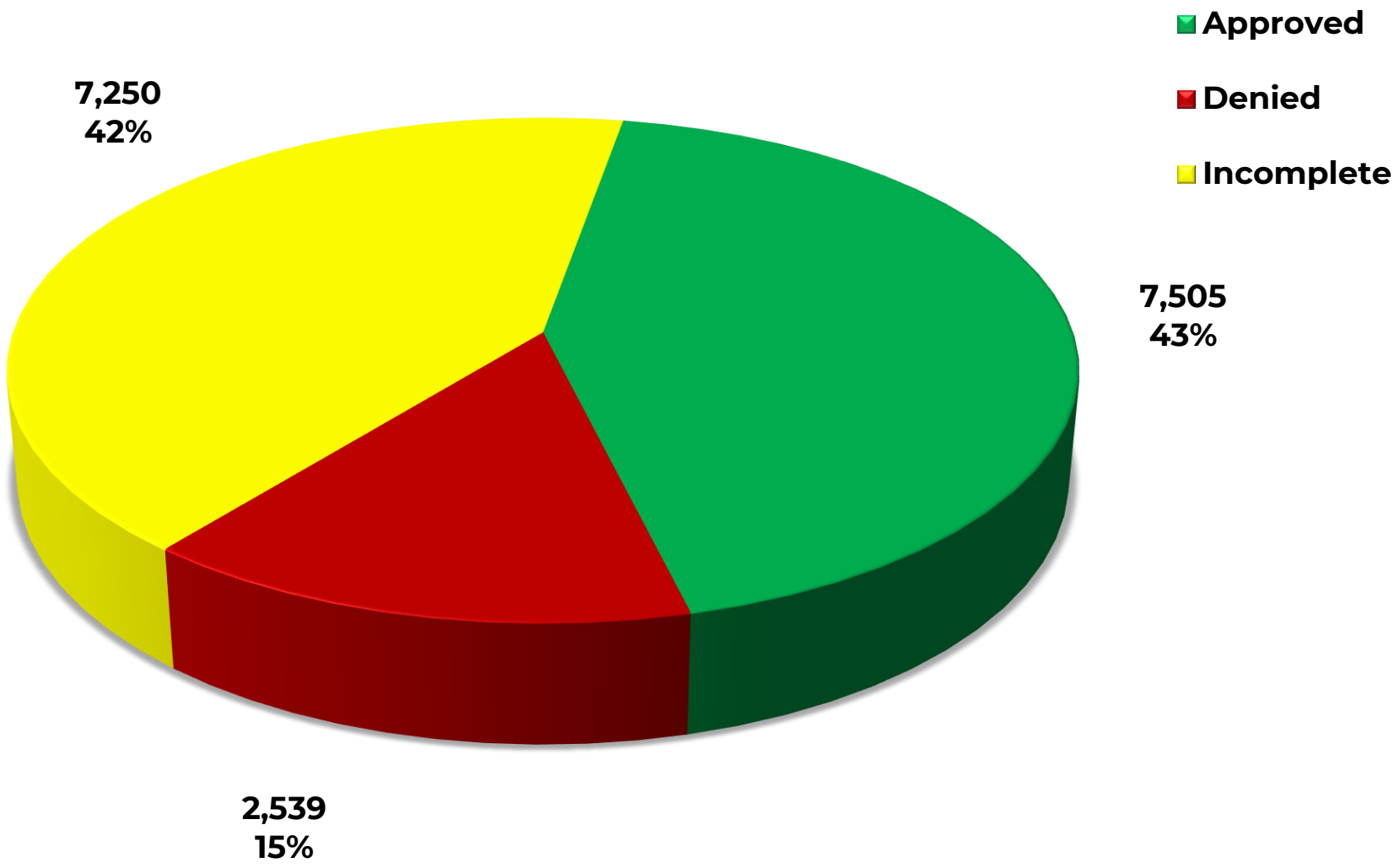
Sincerely,

Maggie Shaffer
Director of Public Policy
Alzheimer's Association - Oklahoma Chapter

[1] Cummings, J., Apostolova, L., Rabinovici, G.D. et al. Lecanemab: Appropriate Use Recommendations. *J Prev Alzheimers Dis* (2023). https://doi.org/10.14283/jpad.2023.30

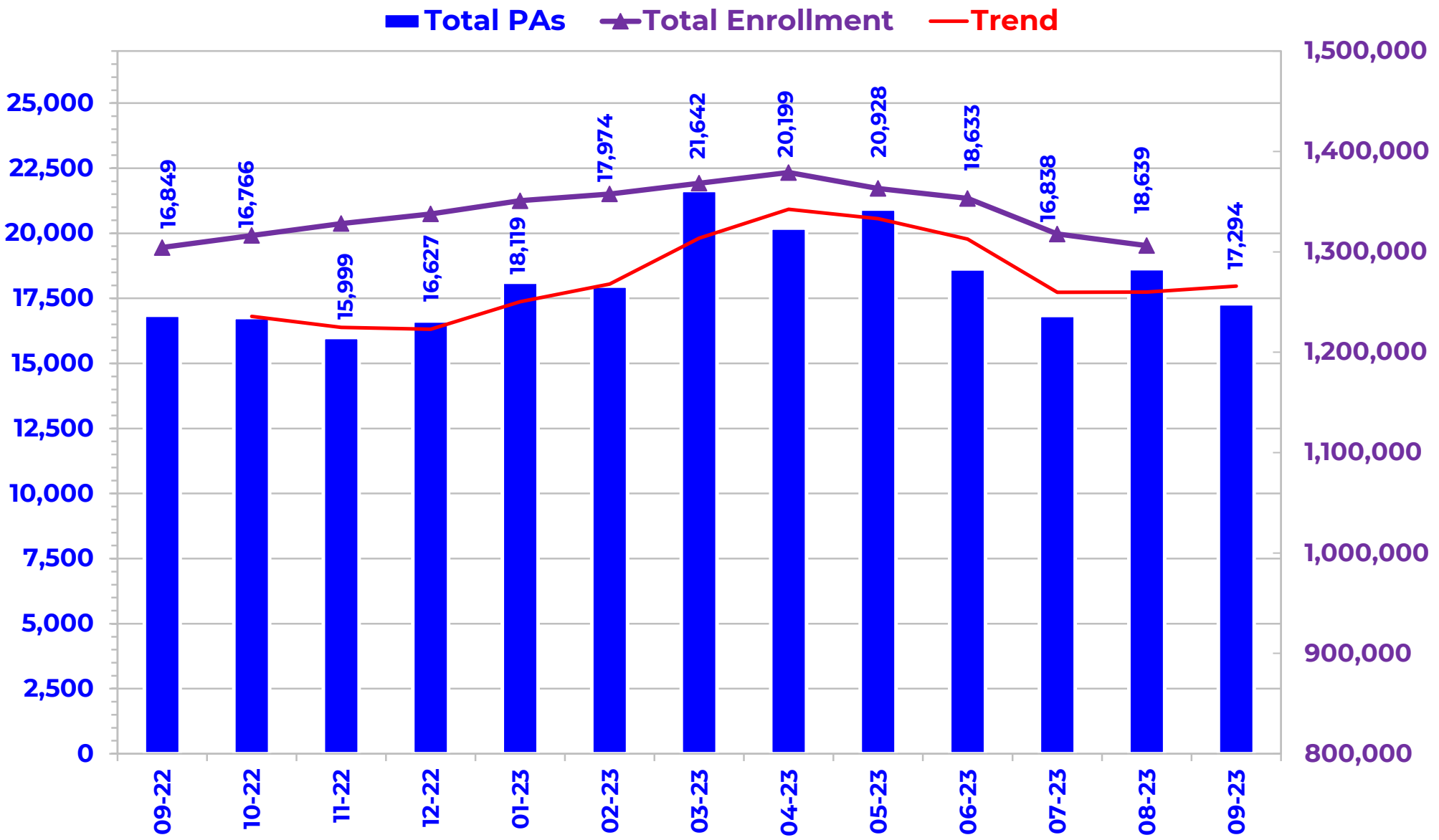
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: SEPTEMBER 2023



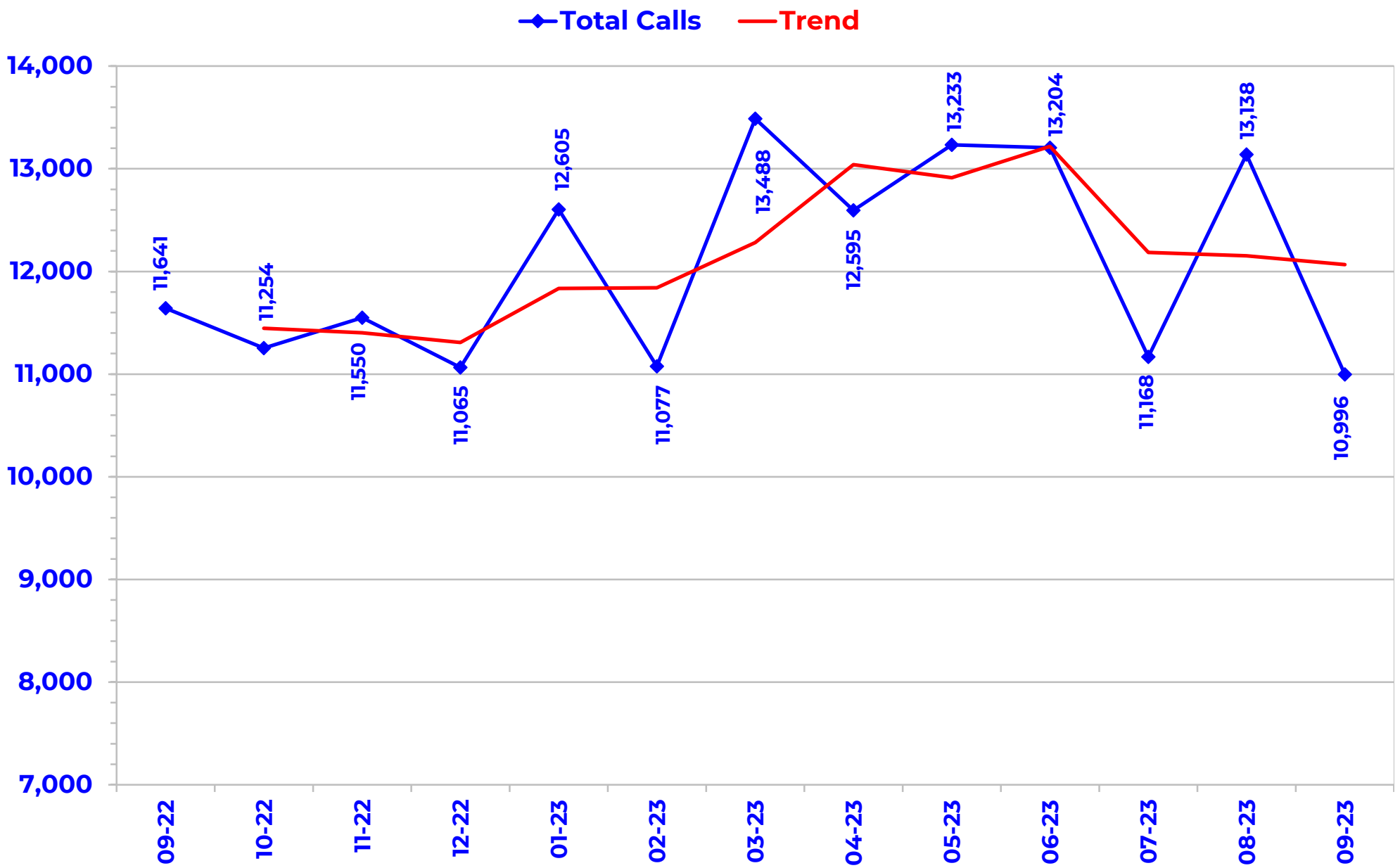
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: SEPTEMBER 2022 – SEPTEMBER 2023



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: SEPTEMBER 2022 – SEPTEMBER 2023



Prior Authorization Activity

9/1/2023 Through 9/30/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	225	108	12	105	357
Analgesic - NonNarcotic	20	0	2	18	0
Analgesic, Narcotic	487	232	46	209	117
Angiotensin Receptor Antagonist	15	4	2	9	361
Anti-inflammatory	16	10	2	4	134
Antiasthma	140	48	28	64	250
Antibiotic	41	19	3	19	251
Anticonvulsant	299	140	14	145	285
Antidepressant	437	112	64	261	280
Antidiabetic	2,414	679	665	1,070	356
Antifungal	15	2	3	10	114
Antigout	12	5	1	6	361
Antihemophilic Factor	12	12	0	0	338
Antihistamine	64	21	11	32	360
Antimigraine	696	129	203	364	255
Antineoplastic	320	216	23	81	169
Antiobesity	52	0	41	11	0
Antiparasitic	22	4	3	15	15
Antiparkinsons	15	0	7	8	0
Antiulcers	45	1	6	38	361
Antiviral	17	3	5	9	91
Anxiolytic	31	3	4	24	353
Atypical Antipsychotics	702	311	59	332	359
Benign Prostatic Hypertrophy	13	2	6	5	360
Biologics	445	233	53	159	299
Bladder Control	114	20	34	60	324
Blood Thinners	45	7	1	37	312
Botox	88	60	18	10	351
Buprenorphine Medications	114	34	17	63	125
Calcium Channel Blockers	13	1	3	9	361
Cardiovascular	189	95	22	72	321
Chronic Obstructive Pulmonary Disease	359	72	76	211	355
Constipation/Diarrhea Medications	344	71	87	186	216
Contraceptive	66	22	9	35	346
Corticosteroid	13	3	7	3	361
Dermatological	652	233	175	244	231
Diabetic Supplies	525	233	46	246	178
Endocrine & Metabolic Drugs	84	34	12	38	264
Erythropoietin Stimulating Agents	31	14	5	12	114
Estrogen Derivative	21	5	3	13	322

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Fibric Acid Derivatives	15	3	1	11	361
Fibromyalgia	15	1	4	10	361
Fish Oils	33	4	7	22	358
Gastrointestinal Agents	187	43	41	103	214
Genitourinary Agents	14	1	5	8	117
Glaucoma	18	4	3	11	197
Growth Hormones	184	123	17	44	137
Hematopoietic Agents	38	16	3	19	209
Hepatitis C	34	14	10	10	8
HFA Rescue Inhalers	24	0	1	23	0
Insomnia	104	11	17	76	244
Insulin	319	110	25	184	351
Miscellaneous Antibiotics	29	2	6	21	33
Multiple Sclerosis	106	50	8	48	245
Muscle Relaxant	89	4	19	66	22
Nasal Allergy	41	4	9	28	361
Neurological Agents	174	66	33	75	199
Neuromuscular Agents	25	15	1	9	219
NSAIDs	50	4	10	36	360
Ocular Allergy	24	3	4	17	241
Ophthalmic	24	2	6	16	192
Ophthalmic Anti-infectives	26	14	1	11	19
Ophthalmic Corticosteroid	26	7	3	16	273
Osteoporosis	43	14	5	24	360
Other*	381	118	51	212	269
Otic Antibiotic	24	3	2	19	19
Pediculicide	14	7	1	6	19
Respiratory Agents	45	25	1	19	311
Statins	74	16	24	34	171
Stimulant	2,955	1,730	142	1,083	315
Testosterone	218	45	61	112	360
Thyroid	43	7	11	25	321
Topical Antifungal	42	7	5	30	82
Topical Corticosteroids	59	4	24	31	142
Vitamin	144	12	89	43	156
Pharmacotherapy	54	51	0	3	307
Emergency PAs	0	0	0	0	
Total	**14,908**	**5,738**	**2,428**	**6,742**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	46	30	3	13	220
Compound	10	8	1	1	19
Dosage Change	384	358	4	22	17
High Dose	3	3	0	0	349
Ingredient Duplication	5	3	0	2	14
Lost/Broken Rx	112	101	7	4	19
MAT Override	328	245	7	76	80
NDC vs Age	336	255	30	51	281
NDC vs Sex	11	7	3	1	137
Nursing Home Issue	65	60	0	5	21
Opioid MME Limit	131	44	9	78	131
Opioid Quantity	33	28	0	5	153
Other	71	46	13	12	20
Prescriber Temp Unlock	1	0	0	1	0
Quantity vs Days Supply	721	496	32	193	247
STBS/STBSM	17	16	0	1	77
Step Therapy Exception	35	21	2	12	279
Stolen	13	11	0	2	17
Third Brand Request	64	35	0	29	22
Overrides Total	**2,386**	**1,767**	**111**	**508**	
Total Regular PAs + Overrides	**17,294**	**7,505**	**2,539**	**7,250**	

Denial Reasons	
Unable to verify required trials.	6,170
Does not meet established criteria.	2,559
Lack required information to process request.	1,093
Other PA Activity	
Duplicate Requests	1,854
Letters	44,351
No Process	3
Changes to existing PAs	1,489
Helpdesk Initiated Prior Authorizations	1,030
PAs Missing Information	1,187

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

Fall 2023 Pipeline Update

Oklahoma Health Care Authority
October 2023

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.

Aprocitentan[1,2,7]

Anticipated Indication(s): Treatment resistant hypertension

Clinical Trial(s): In December 2022, the FDA accepted a New Drug Application (NDA) for aprocitentan, a novel dual endothelin antagonist, for use in treatment-resistant hypertension. The PRECISION Phase 3 clinical trial enrolled patients who had a history of uncontrolled office blood pressure and had taken at least 3 anti-hypertensive medications with different mechanisms of action within the year before screening. Both groups receiving aprocitentan had a reduction of around -3.7mmHg in office systolic blood pressure after 4 weeks of therapy and maintained this reduction through week 40. The 24-hour ambulatory blood pressure taken after 4 weeks of therapy showed a significant reduction in blood pressure compared to placebo with a -7.4mmHg reduction at nighttime and -5.3mmHg reduction in the daytime for the 25mg dose and a -5.1mmHg reduction at nighttime and a -3.8mmHg reduction in the daytime for the 12.5mg dose. The most common side effect was edema with 35 (5%) of the 730 randomized patients.

Place in Therapy: Current American Heart Association (AHA) guidelines recommend optimizing treatment with diuretics and aldosterone antagonists and ruling out secondary causes of continued high blood pressure. The addition of an agent indicated for treatment resistant hypertension could improve care in patients struggling to manage their

blood pressure and could prevent adverse cardiovascular outcomes from occurring.

Projected FDA Decision: 12/20/2023

SoonerCare Impact: During fiscal year 2023 (07/01/2022 to 06/30/2023), a hypertension diagnosis was assigned to 127,209 SoonerCare members and 83,538 unique members were utilizing antihypertensive medications. Controlling hypertension is important in preventing adverse cardiovascular complications and the addition of several medications is often necessary. The addition of this medication to a member's hypertension therapy could improve blood pressure and prevent the need for more medications to be added.

Resmetirom[3,4,7]

Anticipated Indication(s): Nonalcoholic steatohepatitis (NASH)

Clinical Trial(s): Resmetirom is a novel thyroid hormone receptor (THR) β-selective agonist. THR-β is expressed more than THR-α in hepatocytes and regulates the metabolic pathways that contribute to NASH and nonalcoholic fatty liver disease (NAFLD). In the Phase 2 clinical trial, there was a change of -23.1% in the relative fat from baseline when compared to placebo at week 12. In the resmetirom group, 60% (47) of patients saw a 30% or more reduction in fat compared to only 18% (7) in the placebo group. The preliminary results released for the MAESTRO-NASH Phase 3 clinical trial showed a significant increase in the number of patients who saw NASH resolution and improvement of fibrosis in the resmetirom groups compared to placebo. More detailed data has yet to be published from this trial. The MAESTRO-NAFLD-1 Phase 3 clinical trial is also ongoing in patients with NAFLD with presumed NASH.

Place in Therapy: Resmetirom is being evaluated for the treatment of adults with NASH with liver fibrosis. If approved, it would be the first drug therapy approved to treat NASH. Most patients with NAFLD or NASH are currently managed through lifestyle modifications and treatment of associated co-morbidities.

Projected FDA Decision: April – June 2024

SoonerCare Impact: During fiscal year 2023, there were 1,248 members with a diagnosis of NASH and 12,274 members with a diagnosis of NAFLD for a combined total of 13,522 unique members with a diagnosis of either NAFLD or NASH. Co-morbidities of NAFLD and NASH include type 2 diabetes mellitus and obesity, both of which have a high prevalence in Oklahoma.

Sotatercept[5,6,7]

Anticipated Indication(s): Pulmonary arterial hypertension

Clinical Trial(s): Sotatercept is a novel fusion protein that contains the Fc domain of the human IgG and the extracellular domain of the human activin receptor type IIA (ActRIIA). The goal with this protein is to rebalance homeostasis of the pulmonary vasculature to prevent growth and promote apoptosis. Both the PULSAR Phase 2 clinical trial and the STELLAR Phase 3 clinical trial evaluated patients with pulmonary arterial hypertension who were already on background therapy. The primary endpoint in STELLAR was improvement in the 6-minute walk test, and at the end of week 24, a change of 40.1 meters was reported.

Place in Therapy: Sotatercept is being evaluated as an add on therapy for patients with pulmonary arterial hypertension. The PULSAR trial found that it improved the exercise capacity of patients who were already on background therapy. The STELLAR trial achieved similar results. This medication would be added to patients who are already stable on therapy, for additional improvement of their function and quality of life.

Projected FDA Decision: 03/26/2024

SoonerCare Impact: During fiscal year 2023, 343 unique members were utilizing pulmonary hypertension medications. Complications of this disease can become life-threatening, and the overall quality of life can be severely impacted for these patients. Sotatercept provides more options for therapy and has been shown to improve outcomes in Phase 2 trials.

Pipeline Table[7,8]

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
Tirzepatide	Eli Lilly	Chronic weight management	SC	NDA	11/2023
Taurolidine/Citrate/ Heparin	Cormedix	Catheter-related bloodstream infections due to chronic hemodialysis	IV	NDA; Fst Trk; QIDP	11/2023
Vonoprazan	Phathom	Erosive GERD	PO	NDA	11/2023
Aprocitentan	Idorsia Pharmaceuticals/ Janssen	Treatment resistant HTN	PO	NDA	12/2023
Debamestrocel	Brainstorm	ALS	Intra-thecal	NDA; Fst Trk; OD	12/2023

Medication Name*	Manufacturer	Therapeutic Use	Route of Admin	Approval Status	Anticipated FDA Response
Donanemab	Eli Lilly	Alzheimer's disease	IV, SC	BLA; Brk Thru	12/2023
Etrasimod	Pfizer	UC (moderate to severe)	PO	NDA	12/2023
Exagamglogene autotemcel	Vertex/CRISPR	SCD (severe); Beta thalassemia	IV	BLA; Fst Trk; OD	12/2023; 03/2024
Givinostat	Italfarmaco	DMD	PO	NDA; Fst Trk; OD	12/2023
Lovotibeglogene autotemcel	Bluebird Bio	SCD	IV	BLA; Fst Trk; OD	12/2023
Roflumilast Foam	Arcutis	Seborrheic dermatitis (≥9 years of age)	Topical	NDA	12/16/2023
Zilucoplan	UCB	Myasthenia Gravis	SC	NDA; OD	12/2023
Apadamtase Alfa/ Cinaxadamtase Alfa	Takada	Thrombotic thrombocyto-penic purpura (congenital)	IV	BLA; Fst Trk; OD	01/2024
Dihydroergotamine Nasal Powder	Satsuma	Migraine (acute treatment)	IN	505(b)(2) NDA	01/2024
Berdazimer Gel	Novan	Molluscum contagiosum	Topical	NDA	01/2024
Roluperidone	Minerva	Schizophrenia (negative symptoms)	PO	NDA	02/2024
Fidanacogene elaparvovec	Pfizer/ Genentech	Hemophilia B	IV	BLA; Brk Thru; OD	04/2024
Macitentan/Tadalafil	Janssen	PAH (WHO functional class II-III)	PO	NDA; OD	05/2024
Troriluzole	Biohaven	Spinocerebellar ataxia type 3	PO	NDA; Fst Trk; OD	05/2024
Cefepime/ Enmetazobactam	Allecra	UTI (complicated)	IV	NDA; Fst Trk	06/2024
Ensifentrine	Verona	COPD	INH	NDA	06/2024

*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.
ALS = amyotrophic lateral sclerosis; BLA = Biologic License Application; Brk Thru = breakthrough; COPD = chronic obstructive pulmonary disease; DMD = Duchenne muscular dystrophy; Fst Trk = fast track; GERD = gastroesophogeal reflux disease; HTN = hypertension; IN = intranasal; INH = inhaled; IV = intravenous; NDA = New Drug Application; OD = orphan drug; PAH = pulmonary arterial hypertension; PO = by mouth; QIDP = qualified infectious disease product; SC = subcutaneous; SCD = sickle cell disease; UC = ulcerative colitis; UTI = urinary tract infection; WHO = World Health Organization

[1] Schlaich M, Bellet M, Weber M, et al. Dual Endothelin Antagonist Aprocitentan for Resistant Hypertension (PRECISION): a Multicenter, Blinded, Randomized, Parallel-Group, Phase-3 Trial. *Lancet* 2022; 400:1927-37. doi: 10.1016/S0140-6736(22)02034-7.
[2] Unger T, Borghi C, Charchar F, et al. 2020 International Society of Hypertension Global Hypertension Practice Guidelines. *J Am Heart Assoc* 2020; 75:1334-1357. doi: 10.1161/HYPERTENSIONAHA.120.15026.
[3] Harrison S, Bashir M, Guy C, et al. Resmetirom (MGL-3196) for the Treatment of Non-Alcoholic Steatohepatitis: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase-2 Trial. *Lancet* 2019; 394:2012-24. doi: 10.1016/S0140-6736(19)32517-6.
[4] Madrigal Pharmaceuticals, Inc. Madrigal Pharmaceuticals Presents Phase 3 MAESTRO-NASH Data During the Opening General Session of the EASL Congress. Available online at: https://ir.madrigalpharma.com/news-releases/news-release-details/madrigal-pharmaceuticals-presents-phase-3-maestro-nash-data. Issued 06/22/2023. Last accessed 09/27/2023.
[5] Hoeper M, Badesch D, Ghofrani H, et al. Phase 3 Trial of Sotatercept for Treatment of Pulmonary Arterial Hypertension. *N Engl J Med* 2023; 388:1478-90. doi: 10.1056/NEJMoa2213558.
[6] Humbert M, McLaughlin V, Gibbs S, et al. Sotatercept for the Treatment of Pulmonary Arterial Hypertension. *N Engl J Med* 2021; 384:1204-1215. doi: 10.1056/NEJMoa2024277.
[7] MagellanRx Management. *MRx Pipeline*. Available online at: https://issuu.com/magellanrx/docs/mrx_pipeline_jul_2023_mrx1119_0723?fr=sNWVlMTYzMTA3MDY. Issued 07/2023. Last accessed 09/27/2023.
[8] Optum Rx. RxOutlook® 3rd Quarter 2023. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/outlook/ORX6204_230828_B2B-3Q2023_RxOutlook_FINAL.pdf. Issued 08/21/2023. Last accessed 09/27/2023.

Appendix C

Vote to Prior Authorize Rebyota™ (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk) and Update the Approval Criteria for Zinplava™ (Bezlotoxumab)

Oklahoma Health Care Authority
October 2023

Market News and Updates[1,2,3]

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

- **November 2022:** The FDA approved Rebyota™ (fecal microbiota, live-jslm) for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in adults 18 years of age and older who have completed antibiotic treatment for recurrent CDI. Rebyota™ is the first fecal microbiota product approved by the FDA and is administered rectally.
- **April 2023:** The FDA approved Vowst™ (fecal microbiota spores, live-brpk) for the prevention of recurrence of CDI in adults 18 years of age and older following antibacterial treatment for recurrent CDI. Vowst™ is the first fecal microbiota product that is taken orally.
- **May 2023:** The FDA approved Zinplava™ (bezlotoxumab) in pediatric patients 1 year of age and older. Previously, Zinplava™ (bezlotoxumab) was only approved for adults.

Rebyota™ (Fecal Microbiota, Live-jslm) Product Summary[4]

Therapeutic Class: Fecal microbiota transplantation (FMT) agent

Indication(s): Prevention of the recurrence of CDI in individuals 18 years of age and older following antibiotic treatment for recurrent CDI.

- Limitation(s) of Use: Rebyota™ is not indicated for the treatment of CDI.

How Supplied: 150mL rectal suspension

Dosing and Administration:

- The recommended dosage is a single 150mL dose administered rectally.
- Rebyota™ should be administered 24 to 72 hours after the last dose of antibiotics for CDI.

Vowst™ (Fecal Microbiota Spores, Live-brpk) Product Summary[5]

Therapeutic Class: FMT agent

Indication(s): Prevention of the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for the recurrent CDI.

- Limitation(s) of Use: Vowst™ is not indicated for the treatment of CDI.

How Supplied: Oral capsule

Dosing and Administration:

- Prior to taking the first dose:
  - Antibacterial treatment for recurrent CDI should be completed 2 to 4 days before initiating treatment with Vowst™.
  - The patient should drink 296mL (10oz) of magnesium citrate on the day before and at least 8 hours prior to taking the first dose of Vowst™. In clinical studies, participants with impaired kidney function received polyethylene glycol electrolyte solution (250mL GoLYTELY®, not approved for this use).
- The recommended dosage of Vowst™ is 4 capsules taken orally once daily for 3 consecutive days.
- Each dose should be taken on an empty stomach prior to the first meal of the day.

Cost Comparison

Product	Cost Per Unit	Cost Per Treatment
Vowst™ (fecal microbiota spores, live-brpk) capsule	**$1,458.33**	**$17,499.96***
Rebyota™ (fecal microbiota, live-jslm) 150mL	**$60.00**	**$9,000.00***
Zinplava™ (bezlotoxumab) 1,000mg/40mL	$95.00	$3,800.00⁺

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule or mL
*Cost per treatment course is based on the FDA approved dosing for each product.
⁺Cost per treatment course is based on the FDA approved dosing of 10mg/kg as a single dose for a 100kg patient.

Recommendations

The College of Pharmacy recommends the prior authorization of Rebyota™ (fecal microbiota, live-jslm) and Vowst™ (fecal microbiota spores, live-brpk) with the following criteria (shown in red):

Rebyota™ (Fecal Microbiota, Live-jslm) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridium difficile* infection (CDI) in members 18 years of age or older; and

2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days); and
5. The prescriber must verify that administration of Rebyota™ will occur 24 to 72 hours following completion of antibiotic course for CDI treatment; and
6. Rebyota™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and
7. For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI upon presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and
8. The member must not be using Rebyota™ in combination with Vowst™ (fecal microbiota spores, live-brpk) or Zinplava™ (bezlotoxumab); and
9. Initial approvals will be for 1 treatment course. A second treatment course may be considered following a confirmed treatment failure within 8 weeks.

Vowst™ (Fecal Microbiota Spores, Live-brpk) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridium difficile* infection (CDI) in members 18 years of age or older; and
2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days) following 10 to 21 days of antibiotic therapy; and
5. The prescriber must verify that administration of Vowst™ will occur 2 to 4 days following completion of antibiotic course for CDI treatment; and
6. The member must agree to bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst™; and
7. Vowst™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with the expertise in the treatment of CDI; and

8. A patient specific, clinically specific reason (beyond convenience) why the member cannot use Rebyota™ (fecal microbiota, live-jslm) must be provided; and
9. For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI on presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and
10. The member must not be using Vowst™ in combination with Rebyota™ (fecal microbiota, live-jslm) or Zinplava™ (bezlotoxumab); and
11. A quantity limit of 12 capsules for 3 days for 1 treatment course will apply.

Additionally, the College of Pharmacy recommends updating the current approval criteria for Zinplava™ based on the FDA approved age expansion and to be more consistent with clinical practice (changes shown in red):

Zinplava™ (Bezlotoxumab) Approval Criteria:

1. An FDA approved diagnosis of *Clostridium difficile* infection (CDI) in members ~~18~~ 1 year of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence; and
    a. Prescriber must document the member has ≥1 of the following risk factor(s) for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. One or more episodes of CDI within the 6 months prior to the episode under treatment; or
        iii. Need for ongoing therapy with concomitant antibiotics during treatment for CDI; or
        iv. Severe underlying medical disorders; or
        v. Immunocompromised; or
        vi. Clinically severe CDI (Zar score ≥2); and
2. Current or planned antibacterial drug for CDI must be provided on the prior authorization request to ensure medication is within standard of care; and
3. Prescriber must document that Zinplava™ (bezlotoxumab) will be administered while the member is receiving antibacterial drug treatment of CDI; and
4. Zinplava™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and
5. The member must not be using Zinplava™ in combination with Rebyota™ (fecal microbiota, live-jslm) or Vowst™ (fecal microbiota spores, live-brpk); 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. Approvals will be for 1 treatment course.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Fecal Microbiota Product. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product. Issued 11/30/2022. Last accessed 09/20/2023.
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Appendix D

Vote to Prior Authorize Orserdu® (Elacestrant) and Update the Approval Criteria for the Breast Cancer Medications

Oklahoma Health Care Authority
October 2023

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

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

- **December 2022:** The FDA approved Ibrance® (palbociclib) for an expanded indication for the treatment of adult patients 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 indication was previously limited to use in postmenopausal women or men, but the postmenopausal restriction has now been removed.
- **January 2023:** The FDA granted accelerated approval to Tukysa® (tucatinib) for a new indication in combination with trastuzumab for RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
- **January 2023:** The FDA approved Orserdu® (elacestrant) for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, HER2-negative, estrogen receptor 1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy.
- **February 2023:** The FDA approved Trodelvy® (sacituzumab govitecan-hziy) for a new indication for the treatment of patients with unresectable locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received endocrine-based therapy and at least 2 additional systemic therapies in the metastatic setting.
- **March 2023:** The FDA approved an expanded indication for Verzenio® (abemaciclib) with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence. This approval removes the requirement for the patient to also have a Ki-67 score ≥20%.
- **June 2023:** The FDA approved Talzenna® (talazoparib) for a new indication in combination with enzalutamide for the treatment of adult

patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

Guideline Update(s):

- **April 2023:** The current National Comprehensive Cancer Network (NCCN) Guidelines support the use of lapatinib or tucatinib in colon or rectal cancer for HER2-amplified, RAS and BRAF wild-type disease, in combination with trastuzumab, if not previously treated with a HER2 inhibitor based on positive response rates in 2 Phase 2 trials.

Orserdu® (Elacestrant) Product Summary[10]

Therapeutic Class: ER antagonist

Indication(s): Treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy

How Supplied: 86mg and 345mg oral tablets

Dose: 345mg once daily

Cost: The Wholesale Acquisition Cost (WAC) is $712.30 per 345mg tablet, resulting in a cost of $21,369 per month or $256,428 per year based on the recommended dosing.

Recommendations

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

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

The College of Pharmacy also recommends updating the approval criteria for Ibrance® (palbociclib), Talzenna® (talazoparib), Trodelvy® (sacituzumab govitecan-hziy), Tukysa® (tucatinib), and Verzenio® (abemaciclib) based on recent FDA approvals (changes and new criteria noted in red):

Ibrance® (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced, metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. In combination with:

a. An aromatase inhibitor in female members ~~postmenopausal women~~; or
b. Fulvestrant in women with disease progression following endocrine therapy; or
c. An aromatase inhibitor or fulvestrant in male patients.

Talzenna® (Talazoparib) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of metastatic, castration-resistant prostate cancer; and
2. Disease is homologous recombination repair (HRR) gene-mutated; and
3. Used in combination with enzalutamide.

Trodelvy® (Sacituzumab Govitecan-hziy) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of triple-negative breast cancer; and
   a. Unresectable locally advanced or metastatic disease; and
   b. Member must have received ≥2 prior therapies, at least 1 of which was for metastatic disease; or
2. Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
   a. Unresectable locally advanced or metastatic disease; and
   b. Member has previously received endocrine-based therapy and ≥2 additional systemic therapies in the metastatic setting.

Tukysa® (Tucatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of RAS wild-type HER2-positve unresectable or metastatic CRC; and
2. Has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy; and
3. Used in combination with trastuzumab.

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 in advanced or metastatic breast cancer; or
         3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy in metastatic breast cancer; ~~and~~ 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 ~~with Ki-67 ≥20%~~; and
d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the Tykerb® (lapatinib) approval criteria based on NCCN recommendations for use in colorectal cancer (new criteria noted in red):

Tykerb® (Lapatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable, advanced, or metastatic disease; and
2. Member has human epidermal receptor 2 (HER2)-amplified disease; and
3. Member has wild-type RAS and BRAF disease; and
4. Member meets 1 of the following:
   a. Has tried at least 1 chemotherapy regimen; or
   b. Is not a candidate for intensive therapy, according to the prescriber; and
5. Used in combination with trastuzumab; and
6. Member has not been previously treated with a HER2-inhibitor.

Lastly, the College of Pharmacy recommends updating the approval criteria for the trastuzumab products based on NCCN recommendations and net costs (changes shown in red):

Herceptin® (Trastuzumab), Herceptin Hylecta™ (Trastuzumab/ Hyaluronidase-oysk), 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), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or~~ 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), ~~Ontruzant® (trastuzumab-dttb)~~, 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), 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, ~~or~~ 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), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or~~ 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), ~~Ontruzant® (trastuzumab-dttb)~~, 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), 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), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or~~ 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), ~~Ontruzant® (trastuzumab-dttb)~~, 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.

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[1] Ibrance® (Palbociclib) – Updated Label. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/clinical-updates/clinicalupdate_ibrance_2022-1213.pdf. Issued 12/13/2022. Last accessed 09/26/2023.
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[4] U.S. FDA. FDA Approves Sacituzumab Govitecan-hziy for HR-Positive Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-sacituzumab-govitecan-hziy-hr-positive-breast-cancer. Issued 02/03/2023. Last accessed 09/26/2023.
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[8] Strickler JH, Cercek A, Siena S, et al. Additional Analyses of MOUNTAINEER: A Phase II Study of Tucatinib and Trastuzumab for HER2-Positive mCRC [Abstract]. *Ann Oncol* 2022; 33:S808-S869.
[9] Sartore-Bianchi A, Lonardi S, Martino C, et al. Pertuzumab and Trastuzumab Emtansine in Patients with HER2-amplified Metastatic Colorectal Cancer: The Phase II HERACLES-B Trial. *ESMO Open* 2020; 5(5):e000911. doi: 10.1136/esmoopen-2020-000911.
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Appendix E

Fiscal Year 2023 Annual Review of Imcivree® (Setmelanotide)

Oklahoma Health Care Authority
October 2023

Current Prior Authorization Criteria

Imcivree® (Setmelanotide) Approval Criteria:

1. An FDA approved indication of chronic weight management in adult and pediatric members 6 years of age and older with obesity due to 1 of following:
    a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or
    b. Bardet-Biedl syndrome (BBS); and
2. For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance; and
3. For BBS, diagnosis must be confirmed by the following:
    a. Molecular genetic testing to confirm variants in a BBS gene; and
    b. Clinical features of BBS, as follows:
        i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, hypogonadism in males, renal anomalies); or
        ii. Three of the primary features previously listed in 3.b.i. plus two secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, polyuria/polydipsia (nephrogenic diabetes insipidus), ataxia/poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and
4. Requests for Imcivree® for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, or other types of obesity not related to POMC, PCSK1 or LEPR deficiency, or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and
5. Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and

6. Member's baseline weight and body mass index (BMI) must be provided; and
7. Baseline BMI must be ≥30kg/m^2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
8. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree® therapy and throughout treatment; and
9. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
10. Prescriber must verify member does not have moderate, severe, or end stage renal disease [estimated glomerular filtration rate (eGFR) <60mL/min/1.73m^2]; and
11. Prescriber must verify female member is not pregnant or breastfeeding; and
12. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and
13. For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or
14. For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and
15. A quantity limit of 9mL per 30 days will apply.

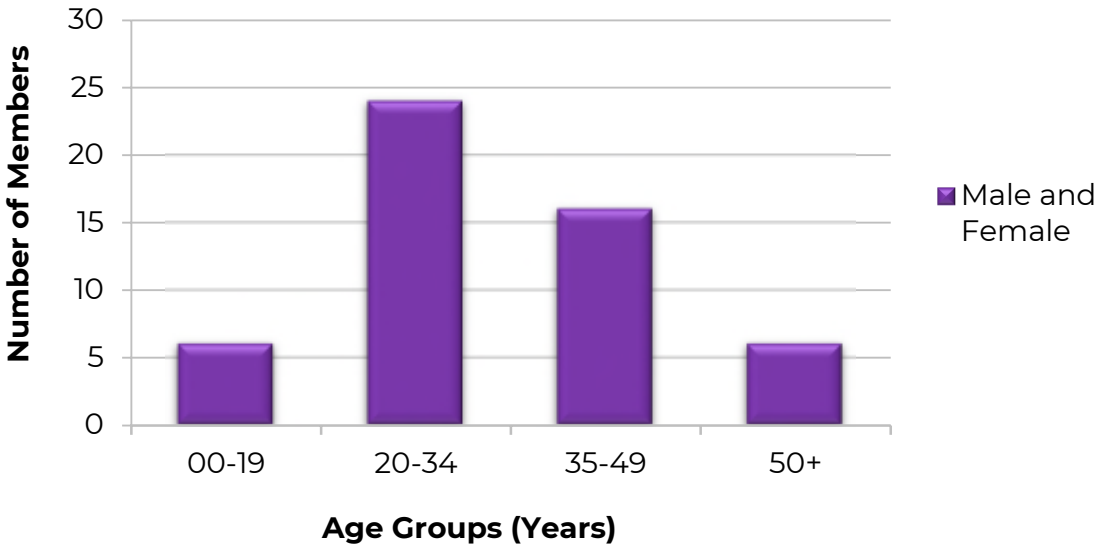
Utilization of Imcivree® (Setmelanotide): Fiscal Year 2023

Fiscal Year 2023 Utilization: Pharmacy Claims

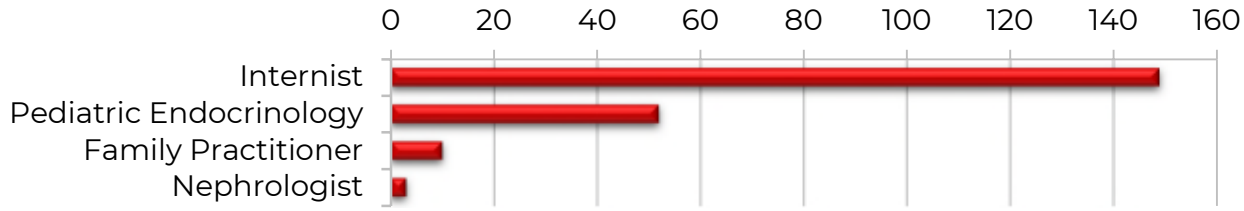
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2023	52	214	$5,476,845.64	$25,592.74	$856.69	1,659	6,393

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no paid pharmacy claims for Imcivree® during fiscal year 2022 (07/01/2021 to 06/30/2022) to allow for a fiscal year comparison.

Demographics of Members Utilizing Imcivree® (Setmelanotide)



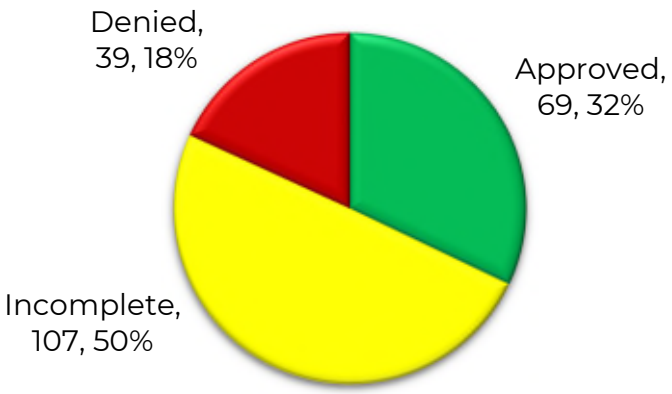
Top Prescriber Specialties of Imcivree® (Setmelanotide) by Number of Claims



Prior Authorization of Imcivree® (Setmelanotide)

There were 215 prior authorization requests submitted for Imcivree® (setmelanotide) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Imcivree® (setmelanotide): July 2034

Recommendations[2]

The College of Pharmacy, in collaboration with the Oklahoma Health Care Authority (OHCA) medical director team, recommend updating the Imcivree® (setmelanotide) approval criteria to be consistent with clinical practice and to be consistent with the current FDA approved label regarding renal function (changes shown in red):

Imcivree® (Setmelanotide) Approval Criteria:

1. An FDA approved indication of chronic weight management in adult and pediatric members 6 years of age and older with obesity due to 1 of following:
    a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or
    b. Bardet-Biedl syndrome (BBS); and
2. For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm homozygous variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (results of genetic testing must be submitted); and
3. For BBS, diagnosis must be confirmed by the following:
    a. Molecular genetic testing to confirm homozygous variants in a BBS gene that are interpreted as pathogenic or likely pathogenic (results of genetic testing must be submitted); and
    b. Clinical features of BBS supported by detailed clinical documentation of each feature (medical records/clinical documentation of each feature must be submitted), as follows:
        i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, ~~hypogonadism in males~~ hypogonadotropic hypogonadism and/or genitourinary anomalies, renal anomalies); or
        ii. Three of the primary features previously listed in 3.b.i. plus two secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, ~~polyuria/polydipsia (nephrogenic diabetes insipidus)~~, ataxia/poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left

ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and

4. Requests for Imcivree® for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign or other types of obesity not related to POMC, PCSK1, or LEPR deficiency or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and
5. Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and
6. Member's baseline weight and body mass index (BMI) must be provided; and
7. Baseline BMI must be ≥30kg/m^2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
8. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree® therapy and throughout treatment; and
9. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
10. Prescriber must verify member does not have ~~moderate, severe, or~~ end stage renal disease [estimated glomerular filtration rate (eGFR) <15~~60~~mL/min/1.73m^2] and must confirm the dose will be adjusted per package labeling for members with severe renal impairment (eGFR 15 to 29mL/min/1.73m^2); and
11. Prescriber must verify female member is not pregnant or breastfeeding; and
12. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and
13. For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or
14. For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and
15. A quantity limit of 9mL per 30 days will apply.

Utilization Details of Imcivree® (Setmelanotide): Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IMCIVREE INJ 10MG/ML	214	52	$5,476,845.64	$25,592.74	4.12	100%
TOTAL	**214**	**52***	**$5,476,845.64**	**$25,592.74**	**4.12**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[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 09/2023. Last accessed 09/27/2023.
[2] Imcivree® (Setmelanotide) Prescribing Information. Rhythm Pharmaceuticals, Inc. Available online at: https://www.rhythmtx.com/IMCIVREE/prescribing-information.pdf. Last revised 06/2022. Last accessed 10/04/2023.

Appendix F

Fiscal Year 2023 Annual Review of Hepatitis C Medications

Oklahoma Health Care Authority
October 2023

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). 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 July 2022, as a result of the VBA and as part of an initiative by the Oklahoma Health Care Authority (OHCA) to cure HCV in the SoonerCare population, Mavyret® (glecaprevir/pibrentasvir) no longer requires prior authorization. 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.

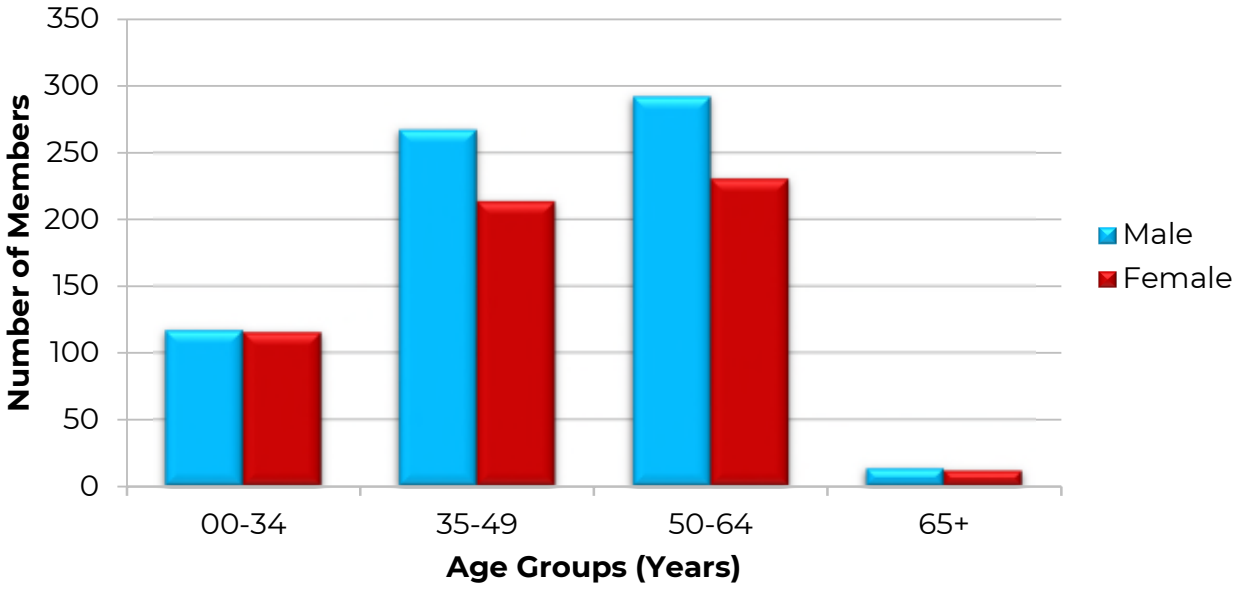
Utilization of Hepatitis C Medications: Fiscal Year 2023

Comparison of Fiscal Years

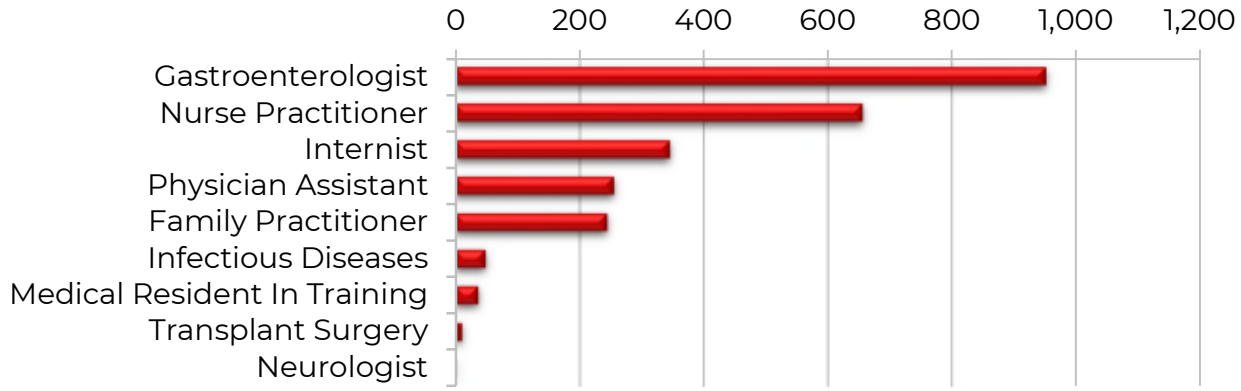
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	655	1,525	$14,704,269.08	$9,642.14	$343.96	67,964	42,750
2023	1,258	2,556	$30,368,868.57	$11,881.40	$424.25	190,923	71,582
% Change	**92.10%**	**67.60%**	**106.50%**	**23.20%**	**23.30%**	**180.90%**	**67.40%**
Change	**603**	**1,031**	**$15,664,599.49**	**$2,239.26**	**$80.29**	**122,959**	**28,832**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Hepatitis C Medications



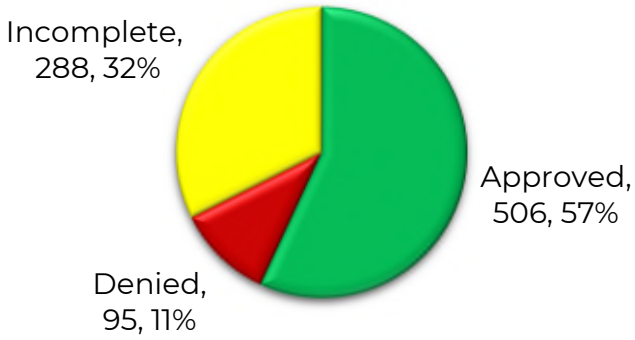
Top Prescriber Specialties of Hepatitis C Medications by Number of Claims



Prior Authorization of Hepatitis C Medications

There were 889 prior authorization requests submitted for hepatitis C medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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):

- **December 2021:** The FDA expanded the approval of Zepatier® (elbasvir/grazoprevir) to include patients 12 years of age and older or weighing at least 30kg with chronic HCV genotype 1 or 4 infection. Previously, Zepatier® was only approved in adults.

Guideline Update(s):

- **October 2022:** The AASLD/IDSA released updated guidance for the identification and management of chronic hepatitis C. Sections of the guidance where key updates occurred are listed below:
  - Initial Treatment of Adults with HCV Infection and Patients with Human Immunodeficiency Virus (HIV)/HCV Coinfection:
    - Removal of HIV as a contraindication to the simplified treatment approach
    - Addition of tenofovir disoproxil fumarate (TDF)-containing regimen with estimated glomerular filtration rate (eGFR) <60mL/min as an exclusion to the HIV coinfection simplified treatment approach given the need for additional monitoring
    - Removal of 12-week glecaprevir/pibrentasvir recommendation for HIV with cirrhosis
    - Re-ordering of all regimens by pan-genotypic activity, level of evidence, and alphabetically
  - Monitoring Patients Who are Starting HCV Treatment, Are on Treatment, or Have Completed Therapy:
    - Addition of data about the minimal monitoring HCV study (MINMON)
  - Pediatrics:
    - Addition of recommendations for sofosbuvir/velpatasvir as a treatment for DAA-experienced children and adults

News:

- **June 2023:** The Centers for Disease Control and Prevention (CDC) released a Morbidity and Mortality Weekly Report (MMWR) that showed the prevalence of viral clearance among patients who were diagnosed with HCV was only 34% overall. The study used United States longitudinal commercial laboratory data for 1.7 million patients with a history of HCV infection from January 1, 2013 to December 31, 2022. The analysis showed that 1.5 million (88%) of those patients received viral RNA testing and of those who received testing, 69% had an initial infection. Among those with an initial infection, 34% were classified as cured or cleared; and among those patients, 7% were categorized as having a persistent infection or reinfection. The report also showed that 40% of the patients covered under Medicare experienced viral clearance while only 31% under Medicaid and 23% of uninsured patients

experienced clearance. The report noted that increased access to diagnosis, treatment, and prevention services for a patient with or at risk for acquiring hepatitis C needs to be addressed to prevent progression of disease and ongoing transmission and to achieve national hepatitis elimination goals.

Recommendations

The College of Pharmacy recommends updating the approval criteria for Zepatier® (elbasvir/grazoprevir) based on the FDA approved age expansion (changes shown in red):

Zepatier® (Elbasvir/Grazoprevir) Approval Criteria:

1. Member must be 12 ~~18~~ years of age or older or weigh at least 30kg; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1 or genotype-4; and
3. Zepatier® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last three months; and
4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
5. If the member has genotype-1a, testing results for the presence of virus with NS5A resistance-associated polymorphisms must be indicated on the prior authorization request; and
6. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one 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 and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
7. The following regimens and requirements based on genotype, polymorphisms, and prior treatment status will apply (all regimens apply to patients with and without cirrhosis, HIV/HCV co-infected patients, and patients with or without renal impairment):
    a. Genotype-1a, treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms:
        i. Zepatier® for 12 weeks

   b. Genotype-1a, treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms:
      i. Zepatier® with weight-based ribavirin for 16 weeks
   c. Genotype-1b, treatment-naïve or peginterferon alfa + ribavirin experienced:
      i. Zepatier® for 12 weeks
   d. Genotype-1a or -1b, peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, teleprevir) experienced:
      i. Zepatier® with weight-based ribavirin for 12 weeks
   e. Genotype-4, treatment-naïve:
      i. Zepatier® for 12 weeks
   f. Genotype-4, treatment-experienced:
      i. Zepatier® with weight-based ribavirin for 16 weeks
   g. New regimens will apply as approved by the FDA
8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
11. Prescriber must agree to counsel members on potential harms of illicit 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
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and
14. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for ribavirin users); and
15. The prescriber must verify that the member's ALT levels will be monitored prior to treatment initiation, at treatment week eight, and as clinically indicated thereafter (patients receiving 16 weeks of therapy should receive additional ALT levels at treatment week 12); and
16. Member must not be taking the following medications: phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, bosentan, etravirine, elvitegravir/cobicstat/emtricitabine/tenofovir, or modafinil; and

17. 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
18. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
20. Members 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.
21. Approvals for treatment regimen initiation for 12 or 16 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Utilization Details of Hepatitis C Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLECAPREVIR/PIBRENTASVIR PRODUCTS						
MAVYRET TAB 100-40MG	2,045	1,051	$26,249,643.07	$12,836.01	1.95	86.44%
MAVYRET PAK 50-20MG	19	8	$200,843.91	$10,570.73	2.38	0.66%
SUBTOTAL	**2,064**	**1,059**	**$26,450,487.00**	**$12,815.16**	**1.95**	**87.10%**
SOFOSBUVIR/VELPATASVIR PRODUCTS						
SOF/VEL TAB 400-100MG	441	193	$3,441,814.01	$7,804.57	2.28	11.33%
EPCLUSA TAB 400-100MG	6	4	$149,580.46	$24,930.08	1.5	0.49%
SUBTOTAL	**447**	**197**	**$3,591,394.47**	**$8,034.44**	**2.27**	**11.83%**
RIBAVIRIN PRODUCTS						
RIBAVIRIN TAB 200MG	24	10	$2,175.52	$90.65	2.4	0.01%
RIBAVIRIN CAP 200MG	8	5	$742.77	$92.85	1.6	0.00%
SUBTOTAL	**32**	**15**	**$2,918.29**	**$91.20**	**2.13**	**0.01%**
SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR PRODUCTS						
VOSEVI TAB 400-100-100MG	13	6	$324,068.83	$24,928.37	2.17	1.07%
SUBTOTAL	**13**	**6**	**$324,068.83**	**$24,928.37**	**2.17**	**1.07%**
TOTAL	**2,556**	**1,258***	**$30,368,868.57**	**$11,881.40**	**2.03**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated members.
CAP = capsule; PAK = pack; SOF/VEL = sofosbuvir/velpatasvir; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: During fiscal year 2023, Mavyret® was the preferred DAA product for SoonerCare, as reflected in the above data.

[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 09/2023. Last accessed 09/15/2023.

[2] Park, B. Zepatier® Approval Expanded to Include HCV Treatment of Pediatric Patients. *Medical Professionals Reference*. Available online at: https://www.empr.com/home/news/zepatier-approval-expanded-to-include-hcv-treatment-of-pediatric-patients/. Issued 12/13/2021. Last accessed 09/27/2023.

[3] American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). What's New, Updates and Changes to the Guidance. Available online at: https://www.hcvguidelines.org/announcements/10242022-0000/whats-new-updates-and-changes-guidance. Last revised 10/24/2022. Last accessed 09/20/2023.

[4] Wester C, Osinubi A, Kaufman H, et al. Hepatitis C Virus Clearance Cascade—United Sates, 2013-2022. *MMWR Morb Mortal Wkly Rep* 2023; 72:716–720. doi: 10.15585/mmwr.mm7226a3.

Appendix G

Fiscal Year 2023 Annual Review of Myeloproliferative Neoplasm (MPN) Medications and 30-Day Notice to Prior Authorize Ojjaara (Momelotinib)

Oklahoma Health Care Authority
October 2023

Current Prior Authorization Criteria

Utilization data for Reblozyl® (luspatercept-aamt) and approval criteria for indications other than MPN can be found in the October 2023 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.

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

1. An FDA approved indication for the 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; and
2. 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
3. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
4. Prescriber must verify the member does not have deletion 5q (del 5q); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
6. 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
7. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
8. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and
9. 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
10. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
11. Initial approvals will be for the duration of 6 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

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

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

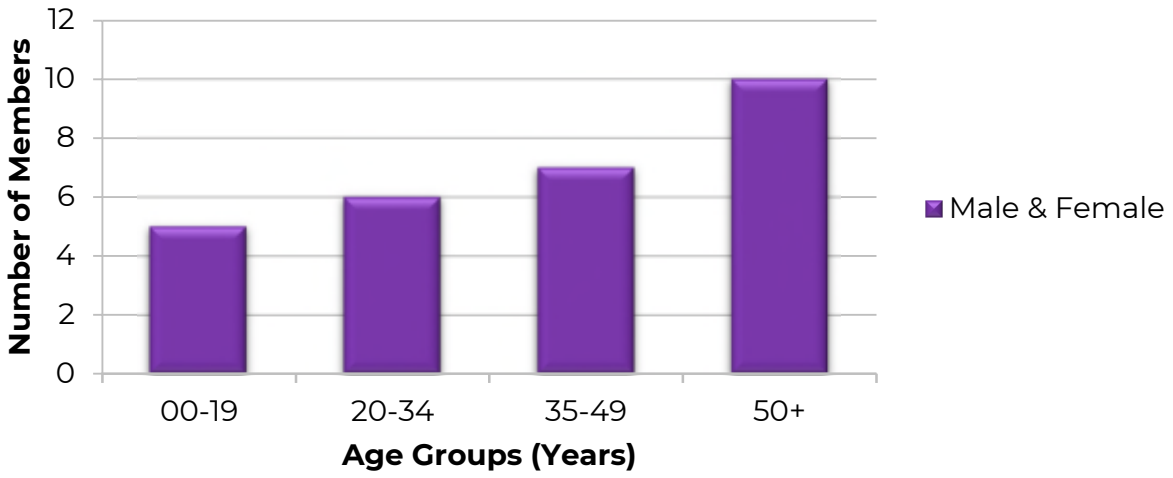
Utilization of MPN Medications: Fiscal Year 2023

Fiscal Year Comparison

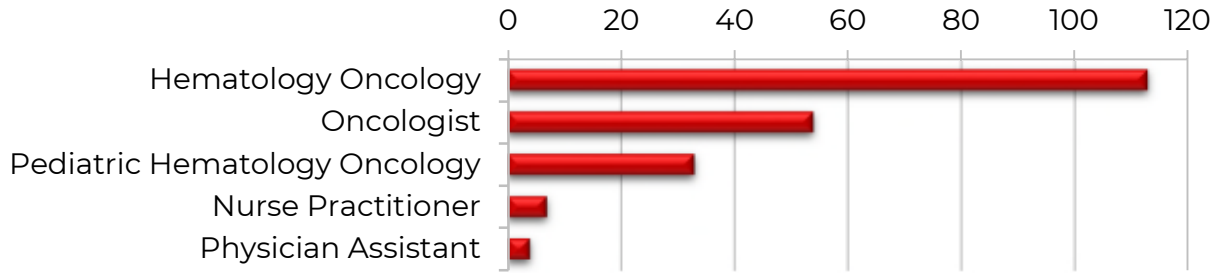
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	24	139	$2,168,007.17	$15,597.17	$484.47	8,542	4,475
2023	28	211	$3,379,741.86	$16,017.73	$520.84	12,340	6,489
% Change	**16.70%**	**51.80%**	**55.90%**	**2.70%**	**7.50%**	**44.50%**	**45.00%**
Change	**4**	**72**	**$1,211,734.69**	**$420.56**	**$36.37**	**3,798**	**2,014**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing MPN Medications



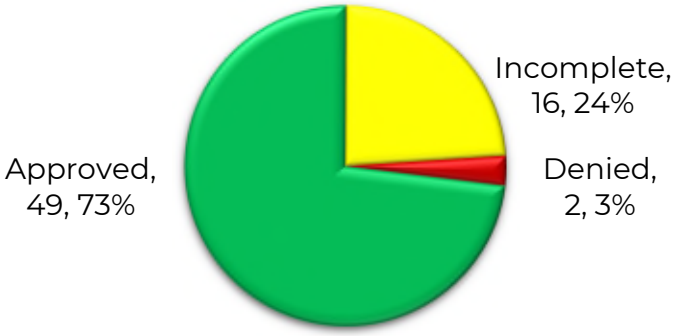
Top Prescriber Specialties of MPN Medications by Number of Claims



Prior Authorization of MPN Medications

There were 67 prior authorization requests submitted for 28 unique members for MPN medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

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

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

- **September 2023:** The FDA approved Ojjaara (momelotinib) for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

Ojjaara (Momelotinib) Product Summary[3]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of intermediate or high-risk MF, including primary MF or secondary MF (post-PV and post-ET), in adults with anemia

How Supplied: 100mg, 150mg, and 200mg oral tablets

Dose: 200mg once daily, with or without food

Cost: Cost information for Ojjaara is not yet available

Recommendations

The College of Pharmacy recommends the prior authorization of Ojjaara (momelotinib) with the following criteria (shown in red):

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.

Utilization Details of MPN Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RUXOLITINIB PRODUCTS						
JAKAFI TAB 5MG	66	12	$1,057,483.66	$16,022.48	5.5	31.29%
JAKAFI TAB 10MG	45	10	$714,987.45	$15,888.61	4.5	21.16%
JAKAFI TAB 20MG	43	5	$705,142.33	$16,398.66	8.6	20.86%
JAKAFI TAB 25MG	30	4	$491,502.35	$16,383.41	7.5	14.54%
JAKAFI TAB 15MG	27	5	$410,626.07	$15,208.37	5.4	12.15%
SUBTOTAL	**211**	**36**	**$3,379,741.86**	**$16,017.73**	**5.86**	**100%**
TOTAL	**211**	**28***	**$3,379,741.86**	**$16,017.73**	**7.54**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[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 09/2023. Last accessed 09/26/2023.
[2] GlaxoSmithKline. Ojjaara (Momelotinib) Approved in the US as the First and Only Treatment Indicated for Myelofibrosis Patients with Anaemia. Available online at: https://www.gsk.com/en-gb/media/press-releases/ojjaara-momelotinib-approved-in-the-us-as-the-first-and-only-treatment-indicated-for-myelofibrosis-patients-with-anaemia/. Issued 09/15/2023. Last accessed 09/26/2023.
[3] Ojjaara (Momelotinib) Prescribing Information. GlaxoSmithKline. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216873s000lbl.pdf. Last revised 09/2023. Last accessed 09/18/2023.

Appendix H

Fiscal Year 2023 Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Jesduvroq™ (Daprodustat)

Oklahoma Health Care Authority
October 2023

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 history of at least 1 documented red blood cell (RBC) transfusion within 6 months of initiation; and
4. Member has a hemoglobin (Hgb) level ≤10g/dL; and
5. Member has a bilirubin level above the normal reference range; and
6. Enjaymo® must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
7. Member has not received rituximab within 3 months of initiation and will not be using rituximab concomitantly with Enjaymo®; and

8. 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
9. Enjaymo® must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
10. 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
11. Prescriber must verify the member has no chronic systemic infections [e.g., hepatitis B, hepatitis C, human immunodeficiency virus (HIV)]; and
12. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
13. 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.

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

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

1. An FDA approved indication for the treatment of adult members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must require regular RBC transfusions (no transfusion-free period >35 days during the prior 6 month period); and
3. Member must not have previously received treatment with Zynteglo® (betibeglogene autotemcel); 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 for the 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; and
2. 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
3. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
4. Prescriber must verify the member does not have deletion 5q (del 5q); and
5. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
6. 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
7. Prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
8. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and
9. 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
10. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
11. Initial approvals will be for the duration of 6 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Siklos® (Hydroxyurea Tablets) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Member must be 2 years of age or older; and
3. Member must have a history of moderate-to-severe, painful crises; and

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

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 6 months 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 2023

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

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	21	120	$63,522.56	$529.35	$33.57	249	1,892
2023	11	115	$51,747.98	$449.98	$44.61	177	1,160
% Change	**-47.6%**	**-4.2%**	**-18.5%**	**-15.0%**	**32.9%**	**-28.9%**	**-38.7%**
Change	**-10**	**-5**	**-$11,774.58**	**-$79.37**	**$11.04**	**-72**	**-732**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: ESAs (Medical Claims)

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	25	98	$71,652.70	$731.15	3.92
2023	32	111	$79,588.14	$717.01	3.47
% Change	**28.0%**	**13.2%**	**11.1%**	**-1.9%**	**-11.5%**
Change	**7**	**13**	**$7,935.44**	**-$14.14**	**-0.45**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	188	934	$850,874.23	$911.00	$27.47	64,776	30,972
2023	233	1,186	$1,395,594.16	$1,176.72	$35.49	81,635	39,323
% Change	**23.9%**	**27.0%**	**64.0%**	**29.2%**	**29.2%**	**26.0%**	**27.0%**
Change	**45**	**252**	**$544,719.93**	**$265.72**	**$8.02**	**16,859**	**8,351**

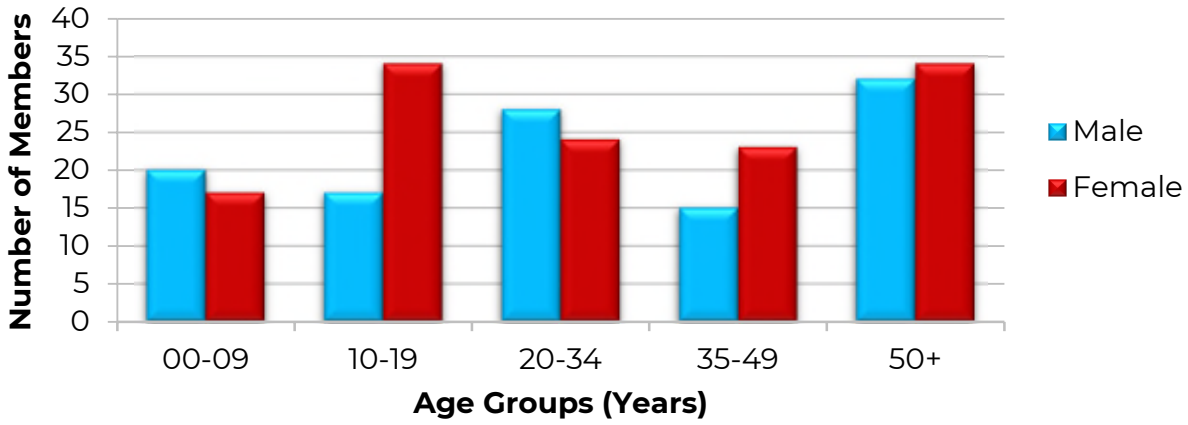
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no pharmacy claims for beta thalassemia medications during fiscal year 2022 and 2023.

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

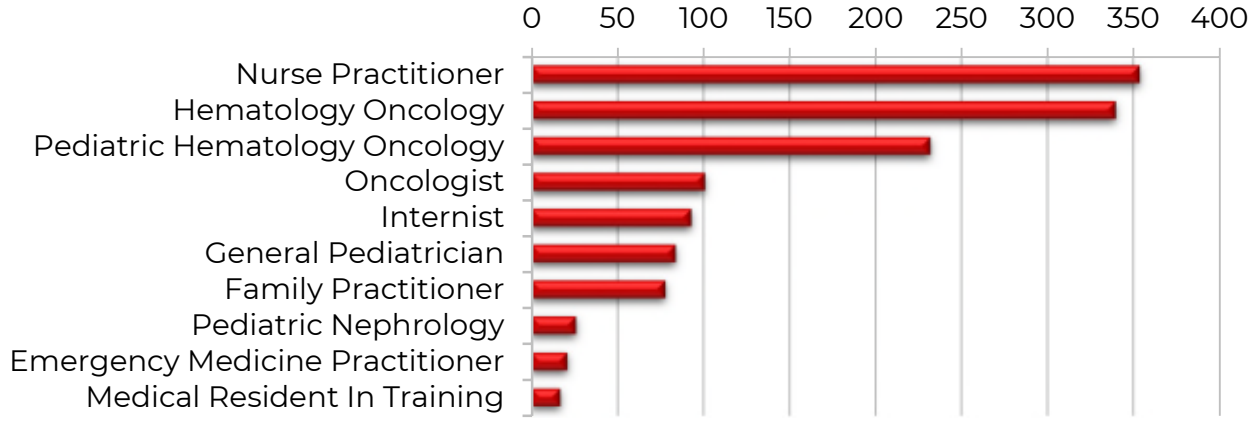
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	23	132	$1,177,699.99	$8,921.97	5.74
2023	24	170	$1,618,357.04	$9,519.75	7.08
% Change	**4.3%**	**28.8%**	**37.4%**	**6.7%**	**23.3%**
Change	**1**	**38**	**$440,657.05**	**$597.78**	**1.34**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Anemia Medications (Pharmacy Claims)



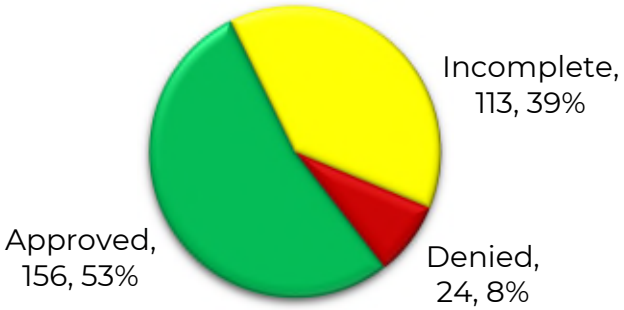
Top Prescriber Specialties of Anemia Medications by Number of Claims (Pharmacy Claims)



Prior Authorization of Anemia Medications

There were 293 prior authorization requests submitted for anemia medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

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

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

- **January 2023:** The FDA approved a supplemental Biologics License Application (sBLA) to expand the indication for Enjaymo® (sutimlimab-jome) to include patients with or without a history of transfusions. Enjaymo® was previously FDA approved for the treatment of hemolysis

in adults with cold agglutinin disease in those with a red blood cell (RBC) transfusion in the last 6 months.
- **February 2023:** The FDA approved Jesduvroq™ (daprodustat), the first oral treatment for anemia due to chronic kidney disease (CKD), in patients who have been on dialysis for at least 4 months.
- **August 2023:** Reblozyl® (luspatercept-aamt) received a label expansion to include patients with anemia who are ESA naïve with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular RBC transfusions. The new expansion places Reblozyl® as a potential first-line treatment option for these patients.

Pipeline:
- **Exagamglogene Autotemcel (Exa-cel):** Exa-cel is an investigational gene therapy that is being studied for SCD and transfusion-dependent beta thalassemia (TDT) that uses the patient's own hematopoietic stem cells to produce high levels of fetal hemoglobin. Vertex and CRISPR submitted a BLA to the FDA that has been accepted for priority review. Exa-cel has been assigned a Prescription Drug User Fee Act (PDUFA) date of December 8, 2023 for SCD and March 30, 2024 for TDT.
- **Lovotibeglogene Autotemcel (Lovo-cel):** Lovo-cel is an investigational gene therapy being studied for patients with SCD who are 12 years of age and older. It is designed to add functional copies of the β-globulin gene and allow the patient's RBCs to produce anti-sickling hemoglobin. The FDA has accepted the BLA for Lovo-cel and set a PDUFA date of December 2023.

Jesduvroq™ (Daprodustat) Product Summary[7]

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

Indication(s): Treatment of anemia due to CKD in adults on dialysis for at least 4 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; or
    - In patients not on dialysis

How Supplied: 1mg, 2mg, 4mg, 6mg, and 8mg tablets

Dosing and Administration:
- Jesduvroq™ should be taken once daily, with or without food.
- The maximum recommended dose is 24mg once daily.

- Jesduvroq™ may be administered without regard to concomitant administration of iron or phosphate binders or the timing or type of dialysis.
- The lowest dose needed to reduce the need for RBC transfusions should be used.
- The recommended starting dose will vary based on patients' hemoglobin levels and if switching from an ESA.
- Refer to the full *Prescribing Information* for the recommended starting dose, titration, and monitoring recommendations.

Cost: The Wholesale Acquisition Cost (WAC) of Jesduvroq™ is $31.28 per 8mg tablet, resulting in a monthly cost of $2,815.20 and $33,782.40 per year, based on the maximum recommended dose of 24mg once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Jesduvroq™ (daprodustat) with the following criteria (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 erythropoietin-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.

Additionally, the College of Pharmacy recommends updating the Enjaymo® (sutimlimab-jome) and Reblozyl® (luspatercept-aamt) approval criteria based on the new FDA approved label expansions (changes shown in red):

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 history of at least 1 documented red blood cell (RBC) transfusion within 6 months of initiation; and~~
4. Member has a hemoglobin (Hgb) level ≤10g/dL; and
5. Member has a bilirubin level above the normal reference range; and
6. Enjaymo® must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
7. Member has not received rituximab within 3 months of initiation and will not be using rituximab concomitantly with Enjaymo®; and
8. 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
9. Enjaymo® must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
10. 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

11. Prescriber must verify the member has no chronic systemic infections [e.g., hepatitis B, hepatitis C, human immunodeficiency virus (HIV)]; and
12. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
13. 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.

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-naïve and who required ≥2 RBC 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. 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 6 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Utilization Details of Anemia Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYUREA PRODUCTS						
HYDROXYUREA CAP 500MG	893	208	$21,241.79	$23.79	4.29	1.47%
DROXIA CAP 300MG	70	16	$3,622.94	$51.76	4.38	0.25%
DROXIA CAP 400MG	59	14	$3,463.95	$58.71	4.21	0.24%
DROXIA CAP 200MG	17	4	$760.54	$44.74	4.25	0.05%
HYDROXYUREA POW	8	3	$314.47	$39.31	2.67	0.02%
SIKLOS TAB 1,000MG	8	1	$26,746.88	$3,343.36	8	1.85%
SUBTOTAL	**1,055**	**246**	**$56,150.57**	**$53.22**	**4.29**	**3.88%**
VOXELOTOR PRODUCTS						
OXBRYTA TAB 500MG	72	13	$736,414.09	$10,227.97	5.54	50.88%
OXBRYTA TAB SUSP 300MG	54	6	$578,412.43	$10,711.34	9	39.96%
OXBRYTA TAB 300MG	1	1	$11,053.43	$11,053.43	1	0.76%
SUBTOTAL	**127**	**20**	**$1,325,879.95**	**$10,440.00**	**6.35**	**91.60%**
EPOETIN ALFA PRODUCTS						
PROCRIT INJ 20,000/ML	65	2	$22,322.17	$343.42	32.5	1.54%
EPOGEN INJ 20,000/ML	19	3	$3,300.67	$173.72	6.33	0.23%
RETACRIT INJ 2,000/ML	17	1	$511.44	$30.08	17	0.04%
EPOGEN INJ 10,000/ML	5	2	$7,352.25	$1,470.45	2.5	0.51%
PROCRIT INJ 10,000/ML	2	1	$3,229.82	$1,614.91	2	0.22%
RETACRIT INJ 40,000/ML	1	1	$6,184.21	$6,184.21	1	0.43%
EPOGEN INJ 2,000/ML	1	1	$1,205.17	$1,205.17	1	0.08%
SUBTOTAL	**110**	**11**	**$44,105.73**	**$400.96**	**10**	**3.05%**
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ 60MCG/0.3ML	3	1	$5,607.03	$1,869.01	3	0.39%
ARANESP INJ 40MCG/0.4ML	1	1	$1,249.81	$1,249.81	1	0.09%
ARANESP INJ 100MCG/ML	1	1	$785.41	$785.41	1	0.05%
SUBTOTAL	**5**	**3**	**$7,642.25**	**$1,528.45**	**1.67**	**0.53%**
GLUTAMINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ENDARI POW 5GM	4	2	$13,563.64	$3,390.91	2	0.94%
SUBTOTAL	**4**	**2**	**$13,563.64**	**$3,390.91**	**2**	**0.94%**
TOTAL	**1,301**	**244***	**$1,447,342.14**	**$1,112.48**	**5.33**	**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 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ADAKVEO INJ J0791	149	22	$1,376,235.32	$9,236.48	6.77
ARANESP INJ J0881	76	23	$73,889.00	$972.22	3.3
PROCRIT INJ J0885	35	9	$5,699.14	$162.83	3.89
REBLOZYL INJ J0896	21	2	$242,121.72	$11,529.61	10.5
TOTAL	**281**	**56**	**$1,697,945.18**	**$6,042.51**	**5.02**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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Appendix I

Fiscal Year 2023 Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Idacio® (Adalimumab-aacf), Litfulo™ (Ritlecitinib), Tofidence™ (Tocilizumab-bavi), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh)

Oklahoma Health Care Authority
October 2023

Current Prior Authorization Criteria

The current product based prior authorization (PBPA) Tier chart for the Targeted Immunomodulator Agents can be found in the *Recommendations* section at the end of this report.

Targeted Immunomodulator Agents Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. 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
3. 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. 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
3. Prior stabilization on the Tier-3 medication documented within the last 100 days; or
4. A unique FDA-approved indication not covered by Tier-2 medications.

Abrilada™ (Adalimumab-afzb), Amjevita™ (Adalimumab-atto), Cyltezo® (Adalimumab-adbm), Hadlima™ (Adalimumab-bwwd), Hulio® (Adalimumab-fkjp), and Hyrimoz® (Adalimumab-adaz) Approval Criteria:

1. Member must meet Tier-3 trial requirements; 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).

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) and Remicade® (Infliximab) Approval Criteria:

1. Member must meet Tier-3 trial requirements; and
2. A patient-specific, clinically significant reason why the member cannot use Inflectra® (Infliximab-dyyb) and Renflexis® (infliximab-abda) 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 18 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 of moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); and
2. Member must be 18 years of age or older; and
3. A minimum of a 4 week trial of a Tier-2 tumor necrosis factor (TNF) blocker indicated for the treatment of CD or UC that did not yield adequate relief of symptoms or resulted in intolerable adverse effects. Current Tier-2 medications include the following:
   a. CD: Humira® (adalimumab); or
   b. UC: Humira® (adalimumab); or
4. Prior stabilization on the medication documented within the last 100 days; and
5. A quantity limit of 300mg every 8 weeks will apply. Approvals will be granted for titration quantities required for initial dosing; and
6. 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 Tier-3 trial requirements; 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 [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.

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.

Riabni™ (Rituximab-arrx), Ruxience® (Rituximab-pvvr), and Truxima® (Rituximab-abbs) Approval Criteria:

1. Member must meet Tier-3 trial requirements; and
2. A patient-specific, clinically significant reason why the member cannot use Rituxan® (rituximab) 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.

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.

Xeljanz® (Tofacitinib) Approval Criteria:

1. Member must meet Tier-3 approval criteria; and
2. Member must have a negative tuberculosis test, successful treatment of active tuberculosis, or close evaluation and appropriate treatment of latent tuberculosis; and
3. Severe hepatic impairment has been ruled out; and
4. Approval will be for 12 weeks, after which time, prescriber must confirm performance of the following tests (and verification that the results are acceptable to prescriber) for further approval:
    a. Lymphocytes; and
    b. Neutrophils; and
    c. Hemoglobin; and
    d. Liver enzymes; and
    e. Lipid panel; and
5. Subsequent approvals will be for the duration of 1 year. Yearly approvals require performance of repeat tuberculosis test.

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.

Xeljanz® XR [Tofacitinib Extended-Release (ER)] Approval Criteria:

1. Member must meet Tier-3 approval criteria and all Xeljanz® approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot take the twice daily formulation of Xeljanz® must be provided.

Utilization of Targeted Immunomodulator Agents: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1,983	12,353	$90,375,492.17	$7,316.08	$243.81	90,069	370,679
2023	2,986	18,881	$150,568,974.72	$7,974.63	$263.21	152,957	572,056
% Change	**50.60%**	**52.80%**	**66.60%**	**9.00%**	**8.00%**	**69.80%**	**54.30%**
Change	**1,003**	**6,528**	**$60,193,482.55**	**$658.55**	**$19.40**	**62,888**	**201,377**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: Medical Claims

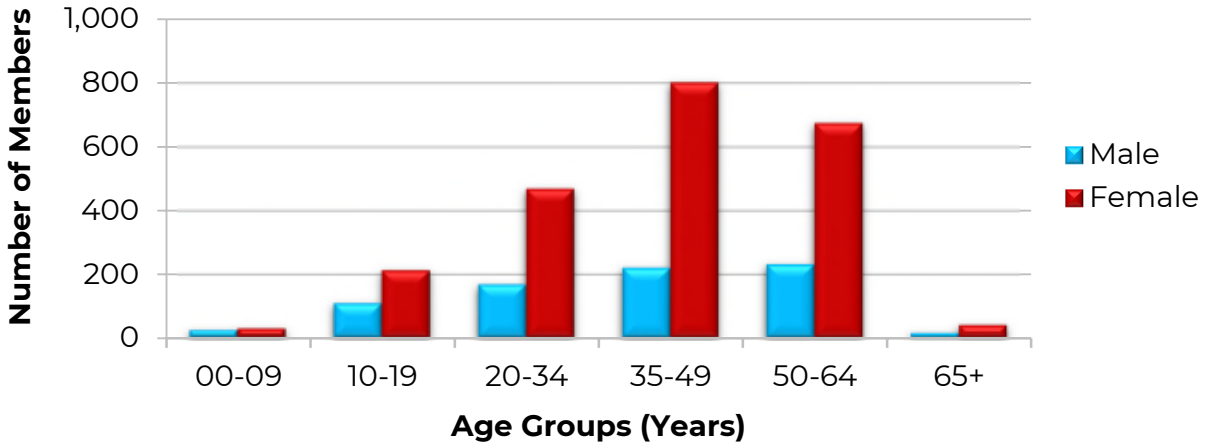
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	530	2,324	$9,054,390.79	$3,896.04	4.38
2023	733	3,289	$12,719,361.88	$3,867.24	4.49
% Change	**38.30%**	**41.52%**	**40.48%**	**-0.74%**	**2.51%**
Change	**203**	**965**	**$3,664,971.09**	**-$28.79**	**0.11**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

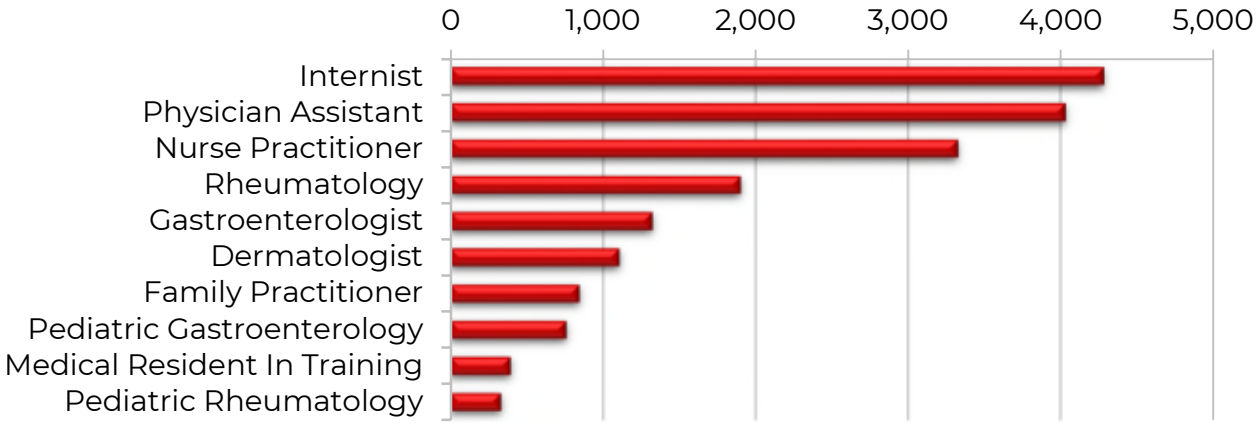
- Aggregate drug rebates collected during calendar year 2022 for Targeted Immunomodulator Agents totaled $90,061,014.62.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, calendar year 2022 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2023 (7/1/2022 to 6/30/2023) are still being collected at this time. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Targeted Immunomodulator Agents: Pharmacy Claims

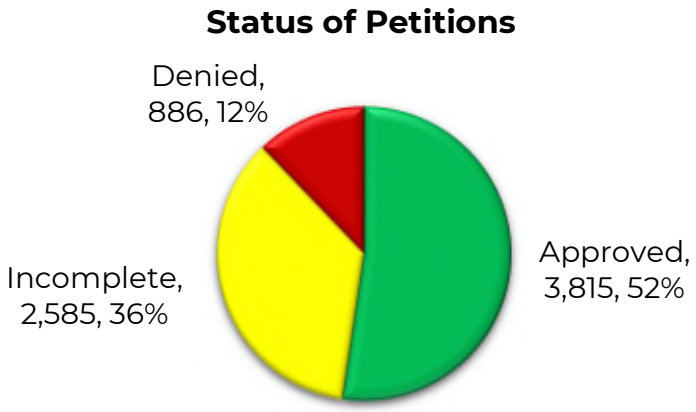


Top Prescriber Specialties of Targeted Immunomodulator Agents by Number of Claims: Pharmacy Claims



Prior Authorization of Targeted Immunomodulator Agents

There were 7,286 prior authorization requests submitted for targeted immunomodulator agents during fiscal year 2023. 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 chart shows the status of the submitted petitions for fiscal year 2023.



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

Anticipated Patent Expiration(s):

- 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): May 2034
- Litfulo™ (ritlecitinib capsule): December 2034
- Lupkynis® (voclosporin capsule): December 2037
- Rinvoq® (upadacitinib tablet): March 2038
- Tavneos® (avacopan capsule): May 2041

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

- **March 2021:** The FDA approved Actemra® (tocilizumab) for a new indication to slow the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
- **December 2021:** The FDA approved Yusimry™ (adalimumab-aqvh) as a new biosimilar to Humira® (adalimumab) for the treatment of all eligible Humira® indications.
- **June 2022:** The FDA approved Olumiant® (baricitinib) for a new indication for the treatment of adults with severe alopecia areata.
- **October 2022:** The FDA approved Rinvoq® (upadacitinib) for a new indication for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to tumor necrosis factor (TNF) blocker therapy.
- **December 2022:** The FDA approved Idacio® (adalimumab-aacf) as a new biosimilar to Humira® (adalimumab) for the treatment of all eligible Humira® indications.

- **December 2022:** The FDA approved Actemra® (tocilizumab) for a new indication for the treatment of hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
- **February 2023:** The FDA approved Kevzara® (sarilumab) for a new indication for the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate a corticosteroid taper.
- **May 2023:** The FDA approved Rinvoq® (upadacitinib) for a new indication for the treatment of adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to 1 or more TNF blockers.
- **May 2023:** The FDA approved Yuflyma® (adalimumab-aaty) as a new biosimilar to Humira® (adalimumab) for the treatment of 8 different Humira® indications.
- **June 2023:** The FDA approved Litfulo™ (ritlecitinib) for the treatment of adults and adolescents 12 years of age and older with severe alopecia areata.
- **August 2023:** The FDA approved Ilaris® (canakinumab) for a new indication for the treatment of gout flares in adults in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.
- **September 2023:** The FDA approved a new subcutaneous (sub-Q) formulation of Entyvio® (vedolizumab) for maintenance treatment of adults with moderately-to-severely active ulcerative colitis (UC) after at least 2 intravenous (IV) doses of vedolizumab. The sub-Q formulation will be available as a 108mg/0.68mL prefilled syringe or pen and the recommended dosing is 108mg every 2 weeks.
- **September 2023:** The FDA approved Tofidence™ (tocilizumab-bavi) as the first biosimilar to Actemra® (tocilizumab) for the treatment of adult patients with moderately-to-severely active rheumatoid arthritis (RA) who have had inadequate response to 1 or more disease-modifying anti-rheumatic drugs (DMARDs), the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA), and the treatment of patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA). Tofidence™ will be available as a solution for IV infusion in 80mg/4mL, 200mg/10mL, and 400mg/20mL single-dose vials (SDVs).

News:

- **January 2023:** Amjevita™ (adalimumab-atto) became the first biosimilar to Humira® (adalimumab) to be launched in the United States. Amjevita™ was the first Humira® biosimilar to be FDA approved in September 2016.
- **July 2023:** Beginning in July 2023, additional Humira® biosimilar products have been launched in the United States, including Cyltezo® (adalimumab-adbm), Hadlima™ (adalimumab-bwwd), Hulio® (adalimumab-fkjp), Hyrimoz® (adalimumab-adaz), Idacio® (adalimumab-aacf), Yuflyma® (adalimumab-aaty), and Yusimry™ (adalimumab-aqvh).

Litfulo™ (Ritlecitinib) Product Summary[19]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of severe alopecia areata in adults and adolescents 12 years of age and older

- Limitations of Use: Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

How Supplied: 50mg oral capsule

Dosing: 50mg orally once daily

Cost: The Wholesale Acquisition Cost (WAC) of Litfulo™ is $134.62 per capsule, resulting in an estimated cost of $3,769.36 per 28 days and $49,001.68 per year based on the recommended dose of 50mg once daily.

Recommendations

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

1. Creation of a new Special Prior Authorization (PA) Tier based on net cost; and
2. Updating the Tier-2 and Tier-3 approval criteria to be consistent with clinical practice to require the recommended clinical monitoring for all Tiers; and
3. Prior authorization and placement of Litfulo™ into the Special PA Tier and moving Olumiant® to the Special PA Tier with additional approval criteria for the diagnosis of alopecia areata; and
4. Prior authorization and placement of Idacio®, Yuflyma®, and Yusimry™ into the Special PA Tier based on net cost; and

5. Prior authorization and placement of Tofidence™ into the Special PA Tier with additional criteria for use of a biosimilar product; and
6. Moving Actemra® to the Special PA Tier and adding new approval criteria for the diagnosis of SSc-ILD; and
7. Moving Ilaris® to the Special PA Tier and adding new approval criteria for the diagnosis of gout flare; and
8. Adding new approval criteria for Kevzara® for the diagnosis of PMR; and
9. Moving all current Humira® and Enbrel® biosimilar products (Abrilada™, Amjevita™, Cyltezo®, Erelzi®, Eticovo™, Hadlima™, Hulio®, and Hyrimoz®), as well as Cosentyx®, Ilumya®, Rinvoq®, Skyrizi®, Sotyktu™, Stelara®, Taltz®, and Tremfya® from Tier-3 to the Special PA Tier based on net cost; and
10. Moving Inflectra®, Riabni®, Ruxience®, and Truxima® from Tier-3 to Tier-2 based on net cost; and
11. Updating the Entyvio® approval criteria based on the new sub-Q formulation and to add Inflectra® as a Tier-2 trial option; and
12. Removing the additional approval criteria for Xeljanz® and Xeljanz XR® based on net cost and to be consistent with other Tier-3 medications; and
13. Placing Arcalyst®, Benlysta®, Lupkynis®, Saphnelo®, Spevigo®, and Tavneos® into the Special PA Tier based on net cost.

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®)	~~**adalimumab-adaz (Hyrimoz®)±**~~	**adalimumab-aaty (Yuflyma®)±**
hydroxychloroquine	apremilast (Otezla®)β	~~**adalimumab-adbm (Cyltezo®)±**~~	**adalimumab-adaz (Hyrimoz®)±**
leflunomide	etanercept (Enbrel®)	~~**adalimumab-afzb (Abrilada™)±**~~	**adalimumab-adbm (Cyltezo®)±**
mesalamine	**infliximab-dyyb (Inflectra®)±**	~~**adalimumab-atto (Amjevita™)±**~~	**adalimumab-afzb (Abrilada™)±**
methotrexate	rituximab (Rituxan®)~	~~**adalimumab-bwwd (Hadlima™)±**~~	**adalimumab-aqvh (Yusimry™)±**
minocycline	**rituximab-abbs (Truxima®)±**	~~**adalimumab-fkjp (Hulio®)±**~~	**adalimumab-atto (Amjevita™)±**
NSAIDs	**rituximab-arrx (Riabni®)±**	~~**baricitinib (Olumiant®)**~~	**adalimumab-bwwd (Hadlima™)±**
oral corticosteroids	**rituximab-pvvr (Ruxience®)±**	brodalumab (Siliq®)**	**adalimumab-fkjp (Hulio®)±**
sulfasalazine		~~**canakinumab (Ilaris®)¥**~~	**anifrolumab-fnia (Saphnelo®)****

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
		certolizumab pegol (Cimzia®)	**avacopan (Tavneos®)****
		~~deucravacitinib (Sotyktu™)~~	**baricitinib (Olumiant®)€**
		~~etanercept-szzs (Erelzi®)±~~	**belimumab (Benlysta®)****
		~~etanercept-ykro (Eticovo™)±~~	**canakinumab (Ilaris®)¥**
		golimumab (Simponi®, Simponi Aria®)	**deucravacitinib (Sotyktu™)**
		~~guselkumab (Tremfya®)~~	**etanercept-szzs (Erelzi®)±**
		infliximab (Remicade®)±	**etanercept-ykro (Eticovo™)±**
		infliximab-axxq (Avsola®)±	**guselkumab (Tremfya®)**
		~~infliximab-dyyb (Inflectra®)±~~	**ixekizumab (Taltz®)**
		infliximab-abda (Renflexis®)±	**rilonacept (Arcalyst®)****
		~~ixekizumab (Taltz®)~~	**risankizumab-rzaa (Skyrizi®)**
		~~risankizumab-rzaa (Skyrizi®)~~	**ritlecitinib (Litfulo™)€**
		~~rituximab-abbs (Truxima®)±~~	**secukinumab (Cosentyx®)**
		~~rituximab-arrx (Riabni®)±~~	**spesolimab-sbzo (Spevigo®)****
		~~rituximab-pvvr (Ruxience®)±~~	**tildrakizumab-asmn (Ilumya®)**
		sarilumab (Kevzara®)§	**tocilizumab (Actemra®)¶**
		~~secukinumab (Cosentyx®)~~	**tocilizumab-bavi (Tofidence™)±**
		~~tildrakizumab-asmn (Ilumya®)~~	**upadacitinib (Rinvoq®)#**
		~~tocilizumab (Actemra®)¶~~	**ustekinumab (Stelara®)**
		tofacitinib (Xeljanz®, Xeljanz® XR, Xeljanz® oral solution)**	**voclosporin (Lupkynis®)****
		~~upadacitinib (Rinvoq®)#~~	
		~~ustekinumab (Stelara®)~~	
		vedolizumab (Entyvio®)**	

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. ~~**Appropriate laboratory monitoring must be verified by the prescriber prior to approval.**~~

[±]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), ~~**or**~~ 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).

[**]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), ~~and~~ Hyrimoz® (Adalimumab-adaz), Idacio® (Adalimumab-aacf), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh) Approval Criteria:

1. Member must meet ~~Tier-3 trial requirements~~ 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 [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.

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

1. Member must meet Tier-3 trial requirements; and
2. A patient-specific, clinically significant reason why the member cannot use Inflectra® (Infliximab-dyyb) ~~and Renflexis® (infliximab-abda)~~ 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.

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 ~~Tier-3 trial requirements~~ 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.

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.

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).

~~**Riabni™ (Rituximab-arrx), Ruxience® (Rituximab-pvvr), and Truxima® (Rituximab-abbs) Approval Criteria:**~~

~~1. Member must meet Tier 3 trial requirements; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use Rituxan® (rituximab) 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.~~

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) Approval Criteria:**~~

~~1. Member must meet Tier-3 approval criteria; and~~
~~2. Member must have a negative tuberculosis test, successful treatment of active tuberculosis, or close evaluation and appropriate treatment of latent tuberculosis; and~~
~~3. Severe hepatic impairment has been ruled out; and~~
~~4. Approval will be for 12 weeks, after which time, prescriber must confirm performance of the following tests (and verification that the results are acceptable to prescriber) for further approval:~~
~~a. Lymphocytes; and~~
~~b. Neutrophils; and~~
~~c. Hemoglobin; and~~
~~d. Liver enzymes; and~~
~~e. Lipid panel; and~~
~~5. Subsequent approvals will be for the duration of 1 year. Yearly approvals require performance of repeat tuberculosis test.~~

~~**Xeljanz® XR [Tofacitinib Extended-Release (ER)] Approval Criteria:**~~

~~1. Member must meet Tier-3 approval criteria and all Xeljanz® approval criteria; and~~
~~2. A patient-specific, clinically significant reason why the member cannot take the twice daily formulation of Xeljanz® must be provided.~~

Utilization Details of Targeted Immunomodulator Agents: Fiscal Year 2023

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	6,546	1,137	$50,041,467.20	$7,644.59	5.76	33.23%
HUMIRA INJ 40MG/0.4ML	631	128	$4,791,401.79	$7,593.35	4.93	3.18%
HUMIRA PEN INJ 40MG/0.8ML	464	111	$3,941,566.00	$8,494.75	4.18	2.62%
HUMIRA PEN INJ 80MG/0.8ML	432	85	$5,770,222.02	$13,357.00	5.08	3.83%
HUMIRA INJ 20MG/0.2ML	219	29	$1,504,164.85	$6,868.33	7.55	1.00%
HUMIRA KIT 40MG/0.8ML	217	51	$1,668,123.10	$7,687.20	4.25	1.11%
HUMIRA PEN KIT CD/UC/HS 80MG/0.8ML	144	137	$2,875,082.78	$19,965.85	1.05	1.91%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HUMIRA PEN KIT PS/UV 80MG/0.8ML & 40MG/0.4ML	135	135	$1,792,769.94	$13,279.78	1	1.19%
HUMIRA INJ 10MG/0.1ML	59	8	$364,299.58	$6,174.57	7.38	0.24%
HUMIRA PEN INJ PS/UV 40MG/0.8ML	10	7	$119,237.93	$11,923.79	1.43	0.08%
HUMIRA PEN INJ CD/UC/HS 40MG/0.8ML	7	6	$136,901.58	$19,557.37	1.17	0.09%
HUMIRA PEN KIT PED UC 80MG/0.8ML	3	3	$81,054.70	$27,018.23	1	0.05%
HUMIRA PED INJ CROHNS 80MG/0.8ML & 40MG/0.4ML	3	2	$28,878.57	$9,626.19	1.5	0.02%
HUMIRA PED INJ CROHNS 80MG/0.8ML	1	1	$19,240.98	$19,240.98	1	0.01%
SUBTOTAL	**8,871**	**1,840**	**$73,134,411.02**	**$8,244.21**	**4.82**	**48.57%**
ETANERCEPT PRODUCTS						
ENBREL SRCLK INJ 50MG/ML	2,868	553	$19,394,134.35	$6,762.25	5.19	12.88%
ENBREL INJ 50MG/ML	438	82	$3,008,459.16	$6,868.63	5.34	2.00%
ENBREL MINI INJ 50MG/ML	123	21	$815,259.91	$6,628.13	5.86	0.54%
ENBREL INJ 25MG	70	19	$361,224.22	$5,160.35	3.68	0.24%
ENBREL INJ 25MG/0.5ML	68	13	$258,001.96	$3,794.15	5.23	0.17%
ENBREL INJ 25MG	1	1	$3,293.23	$3,293.23	1	0.00%
SUBTOTAL	**3,568**	**689**	**$23,840,372.83**	**$6,681.72**	**5.18**	**15.83%**
APREMILAST PRODUCTS						
OTEZLA TAB 30MG	882	207	$3,780,101.23	$4,285.83	4.26	2.51%
OTEZLA TAB 10/20/30MG	125	110	$556,532.57	$4,452.26	1.14	0.37%
SUBTOTAL	**1,007**	**317**	**$4,336,633.80**	**$4,306.49**	**3.18**	**2.88%**
ANAKINRA PRODUCTS						
KINERET INJ 100MG/0.67ML	41	8	$205,372.99	$5,009.10	5.13	0.14%
SUBTOTAL	**41**	**8**	**$205,372.99**	**$5,009.10**	**5.13**	**0.14%**
TIER-2 SUBTOTAL	**13,487**	**2,203***	**$101,516,790.64**	**$7,527.01**	**6.12**	**67.42%**
TIER-3 PRODUCTS						
SECUKINUMAB PRODUCTS						
COSENTYX PEN INJ 300MG DOSE	460	81	$3,786,904.64	$8,232.40	5.68	2.52%
COSENTYX INJ 300MG DOSE	71	12	$553,538.81	$7,796.32	5.92	0.37%
COSENTYX PEN INJ 150MG/ML	70	23	$617,097.39	$8,815.68	3.04	0.41%
COSENTYX INJ 75MG/0.5ML	18	2	$70,128.79	$3,896.04	9	0.05%
COSENTYX INJ 150MG/ML	17	3	$113,654.59	$6,685.56	5.67	0.08%
SUBTOTAL	**636**	**121**	**$5,141,324.22**	**$8,083.84**	**5.26**	**3.41%**
UPADACITINIB PRODUCTS						
RINVOQ TAB 15MG ER	524	110	$3,017,185.66	$5,757.99	4.76	2.00%
RINVOQ TAB 30MG ER	63	14	$377,883.01	$5,998.14	4.5	0.25%
RINVOQ TAB 45MG ER	38	21	$417,902.00	$10,997.42	1.81	0.28%
SUBTOTAL	**625**	**145**	**$3,812,970.67**	**$6,100.75**	**4.31**	**2.53%**
USTEKINUMAB PRODUCTS						
STELARA INJ 90MG/ML SYR	505	109	$12,583,532.53	$24,917.89	4.63	8.36%
STELARA INJ 45MG/0.5ML SYR	46	16	$623,104.48	$13,545.75	2.88	0.41%
STELARA INJ 45MG/0.5ML VIAL	18	4	$299,541.54	$16,641.20	4.5	0.20%
STELARA INJ 5MG/ML VIAL	5	5	$25,533.86	$5,106.77	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**574**	**134**	**$13,531,712.41**	**$23,574.41**	**4.28**	**8.99%**
ABATACEPT PRODUCTS						
ORENCIA INJ 125MG/ML	300	48	$1,517,054.36	$5,056.85	6.25	1.01%
ORENCIA CLICKJECT INJ 125MG/ML	189	40	$959,328.16	$5,075.81	4.73	0.64%
ORENCIA INJ 250MG	79	9	$229,076.64	$2,899.70	8.78	0.15%
SUBTOTAL	**568**	**97**	**$2,705,459.16**	**$4,763.13**	**5.86**	**1.80%**
IXEKIZUMAB PRODUCTS						
TALTZ INJ 80MG/ML AUTO	396	76	$3,343,494.82	$8,443.17	5.21	2.22%
TALTZ INJ 80MG/ML SYR	59	10	$387,008.39	$6,559.46	5.9	0.26%
SUBTOTAL	**455**	**86**	**$3,730,503.21**	**$8,198.91**	**5.29**	**2.48%**
TOFACITINIB PRODUCTS						
XELJANZ TAB 5MG	249	50	$1,251,489.07	$5,026.06	4.98	0.83%
XELJANZ TAB 10MG	72	8	$385,597.06	$5,355.51	9	0.26%
XELJANZ XR TAB 11MG	48	13	$248,374.09	$5,174.46	3.69	0.16%
SUBTOTAL	**369**	**71**	**$1,885,460.22**	**$5,109.65**	**5.2**	**1.25%**
RISANKIZUMAB PRODUCTS						
SKYRIZI PEN INJ 150MG/ML	165	59	$3,157,695.72	$19,137.55	2.8	2.10%
SKYRIZI INJ 360MG/2.4ML	81	36	$1,548,757.85	$19,120.47	2.25	1.03%
SKYRIZI SOL 60MG/ML	62	22	$567,084.22	$9,146.52	2.82	0.38%
SKYRIZI INJ 150MG/ML	18	7	$332,628.58	$18,479.37	2.57	0.22%
SUBTOTAL	**326**	**124**	**$5,606,166.37**	**$17,196.83**	**2.63**	**3.72%**
TOCILIZUMAB PRODUCTS						
ACTEMRA INJ ACTPEN 162MG/0.9ML	207	36	$759,454.57	$3,668.86	5.75	0.50%
ACTEMRA INJ 162MG/0.9ML	64	10	$251,759.04	$3,933.74	6.4	0.17%
ACTEMRA INJ 400MG/20ML	26	5	$66,408.49	$2,554.17	5.2	0.04%
ACTEMRA INJ 80MG/4ML	14	4	$15,268.58	$1,090.61	3.5	0.01%
ACTEMRA INJ 200MG/10ML	4	3	$5,257.21	$1,314.30	1.33	0.00%
SUBTOTAL	**315**	**58**	**$1,098,147.89**	**$3,486.18**	**5.43**	**0.73%**
GUSELKUMAB PRODUCTS						
TREMFYA INJ 100MG/ML PEN	202	57	$2,617,565.80	$12,958.25	3.54	1.74%
TREMFYA INJ 100MG/ML SYR	37	9	$474,706.75	$12,829.91	4.11	0.32%
SUBTOTAL	**239**	**66**	**$3,092,272.55**	**$12,938.38**	**3.62**	**2.05%**
CERTOLIZUMAB PRODUCTS						
CIMZIA PREFL KIT 200MG/ML	159	33	$1,040,215.15	$6,542.23	4.82	0.69%
CIMZIA START KIT 200MG/ML	9	9	$134,519.13	$14,946.57	1	0.09%
SUBTOTAL	**168**	**42**	**$1,174,734.28**	**$6,992.47**	**4**	**0.78%**
INFLIXIMAB PRODUCTS						
REMICADE INJ 100MG	98	16	$714,889.81	$7,294.79	6.13	0.47%
RENFLEXIS INJ 100MG	13	2	$24,728.53	$1,902.19	6.5	0.02%
AVSOLA INJ 100MG	8	1	$24,095.33	$3,011.92	8	0.02%
INFLECTRA INJ 100MG	4	1	$8,216.74	$2,054.19	4	0.01%
SUBTOTAL	**123**	**20**	**$771,930.41**	**$6,275.86**	**6.15**	**0.51%**
CANAKINUMAB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ILARIS INJ 150MG/ML	121	16	$2,266,969.00	$18,735.28	7.56	1.51%
SUBTOTAL	**121**	**16**	**$2,266,969.00**	**$18,735.28**	**7.56**	**1.51%**
GOLIMUMAB PRODUCTS						
SIMPONI INJ 50MG/0.5ML AUTO	98	17	$547,437.36	$5,586.10	5.76	0.36%
SIMPONI INJ 50MG/0.5ML SYR	14	4	$81,697.26	$5,835.52	3.5	0.05%
SUBTOTAL	**112**	**21**	**$629,134.62**	**$5,617.27**	**5.33**	**0.42%**
SARILUMAB PRODUCTS						
KEVZARA INJ 200MG/1.14ML AUTO	60	10	$233,213.44	$3,886.89	6	0.15%
KEVZARA INJ 200MG/1.14ML SYR	14	2	$55,618.22	$3,972.73	7	0.04%
SUBTOTAL	**74**	**12**	**$288,831.66**	**$3,903.13**	**6.17**	**0.19%**
VEDOLIZUMAB PRODUCTS						
ENTYVIO INJ 300MG	38	10	$253,978.43	$6,683.64	3.8	0.17%
SUBTOTAL	**38**	**10**	**$253,978.43**	**$6,683.64**	**3.8**	**0.17%**
BARICITINIB PRODUCTS						
OLUMIANT TAB 2MG	24	4	$67,274.64	$2,803.11	6	0.04%
SUBTOTAL	**24**	**4**	**$67,274.64**	**$2,803.11**	**6**	**0.04%**
DEUCRAVACITINIB PRODUCTS						
SOTYKTU TAB 6MG	9	3	$55,562.11	$6,173.57	3	0.04%
SUBTOTAL	**9**	**3**	**$55,562.11**	**$6,173.57**	**3**	**0.04%**
TILDRAKIZUMAB PRODUCTS						
ILUMYA SOL 100MG/ML	2	1	$27,548.72	$13,774.36	2	0.02%
SUBTOTAL	**2**	**1**	**$27,548.72**	**$13,774.36**	**2**	**0.02%**
TIER-3 SUBTOTAL	**4,778**	**846***	**$46,139,980.57**	**$9,656.76**	**5.65**	**30.64%**
OTHER UTILIZATION						
BELIMUMAB PRODUCTS						
BENLYSTA INJ 200MG/ML AUTO	555	96	$2,377,197.44	$4,283.24	5.78	1.58%
BENLYSTA INJ 200MG/ML SYR	36	10	$163,737.32	$4,548.26	3.6	0.11%
SUBTOTAL	**591**	**106**	**$2,540,934.76**	**$4,299.38**	**5.58**	**1.69%**
VOCLOSPORIN PRODUCTS						
LUPKYNIS CAP 7.9MG	13	2	$157,980.83	$12,152.37	6.5	0.10%
SUBTOTAL	**13**	**2**	**$157,980.83**	**$12,152.37**	**6.5**	**0.10%**
AVACOPAN PRODUCTS						
TAVNEOS CAP 10MG	7	4	$107,557.37	$15,365.34	1.75	0.07%
SUBTOTAL	**7**	**4**	**$107,557.37**	**$15,365.34**	**1.75**	**0.07%**
RILONACEPT PRODUCTS						
ARCALYST INJ 220MG	5	1	$105,730.55	$21,146.11	5	0.07%
SUBTOTAL	**5**	**1**	**$105,730.55**	**$21,146.11**	**5**	**0.07%**
OTHER UTILIZATION SUBTOTAL	**616**	**110***	**$2,912,203.51**	**$4,727.60**	**5.6**	**1.93%**
TOTAL	**18,881**	**2,986***	**$150,568,974.72**	**$7,974.63**	**6.32**	**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 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BENLYSTA IV INJ (J0490)	781	119	$2,989,223.42	$3,827.43	6.56
RITUXAN INJ (J9312)	612	184	$2,992,695.39	$4,890.03	3.33
REMICADE INJ (J1745)	362	78	$744,040.28	$2,055.36	4.64
SIMPONI ARIA INJ (J1602)	289	83	$889,079.09	$3,076.40	3.48
ACTEMRA INJ (J3262)	258	33	$779,842.07	$3,022.64	7.82
ENTYVIO INJ (J3380)	257	58	$1,696,249.54	$6,600.19	4.43
ORENCIA INJ (J0129)	170	34	$576,724.00	$3,392.49	5
SAPHNELO INJ (J0491)	154	42	$745,771.32	$4,842.67	3.67
AVSOLA INJ (Q5121)	132	33	$209,490.16	$1,587.05	4
RENFLEXIS INJ (Q5104)	119	36	$278,425.79	$2,339.71	3.31
INFLECTRA INJ (Q5103)	46	14	$55,558.70	$1,207.80	3.29
SKYRIZI IV INJ (J2327)	39	19	$369,186.00	$9,466.31	2.05
CIMZIA INJ (J0717)	23	5	$47,484.00	$2,064.52	4.6
STELARA IV INJ (J3358)	16	16	$75,017.80	$4,688.61	1
STELARA SQ INJ (J3357)	14	6	$203,358.60	$14,525.61	2.33
TRUXIMA INJ (Q5115)	11	2	$26,660.80	$2,423.71	5.5
RUXIENCE INJ (Q5119)	4	1	$4,686.92	$1,171.73	4
ILARIS INJ (J0638)	2	1	$35,868.00	$17,934.00	2
TOTAL	**3,289⁺**	**733***	**$12,719,361.88**	**$3,867.24**	**4.49**

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 2023 = 07/01/2022 to 06/30/2023

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Appendix J

Fiscal Year 2023 Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl)

Oklahoma Health Care Authority
October 2023

Current Prior Authorization Criteria

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

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must have a confirmed mutation of the *DMD* gene that is amenable to exon skipping for the requested medication (results of genetic testing must be submitted); and
3. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
4. Prescriber must verify the member's renal function will be appropriately assessed prior to initiation of therapy and monitored during treatment; and
5. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
6. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
   a. 6-minute walk test (6MWT); or
   b. Forced vital capacity percent predicted (FVCpp); and
7. The requested exon-skipping therapy will not be approved for concurrent use with any other exon-skipping therapies for DMD; and
8. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
9. Subsequent approvals will be for the duration of 1 year. For yearly approvals, the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or

maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
10. 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.

Emflaza® (Deflazacort) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must be 2 years of age or older; and
3. Emflaza® must be prescribed by, or in consultation with, a prescriber who specializes in the treatment of DMD; and
4. Member must have a minimum 6-month trial of prednisone that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with Emflaza®; and
5. A patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed must be provided; and
6. Patients already established on deflazacort via the ACCESS DMD Program must also document a patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed; and
7. For Emflaza® suspension, a patient-specific, clinically significant reason why the member cannot use the tablet formulation in the place of oral suspension even when the tablets are crushed must be provided; and
8. Prescriber must verify the member has had a baseline eye examination; and
9. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
10. For the tablets, a quantity limit of 30 tablets per 30 days will apply, and for the suspension, a quantity limit of 39mL (3 bottles) per 30 days will apply. Quantity limit override requests will be approved as appropriate based on the member's recent weight taken within the last 30 days.

Utilization of Muscular Dystrophy Medications: Fiscal Year 2023

Comparison of Fiscal Years

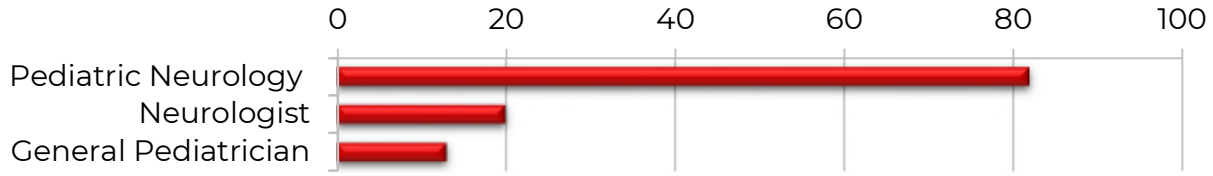
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	10	112	$8,191,595.81	$73,139.25	$2,566.29	10,848	3,192
2023	10	115	$9,220,663.34	$80,179.68	$2,834.51	11,826	3,253
% Change	**0.00%**	**2.70%**	**12.60%**	**9.60%**	**10.50%**	**9.00%**	**1.90%**
Change	**0**	**3**	**$1,029,067.53**	**$7,040.43**	**$268.22**	**978**	**61**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Muscular Dystrophy Medications

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

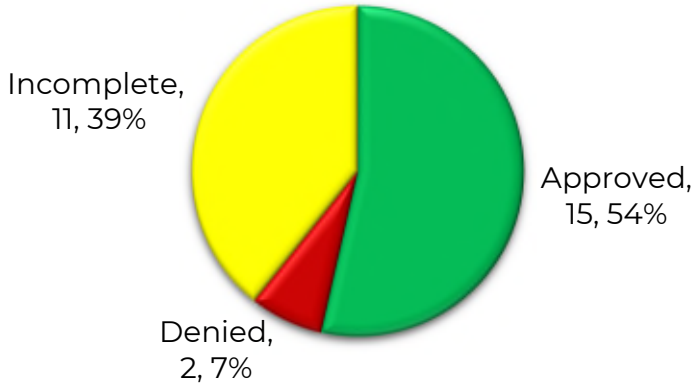
Top Prescriber Specialties of Muscular Dystrophy Medications by Number of Claims



Prior Authorization of Muscular Dystrophy Medications

There were 28 prior authorization requests submitted for muscular dystrophy medications for 9 unique members during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Vyondys 53 (golodirsen injection): June 2025
- Amondys 45 (casimersen injection): November 2030
- Viltepso® (viltolarsen injection): August 2031
- Exondys 51 (eteplirsen injection): March 2034

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

- **June 2023:** The FDA approved Elevidys (delandistrogene moxeparvovec-rokl) under the accelerated approval pathway for the treatment of pediatric patients 4 years through 5 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene. It is the first gene therapy for the treatment of DMD.

DMD is a genetic condition that is caused by a defective gene that results in the reduction or absence of dystrophin, a protein that helps keep muscle cells intact. Elevidys is a recombinant gene therapy designed to deliver a gene into the body that encodes the Elevidys micro-dystrophin protein that contains selected domains of the dystrophin protein present in normal cells. The accelerated approval is based on an increase in Elevidys micro-dystrophin protein expression in skeletal muscle in patients treated with Elevidys.

Pipeline:

- **Fordadistrogene movaparvovec:** Fordadistrogene movaparvovec is currently being studied by Pfizer in the CIFFREO Phase 3 ambulatory study. It is a gene therapy that uses an investigational recombinant adeno-associated virus serotype 9 (AAV9) capsid carrying a mini-dystrophin gene under the control of a human muscle-specific promoter. The study is still ongoing.

Elevidys (Delandistrogene Moxeparvovec-rokl) Product Summary[4]

Therapeutic Class: Adeno-associated virus (AAV) vector-based gene therapy

Indication(s): Treatment of ambulatory pediatric patients 4 through 5 years of age with DMD with a confirmed mutation in the *DMD* gene

- This indication is approved under accelerated approval based on expression of Elevidys micro-dystrophin in skeletal muscle observed in patients treated with Elevidys. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

How Supplied: Suspension for intravenous (IV) infusion with a nominal concentration of 1.33×10^{13} vector genomes (vg)/mL

Dosing and Administration:

- Elevidys is a single dose IV infusion which should be delivered over 1-2 hours at a rate of less than 10mL/kg/hr.
- Patients should be selected for treatment with Elevidys with anti-AAVrh74 total binding antibody titers <1:400.
- The recommended dosage is 1.33×10^{14} vg per kg of body weight.
- Treatment should be postponed in patients with concurrent infections until the infection has resolved.
- Patient's liver function, platelet counts, and troponin-I levels should be assessed before infusion.
- One day prior to infusion, a corticosteroid regimen should be initiated and continued for a minimum of 60 days. The dose should be modified for patients with liver abnormalities.

Cost: The Wholesale Acquisition Cost (WAC) for Elevidys is $3.2 million for the one-time treatment, regardless of the weight-based dose required.

Recommendations

The College of Pharmacy recommends the prior authorization of Elevidys (delandistrogene moxeparvovec-rokl) with the following criteria (shown in red):

Elevidys (Delandistrogene Moxeparvovec-rokl) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 4 years through 5 years of age; and
3. Prescriber must attest the member is ambulatory and the results of 1 of the following tests must be submitted:
    a. North Star Ambulatory Assessment (NSAA); or
    b. 6-minute walk test (6MWT); or
    c. 10-meter walk test (10mWT); or
    d. Ascend 4 Steps; or
    e. Time to Rise (TTR); or
    f. 100-meter timed test; and
4. Elevidys must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Member's baseline anti-AAVrh74 total binding antibody titers must be <1:400; and
6. Member must not have any deletion in exon 8 and/or exon 9 in the *DMD* gene; and
7. If the member has a deletion in the *DMD* gene in exon 1 to 17 and/or exons 59 to 71, the prescriber must verify the member will be monitored for a severe immune-mediated myositis reaction; and
8. Member must not have any active infections and if the member does have an active infection, the prescriber must verify Elevidys infusion will be postponed until infection has resolved; and
9. Prescriber must verify the member will initiate a corticosteroid regimen 1 day prior to the infusion of Elevidys and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling; and
10. Prescriber must verify liver function tests (LFTs) (e.g., GGT, total bilirubin) will be performed prior to Elevidys administration and will be monitored weekly for the first 3 months following Elevidys infusion then as clinically indicated; and

11. Prescriber must verify troponin-I will be monitored before the Elevidys infusion and weekly for the first month following infusion then as clinically indicated; and
12. Prescriber must verify that platelet counts will be monitored before the Elevidys infusion and weekly for the first 2 weeks following infusion then as clinically indicated; and
13. Member will not be approved for concomitant treatment with exon skipping therapy (e.g., Amondys 45, Exondys 51, Viltepso®, Vyondys 53) following Elevidys infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys approval); and
14. Member's current weight (kg) taken within the past 3 weeks must be provided on the request to ensure accurate weight-based dosing according to package labeling; and
15. Approvals will be for 1 dose per member per lifetime.

Additionally, the College of Pharmacy recommends the following change to the Amondys 45 (casimersen), Exondys 51 (eteplirsen), Viltepso® (viltolarsen), and Vyondys 53 (golodirsen) approval criteria based on the FDA approval of Elevidys (delandistrogene moxeparvovec-rokl) (changes shown in red):

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

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must have a confirmed mutation of the *DMD* gene that is amenable to exon skipping for the requested medication (results of genetic testing must be submitted); and
3. Member must not have previously received Elevidys (delandistrogene moxeparvovec-rokl); and
4. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Prescriber must verify the member's renal function will be appropriately assessed prior to initiation of therapy and monitored during treatment; and
6. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
7. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. 6-minute walk test (6MWT); or
    b. Forced vital capacity percent predicted (FVCpp); and

8. The requested exon-skipping therapy will not be approved for concurrent use with any other exon-skipping therapies for DMD; and
9. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
10. Subsequent approvals will be for the duration of 1 year. For yearly approvals, the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
11. 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.

Utilization Details of Muscular Dystrophy Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VYONDYS 53 INJ 100MG/2ML	41	4	$3,136,467.81	$76,499.21	10.25
AMONDYS 45 INJ 50MG/ML	38	3	$5,435,588.08	$143,041.79	12.67
EMFLAZA TAB 30MG	14	2	$163,958.40	$11,711.31	7
EXONDYS 51 SOL 100MG/2ML	8	1	$153,691.28	$19,211.41	8
EXONDYS 51 SOL 500MG/10ML	8	1	$256,091.28	$32,011.41	8
EMFLAZA TAB 36MG	6	1	$74,866.49	$12,477.75	6
TOTAL	**115**	**10***	**$9,220,663.34**	**$80,179.68**	**11.5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 09/2023. Last accessed 09/15/2023.
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Appendix K

Fiscal Year 2023 Annual Review of Spinal Muscular Atrophy (SMA) Medications

Oklahoma Health Care Authority
October 2023

Current Prior Authorization Criteria

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Molecular genetic testing to confirm bi-allelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene; and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
6. Pharmacy must confirm Evrysdi® will be constituted to an oral solution by a pharmacist prior to dispensing and must confirm Evrysdi® will be shipped via cold chain supply to adhere to the storage and handling requirements in the package labeling; and
7. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® prior to administration of the first dose; and
8. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
9. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and
10. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
11. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
12. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and

13. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and
14. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and
15. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
16. A quantity limit of 240mL per 36 days will apply.

Spinraza® (Nusinersen) Approval Criteria:

1. Diagnosis of spinal muscular atrophy (SMA):
    a. Type 1; or
    b. Type 2; or
    c. Type 3 with symptoms; and
2. Molecular genetic testing to confirm bi-allelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene; and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam); and
7. Prescriber must verify platelet count, coagulation laboratory testing, and quantitative spot urine protein testing have been assessed at baseline, levels are acceptable to the prescriber, and levels will be monitored prior to each dose; and
8. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
    a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
9. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. Hammersmith Infant Neurological Exam (HINE); or

   b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
   c. Upper Limb Module (ULM) Test; or
   d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
10. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment:
    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or
    d. HFMSE; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. Only (1) 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric members younger than 2 years of age; and
2. Member must have reached full-term gestational age prior to Zolgensma® infusion; and
3. Molecular genetic testing to confirm bi-allelic mutations in the *survival motor neuron 1* (*SMN1*) gene; and
4. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
5. Zolgensma® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests, platelet counts, and troponin-I at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Zolgensma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Zolgensma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam) or Spinraza® (nusinersen) following Zolgensma® infusion

(current authorizations for risdiplam or nusinersen will be discontinued upon Zolgensma® approval); and

11. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
12. Only 1 Zolgensma® infusion will be approved per member per lifetime.

Utilization of SMA Medications: Fiscal Year 2023

Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	28	177	$10,035,708.96	$56,698.92	$1,702.70	22,922	5,894
2023	28	213	$11,321,820.64	$53,154.09	$1,718.55	26,688	6,588
% Change	**0.0%**	**20.3%**	**12.8%**	**-6.25%**	**0.9%**	**16.4%**	**11.8%**
Change	**0**	**36**	**$1,286,111.68**	**-$3,544.83**	**$15.85**	**3,766**	**694**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Fiscal Year Comparison: Medical Claims

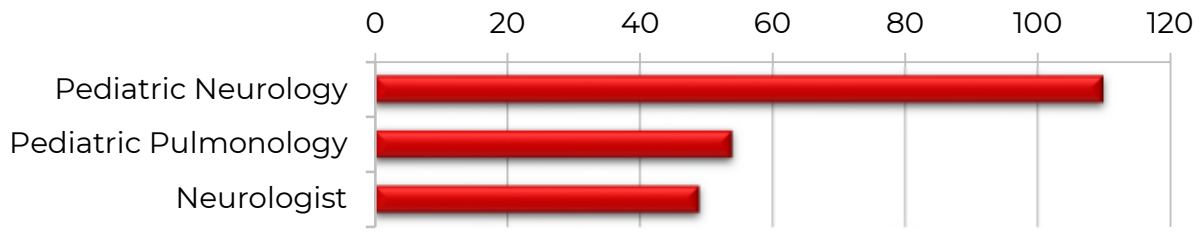
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	1	3	$510,000.00	$170,000.00	3
2023	1	3	$388,237.20	$129,412.40	3
% Change	**0.0%**	**0.0%**	**-23.88%**	**-23.88%**	**0.0%**
Change	**0**	**0**	**-$121,762.80**	**-$40,587.60**	**0**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing SMA Medications

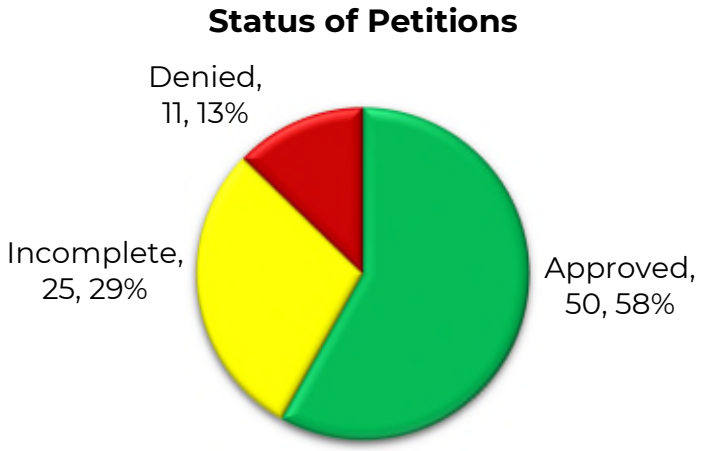
- Due to the limited number of members utilizing SMA medications during fiscal year 2023, detailed demographic information could not be provided.

Top Prescriber Specialties of SMA Medications by Number of Claims: Pharmacy Claims



Prior Authorization of SMA Medications

There were 86 prior authorization requests submitted for SMA medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



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

Anticipated Patent Expiration(s):

- Spinraza® (nusinersen): September 2035
- Evrysdi® (risdiplam): October 2038

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

- **February 2023:** The FDA approved a label update for Zolgensma® to add additional information to the *Boxed Warning* for acute liver failure to mention the deaths that have occurred due to acute liver failure and update the liver monitoring recommendations. Some notable updates include: monitoring as clinically indicated, for at least 3 months after infusion, weekly for the first month, and weekly during the corticosteroid taper. Another update included the recommendation of waiting until a patient is free of infection and clinically stable prior to administering Zolgensma®. Additionally, the recommended weight range has increased.

News:

- **March 2023:** Two long-term follow up studies have been presented that showed positive results 7.5 years after administration of Zolgensma®. LT-001 is a 15-year follow up study from the Phase 1 START study of patients who received the intravenous (IV) form of Zolgensma® and LT-002 is a 15-year follow up study from multiple Phase 3 studies of IV Zolgensma® and a Phase 1 study of an investigational intrathecal form of Zolgensma®. Both studies have shown durable response after

Zolgensma® treatment, and the results have held up over time with continued milestone success.

- **March 2023:** Genentech, the manufacturer of Evrysdi®, announced new data that shows Evrysdi® provides continuous success for the treatment of type 2/3 SMA in people 2 to 25 years of age. This data comes from the Phase 3 pivotal SUNFISH study where Evrysdi® was dosed once daily and showed lasting results over the course of 4 years. Genentech has ongoing studies being conducted that involve Evrysdi® such as JEWELFISH, RAINBOWFISH, and MANATEE; these studies are currently recruiting or have just finished enrollment.

Pipeline:

- **Apitegromab:** Scholar Rock is actively studying apitegromab (previously known as SRK-015), a human anti-proMyostatin monoclonal antibody that selectively inhibits activation of myostatin. Apitegromab will be given by IV administration every 4 weeks in the Phase 3 study SAPPHIRE in patients with type 2/3 SMA. Apitegromab will be added to either Spinraza® or Evrysdi® therapy. The main focus will be improvements in the Hammersmith Functional Motor Scale Expanded (HFMSE) total score that evaluates motor function; a higher score is indicative of being able to perform activities without the need for modification or adaptation. Scholar Rock has completed enrollment of the SAPPHIRE trial and expects results in the fourth quarter of 2024.
- **OAV-101 IT:** OAV-101 IT (an intrathecal version of Zolgensma®) is currently being investigated in 15 different countries. The STEER Phase 3 study is comparing OAV-101 IT to sham controls; after 52 weeks, the sham control group will get a one-time dose of OAV-101 IT if eligible. Novartis is also researching the benefits of OAV-101 IT in patients 2 to 12 years of age who have had either Spinraza® for at least 4 doses or Evrysdi® for at least 3 months and are currently symptomatic. This study started in January 2023 and is expected to be completed by December 2024.

Recommendations

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

Utilization Details of SMA Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
RISDIPLAM PRODUCTS					
EVRYSDI SOL 0.75MG/ML	186	16	$3,778,413.24	11.63	$20,314.05
SUBTOTAL	**186**	**16**	**$3,778,413.24**	**11.63**	**$20,314.05**
NUSINERSEN PRODUCTS					
SPINRAZA INJ 12MG/5ML	24	10	$3,032,968.12	2.4	$126,373.67
SUBTOTAL	**24**	**10**	**$3,032,968.12**	**2.4**	**$126,373.67**
ONASEMNOGENE ABEPARVOVEC-XIOI PRODUCTS					
ZOLGENSMA INJ 4x8.3ML KIT	1	1	$2,254,412.00	1	$2,254,412.00
ZOLGENSMA INJ 1x5.5ML/4x8.3ML KIT	1	1	$2,254,412.00	1	$2,254,412.00
ZOLGENSMA INJ 3x8.3MLML KIT	1	1	$1,615.28†	1	$1,615.28
SUBTOTAL	**3**	**3**	**$4,510,439.28**	**1**	**$1,503,479.76**
TOTAL	**213**	**28***	**$11,321,820.64**	**7.61**	**$53,154.09**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†This claim is for a member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.
INJ = injection; SOL = solution
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NUSINERSEN INJ J2326	3	1	$388,237.20	3	$129,412.40
TOTAL	**3**	**1**	**$388,237.20**	**3**	**$129,412.40**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 09/2023. Last accessed 09/19/2023.
[2] Zolgensma® (Onasemnogene Abeparvovec-xioi) Prescribing Information. Novartis. Available online at: https://www.novartis.com/us-en/sites/novartis_us/files/zolgensma.pdf. Last revised 02/2023. Last accessed 09/20/2023.
[3] Novartis. Novartis Shares Zolgensma® Long-term Data Demonstrating Sustained Durability Up to 7.5 Years Post-dosing; 100% Achievement of All Assessed Milestones in Children Treated Prior to SMA Symptom Onset. Available online at: https://www.novartis.com/news/media-releases/novartis-shares-zolgensma-long-term-data-demonstrating-sustained-durability-75-years-post-dosing-100-achievement-all-assessed-milestones-children-treated-prior-sma-symptom-onset. Issued 03/20/2023. Last accessed 09/19/2023.
[4] Genentech. New Four-Year Data for Genentech's Evrysdi® Reinforce Long-Term Efficacy and Safety Profile in Some of the Most Severely Affected People With Types 2 and 3 Spinal Muscular Atrophy (SMA). Available online at: https://www.gene.com/media/press-releases/14985/2023-03-19/new-four-year-data-for-genentechs-evrysd. Issued 03/19/2023. Last accessed 09/20/2023.
[5] Scholar Rock. Scholar Rock Announces Completion of Enrollment for the Phase 3 SAPPHIRE Trial. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20230919943390/en/. Issued 09/19/2023. Last accessed 09/20/2023.
[6] Novartis. Efficacy and Safety of Intrathecal OAV101 (AVXS-101) in Pediatric Patients with Type 2 Spinal Muscular Atrophy (SMA). Available online at: https://www.novartis.com/clinicaltrials/study/nct05089656. Last updated 07/18/2023. Last accessed 09/19/2023.
[7] Novartis. Phase IIIb, Open-label, Multi-center Study to Evaluate Safety, Tolerability and Efficacy of OAV101 Administered Intrathecally to Participants with SMA Who Discontinued Treatment with Nusinersen or Risdiplam. Available online at: https://www.novartis.com/clinicaltrials/study/nct05386680. Last updated 07/10/2023. Last accessed 09/19/2023.

Appendix L

30-Day Notice to Prior Authorize Veopoz™ (Pozelimab-bbfg)

Oklahoma Health Care Authority
October 2023

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

CD55-deficient protein-losing enteropathy (PLE), also known as complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease, is an ultra-rare autosomal recessive immune disease that causes an overactivation of the complement system due to mutations in the *CD55* gene. These mutations lead to the complement system attacking normal cells, causing damage to blood and lymph vessels along the upper digestive tract and leading to the loss of circulating proteins, or PLE.

It is estimated that CHAPLE disease has been diagnosed in fewer than 100 patients worldwide and fewer than 10 patients have been identified in the Unites States. Many patients begin to experience symptoms as early as 1 to 3 years of age, and symptoms can become very severe and even life threatening. Some of the common symptoms include abdominal pain, nausea, vomiting, diarrhea, loss of appetite, weight loss, impaired growth, malnutrition, anasarca, hypoalbuminemia, hypoproteinemia, hypogammaglobulinemia, and potentially severe thrombotic vascular thrombosis. Patients will also often experience recurrent flares of acute gastrointestinal symptoms and edema throughout their childhood.

CHAPLE disease is typically diagnosed through a patient's clinical history of PLE and confirmatory genetic testing showing bi-allelic mutations in the *CD55* gene. The management of CH APLE disease has historically been symptom based and supportive, and each patient's treatment should be personalized based on the symptoms. There have been limited pharmacological treatment options until August 2023 when the U.S Food and Drug Administration (FDA) approved Veopoz™ (pozelimab-bbfg) for the treatment of adult and pediatric patients 1 year of age and older with CHAPLE disease.

Veopoz™ (Pozelimab-bbfg) Product Summary[6]

Therapeutic Class: Complement inhibitor

Indication(s): Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient PLE, also known as CHAPLE disease

How Supplied: 400mg/2mL single dose vial (SDV)

Dosing and Administration:

- Loading Dose: 30mg/kg intravenous (IV) infusion
- Maintenance Dose: 10mg/kg subcutaneous (sub-Q) injection once weekly starting on day 8
  - Dose may be increased to 12mg/kg once weekly if there is inadequate clinical response after at least 3 weekly doses
  - Maximum maintenance dosage is 800mg once weekly
- Meningococcal vaccination should be completed or updated at least 2 weeks prior to administering the first dose, unless the risks of delaying therapy outweigh the risk of developing a meningococcal infection.

Cost: The Wholesale Acquisition Cost (WAC) of Veopoz™ is $17,307.69 per mL, or $34,615.38 per 400mg/2mL SDV, resulting in an estimated cost of $276,923.04 per month and $3,599,999.52 per year, based on the maximum recommended maintenance dose of 800mg once weekly.

Recommendations

The College of Pharmacy recommends the prior authorization of Veopoz™ (pozelimab-bbfg) with the following criteria (shown in red):

Veopoz™ (Pozelimab-bbfg) Approval Criteria:

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

responding well to treatment as indicated by a normalization of serum albumin or documentation of a positive clinical response to therapy.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for CD55-Deficient Protein-Losing Enteropathy (CHAPLE disease). Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-treatment-cd55-deficient-protein-losing-enteropathy-chaple-disease. Issued 08/18/2023. Last accessed 09/20/2023.

[2] Ozen A, Comrie W, Ardy R, et. al. CD55 Deficiency, Early-Onset Protein-Losing Enteropathy, and Thrombosis. *N Engl J Med* 2017; 377:52-61. doi: 10.1056/NEJMoa1615887.

[3] Regeneron Pharmaceuticals, Inc. Veopoz™ (Pozelimab-bbfg) Receives FDA Approval as the First Treatment for Children and Adults with CHAPLE Disease. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2023/08/18/2728227/0/en/Veopoz-pozelimab-bbfg-Receives-FDA-Approval-as-the-First-Treatment-for-Children-and-Adults-with-CHAPLE-Disease.html. Issued 08/18/2023. Last accessed 09/20/2023.

[4] Regeneron Pharmaceuticals, Inc. CHAPLE. Available online at: https://www.whatischaple.com/. Last revised 06/2023. Last accessed 09/20/2023.

[5] Human Disease Genes. CD55. Available online at: https://humandiseasegenes.nl/cd55. Last revised 03/14/2023. Last accessed 09/20/2023.

[6] Veopoz™ (Pozelimab-bbfg) Prescribing Information. Regeneron Pharmaceuticals. Available online at: https://www.regeneron.com/downloads/veopoz_fpi.pdf. Last revised 08/2023. Last accessed 09/20/2023.

Appendix M

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

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

FDA NEWS RELEASE

For Immediate Release: October 4, 2023

FDA Takes Steps to Advance the Development of Novel Therapies for Stimulant Use Disorders

The FDA published a new draft guidance to assist sponsors in developing treatments for stimulant use disorders. The guidance, Stimulant Use Disorders: Developing Drugs for Treatment, when finalized, will be the first to provide the FDA's current thinking on the overall development program and clinical trial design to develop drugs and biologics to support treatment of moderate to severe cocaine use disorder, methamphetamine use disorder and prescription stimulant use disorder.

Among other things, the draft guidance contains recommendations regarding clinical trial design related to evaluating stimulant use disorder treatments. Designing clinical studies to evaluate the safety and effectiveness of stimulant use disorder treatments presents a number of unique challenges, from selecting appropriate populations for studies to determining the most appropriate clinical endpoints, that require careful review. However, there are opportunities to improve clinical trial design and develop trials that are more person-centered, which may result in increased sensitivity to detect a treatment effect, with the potential for treatment effects to be linked to meaningful long-term outcomes.

The draft guidance also describes basic considerations throughout the drug development process including trial conduct, data collection, methods to assess treatment response, subject safety, and new drug application requirements. For example, the guidance incorporates lessons learned about approaches that are unlikely to be successful and reflects current recommendations about approaches for treating stimulant use disorders and evaluating response to treatment.

Stimulant use disorder describes a range of symptoms associated with the use of stimulant drugs, including methamphetamine, cocaine, and amphetamines, but not including caffeine or nicotine. A diagnosis of stimulant use disorder is made when a clinician identifies a pattern of use of an amphetamine-type substance, cocaine, or other stimulant that leads to clinically significant impairment or distress, including an inability to reduce or control consumption, cravings to use a stimulant, continued use of a stimulant despite it causing negative consequences, and the need to use increased amounts of a stimulant to achieve the desired effect.

The FDA has taken action to promote safe use and appropriate prescribing of prescription stimulants by requiring sponsors to update and standardize prescribing information for medications used to treat attention deficit/hyperactivity disorder (ADHD) and other disorders where stimulants are prescribed. Additionally, the FDA awarded the National Academies of Sciences, Engineering, and Medicine a grant to convene a workshop on the diagnosis and treatment of ADHD in adults. It has also funded several research projects to inform prevention of prescription stimulant misuse, addiction, and overdose.

The FDA continues to encourage the development of treatments for stimulant use disorder and novel trial designs. Over the last several years, the FDA has held workshops and public meetings with patients and patient advocates, researchers, industry, and

other stakeholder groups to better understand the stimulant use disorder landscape and inform the FDA's understanding of the clinical context for drug review and regulatory decision making.

FDA NEWS RELEASE

For Immediate Release: September 29, 2023

FDA Grants First Marketing Authorization for a DNA Test to Assess Predisposition for Dozens of Cancer Types

The FDA granted de novo marketing authorization for the Invitae Common Hereditary Cancers Panel, an in vitro diagnostic test that can help detect hundreds of genetic variants associated with an elevated risk of developing certain cancers. The test can also help identify potentially cancer-associated hereditary variants in individuals with already-diagnosed cancer. The test, which is the first of its kind to be granted FDA marketing authorization, evaluates DNA extracted from a blood sample to identify variants in 47 genes known to be associated with an elevated risk of developing certain types of cancer.

According to the Centers for Disease Control and Prevention, there are more than 100 different documented types of cancer. It is the second leading cause of death in the United States behind heart disease. The Invitae Common Hereditary Cancers Panel can be used as a tool to help identify inherited causes of various types of cancers. Patients should speak with a healthcare professional, such as a genetic counselor, to discuss any personal/family history of cancer, as such information can be helpful in interpreting test results. Importantly, this test is not intended to identify or evaluate all known genes that can provide insight into predisposition for cancer.

For this prescription test, the specimen is collected at the point of care and sent to a laboratory for testing. The clinical interpretation of the variants is based on evidence from published literature, public databases, prediction programs and Invitae's internal curated variants database using Invitae's variant interpretation criteria consistent with those established by appropriate professional organizations or accredited boards. Some of the most clinically significant genes that the test identifies are: BRCA1 and BRCA2, which are genes with known associations to hereditary breast and ovarian cancer syndrome, Lynch syndrome associated genes (MLH1, MSH2, MSH6, PMS2 and EPCAM), CDH1 (mainly associated with hereditary diffuse gastric cancer, and lobular breast cancer) and STK11 (associated with Peutz-Jeghers Syndrome).

The FDA reviewed the Invitae Common Hereditary Cancers Panel under the FDA's De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type. To validate the performance, Invitae tested over 9,000 clinical samples, and achieved ≥99.0% accuracy for all tested variant types. The risks associated with the test are mainly the possibility of false positive and false negative test results, as well as possible misunderstanding of the results. False negative test results may provide a false sense of assurance and these patients may not receive appropriate surveillance or clinical management. False positive test results could lead to inappropriate decision-making regarding healthcare and lifestyle, which can be associated with other undesirable clinical consequences. Further, since this test is not intended to identify or evaluate all known genes associated with a predisposition for cancer, and genetics are not the only factor in development of cancer, there is a risk of patients misunderstanding that they still have some risk of developing cancer following a negative test result. These risks are mitigated by the analytical performance validation, clinical validation, and appropriate labeling of this test.

Along with this De Novo authorization, the FDA is establishing special controls that define the requirements related to labeling and performance testing. For example, accuracy for reporting of substitutions, insertions/deletions and copy number variants must be ≥99.0% for positive agreement and ≥99.9% for negative agreement with a validated orthogonal method. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type.

This action creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through FDA's 510(k) premarket process, whereby devices can obtain marketing authorization by demonstrating substantial equivalence to a predicate device, which may save a developer time and expense compared to other review pathways.

FDA NEWS RELEASE

For Immediate Release: September 29, 2023

FDA Launches Pilot Program to Help Further Accelerate Development of Rare Disease Therapies

The FDA is taking steps to help further accelerate the development of novel drug and biological products for rare diseases. The FDA is announcing the opportunity for a limited number of sponsors to participate in a pilot program allowing for more frequent communication with FDA staff to provide a mechanism for addressing clinical development issues.

Selected participants of the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program will be able to obtain frequent advice and regular ad-hoc communication with FDA staff to address product-specific development issues, including, but not limited to, clinical study design, choice of control group and fine-tuning the choice of patient population. The program will be open to sponsors of products currently in clinical trials under an active Investigational New Drug application (IND), regulated by the Center for Biologics Evaluation and Research (CBER) and/or the Center for Drug Evaluation and Research (CDER). Eligibility criteria for the pilot differs between CBER and CDER-regulated products.

In addition to having an active IND, eligible CBER-regulated products must be a gene or cellular therapy intended to address an unmet medical need as a treatment for a rare disease or serious condition, which is likely to lead to significant disability or death within the first decade of life. Under CDER's eligibility criteria, the product must be intended to treat rare neurodegenerative conditions, including those of rare genetic metabolic type. More information on the program's eligibility requirements can be found in the Federal Register Notice.

The FDA will be accepting applications to the START program between Jan. 2, 2024, and March 1, 2024. Pilot participants will be selected based on application readiness. The FDA will select up to 3 participants for each center. Following an evaluation of this pilot and feedback from selected sponsors, the FDA may consider a second iteration, which would be announced in the Federal Register at a later date. Sponsor participation in the pilot will be considered concluded when the development program has reached a significant regulatory milestone, such as initiation of the pivotal clinical study stage or reaching the stage prior to submitting a marketing application (pre-Biologics License Application or pre-New Drug Application meeting stage), as agreed upon with the sponsor.

The FDA has undertaken additional efforts to further enhance and expedite the availability of therapies intended to treat rare diseases. The FDA recently published a Request for Information for stakeholders to provide feedback regarding critical scientific challenges and opportunities to advance the development of cellular and gene therapies designed for an individual or very small number of patients diagnosed with a rare disease. The FDA plans to use this information to inform the planning of possible future meetings, workshops, educational programs, or discussion papers to ultimately facilitate the development of additional regulatory tools and/or framework.

The FDA additionally published a docket for stakeholder feedback as part of the Learning and Education to Advance and Empower Rare Disease Drug Developers (LEADER 3D) program under the CDER Accelerating Rare disease Cures (ARC) program. Feedback will be used for the identification of knowledge gaps in rare disease drug development and the development of publicly available resources to inform stakeholders who design and conduct rare disease drug development programs on regulatory considerations surrounding clinical trial design.

The FDA will continue to enhance its evidence-based regulatory framework and recommendations for sponsors of rare disease products, as demonstrated by its active guidance pipeline. The FDA recently published the draft guidance, Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence, and in the coming months, plans to publish a number of cell and gene therapy guidance documents, further exemplifying the FDA's commitment to help deliver important products to patients in need.

FDA NEWS RELEASE

For Immediate Release: September 12, 2023

FDA Issues Warning Letters to Firms Marketing Unapproved Eye Products

The FDA has issued warning letters to 8 companies for manufacturing or marketing unapproved ophthalmic drug products in violation of federal law. These warning letters are part of the ongoing effort to protect Americans from potentially harmful ophthalmic products.

Eye products addressed in the 8 warning letters are illegally marketed to treat conditions such as conjunctivitis, cataracts, glaucoma, and others. Some of the FDA warning letters also cite the companies involved for quality issues related to product sterility. The FDA is particularly concerned that these illegally marketed, unapproved ophthalmic drug products pose a heightened risk of harm to users because drugs applied to the eyes bypass some of the body's natural defenses. Some of these eye products are labeled to contain silver, which may be characterized as silver sulfate, silver sulphate, or argentum. Long-term use of drugs containing silver can cause some areas of the skin and other body tissues, including in the eye, to permanently turn gray or blue-gray. Additionally, unapproved drugs that claim to cure, treat, or prevent serious conditions may cause consumers to delay or stop medical treatments that have been found safe and effective through the FDA review process.

The FDA issued warning letters to the following companies:

- Boiron Inc.
- CVS Health
- DR Vitamin Solutions
- Natural Ophthalmics, Inc.
- OcluMed LLC
- Similasan AG/Similasan USA

- TRP Company, Inc.
- Walgreens Boots Alliance, Inc.

Consumers currently using eye products included in these warning letters should speak to their health care professional. The FDA encourages consumers and health care professionals to report any adverse reaction to the FDA's MedWatch program. The FDA has asked the companies to respond within 15 days of receipt of the letters, stating how they will correct the violations. Failure to correct the violations promptly may result in the FDA pursuing legal action, including product seizure and/or a court order requiring a company to stop manufacturing and distributing an unapproved product. Additionally, the FDA has placed some of these companies on import alert to help stop their products from entering the United States and reaching consumers.

Current Drug Shortages Index (as of October 4, 2023):

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

Albuterol Sulfate Solution	***Currently in Shortage***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Azacitidine Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Bazedoxifene Acetate, Estrogens, Conjugated Tablet, Film Coated	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection, Solution	***Currently in Shortage***
Capecitabine Tablet	***Currently in Shortage***
Carboplatin Injection, Solution	***Currently in Shortage***
Cefixime Capsule	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection, Powder, For Solution	***Currently in Shortage***
Chloramphenicol Sodium Succinate Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection, Solution	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***

Clindamycin Phosphate Injection, Solution	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Collagenase Clostridium Histolyticum Ointment	***Currently in Shortage***
Conivaptan Hydrochloride Injection, Solution	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cyclopentolate Hydrochloride, Phenylephrine Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection, 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 Injection, Solution	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection, Solution	***Currently in Shortage***
Diazepam Gel	***Currently in Shortage***
Difluprednate Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Digoxin Injection, Solution	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol Injection	***Currently in Shortage***
Disopyramide Phosphate Capsule	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection, Solution	***Currently in Shortage***
Dulaglutide Injection, Solution	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection	***Currently in Shortage***
Erythromycin Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Fluconazole Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Sodium Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablet	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Heparin Sodium Injection, Solution	***Currently in Shortage***

Hydrocortisone Sodium Succinate Injection, Powder, For Solution	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection, Solution	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
I.V. Fat Emulsion	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Tablet, Film Coated	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection, Solution	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection, Solution	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu-177 Vipivotide Tetraxetan Injection, Solution	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mannitol Injection, Solution	***Currently in Shortage***
Mepivacaine Hydrochloride Injection, Solution	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methotrexate Sodium Injection, Solution	***Currently in Shortage***
Methotrexate Sodium Tablet	***Currently in Shortage***
Methyldopa Tablet, Film Coated	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection, Suspension	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection, Solution	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric) Injection	***Currently in Shortage***
Neomycin Sulfate Tablet	***Currently in Shortage***
Nizatidine Capsule	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Palifermin Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection, Suspension	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection, Solution, Concentrate	***Currently in Shortage***

Potassium Chloride Injection	***Currently in Shortage***
Potassium Chloride Injection, Solution	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Remifentanil Hydrochloride Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Rocuronium Bromide Injection, Solution	***Currently in Shortage***
Rocuronium Bromide Solution	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection, Solution	***Currently in Shortage***
Semaglutide Injection, Solution	***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 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection	***Currently in Shortage***
Sodium Chloride Irrigant	***Currently in Shortage***
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Somatropin Injection, Solution	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sucralfate Tablet	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablet	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection, Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injection, Suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsule	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***
Water Injection	***Currently in Shortage***
Water Irrigant	***Currently in Shortage***