OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
June 12, 2024
4:00pm

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

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

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 – June 12, 2024

DATE: June 5, 2024

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

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

Viewing Access Only via Zoom:
Please register for the meeting at:
https://oklahoma.zoom.us/webinar/register/WN_R_AmCBepQpGQggKXT40uxg
After registering, you will receive a confirmation email containing information about joining the webinar.

Enclosed are the following items related to the June 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/Concomitant Use of Opioids and Gabapentinoids Mailing Update – Appendix B

Action Item – Vote to Prior Authorize Glipizide 2.5mg Tablet, Inpefa® (Sotagliflozin), Lantidra™ (Donislecel-jujn), Metformin 625mg Tablet, Zituvio™ (Sitagliptin), and Zituvimet™ (Sitagliptin/Metformin) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone) – Appendix C

Action Item – Vote to Prior Authorize Izervay™ (Avacincaptad Pegol) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications – Appendix D

Action Item – Vote to Prior Authorize Rezzayo™ (Rezafungin) – Appendix E

Action Item – Vote to Prior Authorize PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin), Voquenza® (Vonoprazan), Voquenza® Dual Pak® (Vonoprazan/Amoxicillin), and Voquenza® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin) and Update the Approval Criteria for the Anti-Ulcer Medications – Appendix F

Action Item – Vote to Prior Authorize Augtyro™ (Repotrectinib) and Pemrydi RTU® (Pemetrexed) and Update the Approval Criteria for the Lung Cancer Medications – Appendix G

Action Item – Annual Review of Nasal Allergy Medications – Appendix H

Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Akeega® (Niraparib/Abiraterone) and Anktiva® (Nogapendekin Alfa Inbakicept-pmln) – Appendix I

Annual Review of the SoonerCare Pharmacy Benefit – Appendix J

30-Day Notice to Prior Authorize Rezdiffra™ (Resmetirom) – Appendix K

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Risvan® [Risperidone Intramuscular (IM) Injection] – Appendix L

Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-Day Notice to Prior Authorize Qalsody® (Tofersen) and Rilutek® (Riluzole Oral Tablet) – Appendix M

Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Liqrev® (Sildenafil Oral Suspension), Opsynvi® (Macitentan/Tadalafil), and Winrevair™ (Sotatercept-csrk) – Appendix N

Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Baclofen 15mg Tablet, Chlorzoxazone 250mg Tablet, Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser), Combogesic® IV [Acetaminophen/Ibuprofen Intravenous (IV)], Elyxyb™ (Celecoxib Oral Solution), Ingrezza® Sprinkle (Valbenazine), Lodoco® (Colchicine), Millipred™ (Prednisolone 5mg Tablet), Motpoly XR™ [Lacosamide

Extended-Release (ER) Capsule], Neo-Synalar® (Neomycin/Fluocinolone Cream), Ozobax® DS [Baclofen Double Strength (DS) 10mg/5mL Oral Solution], Pokonza™ (Potassium Chloride 10mEq Packet for Oral Solution), Suflave™ [Polyethylene Glycol (PEG)-3350/Sodium Sulfate/ Potassium Chloride/Magnesium Sulfate/Sodium Chloride], and Valsartan Oral Solution – Appendix O

Annual Review of Daybue™ (Trofinetide) – Appendix P

Annual Review of Joenja® (Leniolisib) – Appendix Q

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 12, 2024 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

Viewing Access Only via Zoom:

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

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

Public Comment for Meeting:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. April 10, 2024 DUR Board Meeting Minutes
   B. April 10, 2024 DUR Board Recommendations Memorandum
   C. Correspondence

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

4. **Update on Medication Coverage Authorization Unit/Concomitant Use of Opioids and Gabapentinoids Mailing Update – See Appendix B**
   A. Pharmacy Help Desk Activity for April 2024
   B. Medication Coverage Activity for April 2024
   C. Pharmacy Help Desk Activity for May 2024
   D. Medication Coverage Activity for May 2024
   E. Concomitant Use of Opioids and Gabapentinoids Mailing Update

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

5. **Action Item – Vote to Prior Authorize Glipizide 2.5mg Tablet, Inpefa® (Sotagliflozin), Lantidra™ (Donislecel-jujn), Metformin 625mg Tablet, Zituvio™ (Sitagliptin), and Zituvimet™ (Sitagliptin/Metformin) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone) – See Appendix C**
   A. Market News and Updates
   B. Product Summaries

C. Cost Comparisons
D. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Izervay™ (Avacincaptad Pegol) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications – See Appendix D**

A. Market News and Updates
B. Izervay™ (Avacincaptad Pegol) Product Summary
C. Cost Comparison: Complement Inhibitors
D. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Rezzayo™ (Rezafungin) – See Appendix E**

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

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

8. **Action Item – Vote to Prior Authorize PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin), Voquenza® (Vonoprazan), Voquenza® Dual Pak® (Vonoprazan/Amoxicillin), and Voquenza® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin) and Update the Approval Criteria for the Anti-Ulcer Medications – See Appendix F**

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

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

9. **Action Item – Vote to Prior Authorize Augtyro™ (Repotrectinib) and Pemrydi RTU® (Pemetrexed) and Update the Approval Criteria for the Lung Cancer Medications – See Appendix G**

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

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

10. **Action Item – Annual Review of Nasal Allergy Medications – See Appendix H**

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

F. Utilization Details of Nasal Allergy Medications

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

11. Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Akeega® (Niraparib/Abiraterone) and Anktiva® (Nogapendekin Alfa Inbakicept-pmln) – See Appendix I

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

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

12. Annual Review of the SoonerCare Pharmacy Benefit – See Appendix J

A. Summary
B. Medicaid Drug Rebate Program
C. Alternative Payment Models
D. Drug Approval Trends
E. Traditional Versus Specialty Pharmacy Products
F. Top 10 Traditional Therapeutic Classes by Reimbursement
G. Top 10 Specialty Therapeutic Classes by Reimbursement
H. Top 10 Medications by Reimbursement
I. Cost Per Claim
J. Market Projections
K. Conclusion
L. Top 50 Reimbursed Drugs by Calendar Year
M. Top 50 Medications by Total Number of Claims: Calendar Year 2023
N. Top 10 Traditional and Specialty Therapeutic Categories by Calendar Year
O. Calendar Year Age Group Comparison

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

13. 30-Day Notice to Prior Authorize Rezdiffra™ (Resmetirom) – See Appendix K

A. Introduction
B. Rezdiffra™ (Resmetirom) Product Summary
C. College of Pharmacy Recommendations

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

14. Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Risvan® [Risperidone Intramuscular (IM) Injection) – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of Atypical Antipsychotic Medications

C. Prior Authorization of Atypical Antipsychotic Medications
D. Oklahoma Resources
E. Market News and Updates
F. College of Pharmacy Recommendations
G. Utilization Details of Atypical Antipsychotic Medications

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

15. **Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-Day Notice to Prior Authorize Qalsody® (Tofersen) and Rilutek® (Riluzole Oral Tablet) – See Appendix M**

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

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

16. **Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Liqrev® (Sildenafil Oral Suspension), Opsynvi® (Macitentan/Tadalafil), and Winrevair™ (Sotatercept-csrk) – See Appendix N**

A. Current Prior Authorization Criteria
B. Utilization of Pulmonary Hypertension Medications
C. Prior Authorization of Pulmonary Hypertension Medications
D. Market News and Updates
E. Winrevair™ (Sotatercept-csrk) Product Summary
F. Cost Comparisons
G. College of Pharmacy Recommendations
H. Utilization Details of Pulmonary Hypertension Medications

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

17. **Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Baclofen 15mg Tablet, Chlorzoxazone 250mg Tablet, Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser), Combogesic® IV [Acetaminophen/Ibuprofen Intravenous (IV)], Elyxyb™ (Celecoxib Oral Solution), Ingrezza® Sprinkle (Valbenazine), Lodoco® (Colchicine), Millipred™ (Prednisolone 5mg Tablet), Motpoly XR™ [Lacosamide Extended-Release (ER) Capsule], Neo-Synalar® (Neomycin/Fluocinolone Cream), Ozobax® DS [Baclofen Double Strength (DS) 10mg/5mL Oral Solution], Pokonza™ (Potassium Chloride 10mEq Packet for Oral Solution), Suflave™ [Polyethylene Glycol (PEG)-3350/Sodium Sulfate/Potassium Chloride/Magnesium Sulfate/Sodium Chloride], and Valsartan Oral Solution – See Appendix O**

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Various Special Formulations
D. Prior Authorization of Various Special Formulations
E. Market News and Updates
F. Product Summaries
G. College of Pharmacy Recommendations
H. Utilization Details of Various Special Formulations

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

18. Annual Review of Daybue™ (Trofinetide) – See Appendix P

A. Current Prior Authorization Criteria
B. Utilization of Daybue™ (Trofinetide)
C. Prior Authorization of Daybue™ (Trofinetide)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Daybue™ (Trofinetide)

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

19. Annual Review of Joenja® (Leniolisib) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Joenja® (Leniolisib)
C. Prior Authorization of Joenja® (Leniolisib)
D. Market News and Updates
E. College of Pharmacy Recommendations

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

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

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

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

A. Alzheimer's Disease Medications
B. Colorectal Cancer Medications
C. Epidermolysis Bullosa (EB) Medications
D. Testosterone Products

*Future product and class reviews subject to change.

22. Adjournment

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING APRIL 10, 2024

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

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Mattie Morgan, Pharm.D.; Pharmacy Resident	X	
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Tad Autry Pharm.D., BCPS, BCOP		X
Brooke Daugherty, Pharm. D., BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.		X
Visiting Pharmacy Student(s): N/A		

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

Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director	X	

OTHERS PRESENT:	
Saurabh Patel, AbbVie	JJ Roth, Mirum
Chad Sanders, Ipsen	Ronnie DePue, Axsome
Dan O'Donnell, Axsome	Frank Alverado, Johnson & Johnson
Jessica Hurtig, Ipsen	Nima Nabavi, Amgen
Todd Ness, AbbVie	Lindsey Baker, Genentech
Rodney Brown, Genentech	Matt Latham, Ipsen
Ed Clasby, Medtronic	Deidra Williams, Humana
Kristen Winters, Centene	Tara McKinley, Madrigal
Irene Chung, Aetna	John Omick, Travere Therapeutics
Janie Huff, Madrigal	Rhonda Clark, Indivior
Scott Stepien, Ipsen	Melissa Abbott, Eisai
Paul Ford, Johnson & Johnson	Rusty Hailey, Intra-Cellular Therapies
Dana Mennen, Apellis	Bob Atkins, Biogen
Brielle Dozier, Artia Solutions	Cathy Paulson, Tarsus
Todd Dickerson, Jazz	Michael Faithe, Jazz
Jody Legg, Mirum	Mark Mohr, Genmab
John Valenti, Ipsen	David Murray, Ipsen
Nicole Willing, Genmab	Logan Poole, Novo Nordisk
Jennifer Lessor, BioLineRx	Rick Kegler, Biomarin
Ruel Martens, BioLineRx	Michaela Metts
Brent Young, Karuna	Camille Kerr, Regeneron
Alise Wagner	Garth Wright, Genentech
Chrystal Mayes, Sanofi	

PRESENT FOR PUBLIC COMMENT:	
Ronnie DePue, Axsome	Jessica Hurtig, Ipsen
John Omick, Travere Therapeutics	

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 11 RONNIE DEPUE

2B: AGENDA ITEM NO. 13 JESSICA HURTIG

2C: AGENDA ITEM NO. 19 JOHN OMICK

ACTION: NONE REQUIRED

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

3A: MARCH 13, 2024 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SOONERPSYCH AND PEDIATRIC SOONERPSYCH ANTIPSYCHOTIC MONITORING PROGRAM UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR MARCH 2024
4B: MEDICATION COVERAGE ACTIVITY FOR MARCH 2024
4C: SOONERPSYCH AND PEDIATRIC SOONERPSYCH ANTIPSYCHOTIC MONITORING PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Moss, Dr. Travers
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE ROCTAVIAN™ (VALOCTOCOGENE ROXAPARVOVEC-RVOX)**

5A: MARKET NEWS AND UPDATES
5B: ROCTAVIAN™ (VALOCTOCOGENE ROXAPARVOVEC-RVOX) PRODUCT SUMMARY
5C: OHCA RECOMMENDATIONS

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

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE NGENLA™ (SOMATROGON-GHLA) AND UPDATE THE APPROVAL CRITERIA FOR THE GROWTH HORMONE PRODUCTS AND VOXZOGO® (VOSORITIDE)**

6A: MARKET NEWS AND UPDATES
6B: NGENLA™ (SOMATROGON-GHLA) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE RYZNEUTA® (EFBEMALENOGRASTIM ALFA-VUXW) AND UPDATE THE APPROVAL CRITERIA FOR THE GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS)**

7A: MARKET NEWS AND UPDATES
7B: RYZNEUTA® (EFBEMALENOGRASTIM ALFA-VUXW) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE TYRUKO® (NATALIZUMAB-SZTN) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE SCLEROSIS (MS) MEDICATIONS**

8A: MARKET NEWS AND UPDATES
8B: TYRUKO® (NATALIZUMAB-SZTN) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE APHEXDA™ (MOTIXAFORTIDE) AND UPDATE THE APPROVAL CRITERIA FOR THE STEM CELL MOBILIZERS**

9A: MARKET NEWS AND UPDATES

9B: APHEXDA™ (MOTIXAFORTIDE) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Walton moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE COLUMVI™ (GLOFITAMAB-GXBM) AND EPKINLY™ (EPCORITAMAB-BYSP) AND UPDATE THE APPROVAL CRITERIA FOR THE LYMPHOMA MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: PRODUCT SUMMARIES
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Mr. Foster moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
11C: PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
Mr. Foster moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF PHENYLKETONURIA (PKU) MEDICATIONS
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF PKU MEDICATIONS
12C: PRIOR AUTHORIZATION OF PKU MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF PKU MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF ILEAL BILE ACID TRANSPORTER (IBAT) INHIBITORS
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF IBAT INHIBITORS
13C: PRIOR AUTHORIZATION OF IBAT INHIBITORS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF IBAT INHIBITORS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: **ANNUAL REVIEW OF LUNG CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AUGTYRO™ (REPOTRECTINIB) AND PEMRYDI RTU® (PEMETREXED)**

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF LUNG CANCER MEDICATIONS
14C: PRIOR AUTHORIZATION OF LUNG CANCER MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: AUGTYRO™ (REPOTRECTINIB) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF LUNG CANCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 15: **ANNUAL REVIEW OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE) AND 30-DAY NOTICE TO PRIOR AUTHORIZE GLIPIZIDE 2.5MG TABLET, INPEFA® (SOTAGLIFLOZIN), LANTIDRA™ (DONISLECEL-JUJN), METFORMIN 625MG TABLET, ZITUVIO™ (SITAGLIPTIN), AND ZITUVIMET™ (SITAGLIPTIN/METFORMIN)**

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15C: PRIOR AUTHORIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15D: MARKET NEWS AND UPDATES
15E: PRODUCT SUMMARIES
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)

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

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 16: **ANNUAL REVIEW OF AGE-RELATED MACULAR DEGENERATION (AMD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE IZERVAY™ (AVACINCAPTAD PEGOL)**

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF AMD MEDICATIONS
16C: PRIOR AUTHORIZATION OF AMD MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: IZERVAY™ (AVACINCAPTAD PEGOL) PRODUCT SUMMARY
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF AMD MEDICATIONS

Materials included in agenda packet; presented by Dr. Moss

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 17: **ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE PREVPAC® (LANSOPRAZOLE/ AMOXICILLIN/CLARITHROMYCIN), VOQUENZA® (VONOPRAZAN), VOQUENZA® DUAL PAK® (VONOPRAZAN/AMOXICILLIN), VOQUENZA® TRIPLE PAK® (VONOPRAZAN/AMOXICILLIN/CLARITHROMYCIN)**

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF ANTI-ULCER MEDICATIONS
17C: PRIOR AUTHORIZATION OF ANTI-ULCER MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: PRODUCT SUMMARIES

17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF ANTI-ULCER MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 18: ANNUAL REVIEW OF SYSTEMIC ANTIFUNGAL MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE REZZAYO™ (REZAFUNGIN)
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF SYSTEMIC ANTIFUNGAL MEDICATIONS
18C: PRIOR AUTHORIZATION OF SYSTEMIC ANTIFUNGAL MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: REZZAYO™ (REZAFUNGIN) PRODUCT SUMMARY
18F: COLLEGE OF PHARMACY RECOMMENDATIONS
18G: UTILIZATION DETAILS OF SYSTEMIC ANTIFUNGAL MEDICATIONS
Materials included in agenda packet; presented by Dr. Morgan
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 19: ANNUAL REVIEW OF FILSPARI™ (SPARSENTAN)
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF FILSPARI™ (SPARSENTAN)
19C: PRIOR AUTHORIZATION OF FILSPARI™ (SPARSENTAN)
19D: MARKET NEWS AND UPDATES
19E: COLLEGE OF PHARMACY RECOMMENDATIONS
19F: UTILIZATION DETAILS OF FILSPARI™ (SPARSENTAN)
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

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

AGENDA ITEM NO. 21: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
21A: NO DUR BOARD MEETING IS SCHEDULED FOR MAY 2024
21B: AMYOTROPHIC LATERAL SCLEROSIS (ALS) MEDICATIONS
21C: ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT
21D: ATYPICAL ANTIPSYCHOTIC MEDICATIONS
21E: VARIOUS SPECIAL FORMULATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 22: ADJOURNMENT
The meeting was adjourned at 5:52pm.

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

Memorandum

Date: April 11, 2024

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

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

Subject: DUR Board Recommendations from Meeting on April 10, 2024

Recommendation 1: SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote Prior Authorize Roctavian™ (Valoctocogene Roxaparvovec-rvox)

MOTION CARRIED by unanimous approval.

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

Roctavian™ (Valoctocogene Roxaparvovec-rvox) Approval Criteria:

1. An FDA approved diagnosis of severe congenital (or X-linked) hemophilia A; and
2. Member must be a male 18 years of age or older; and
3. Member must not have a history of or a recent positive screening of an inhibitor defined as ≥0.6 Bethesda units; and
4. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
5. Member must not have acute infections; and

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

Recommendation 3: Vote to Prior Authorize Ngenla® (Somatrogon-ghla) and Update the Approval Criteria for the Growth Hormone Products and Voxzogo® (Vosoritide)

MOTION CARRIED by unanimous approval.

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

Growth Hormone Products	
Tier-1*	**Tier-2**
Genotropin® (somatropin) (Pfizer) - Cartridge, MiniQuick	**Humatrope®** (somatropin) (Eli Lilly) - Vial, Cartridge Kit
	ᵗ**Ngenla®** (somatrogon-ghla) (Pfizer) - Pen
	Norditropin® (somatropin) (Novo Nordisk) - FlexPro® Pen
	Nutropin® and Nutropin AQ® (somatropin) (Genentech) - Vial, Pen Cartridge, NuSpin®
	Omnitrope® (somatropin) (Sandoz) - Vial, Cartridge
	Saizen® (somatropin) (EMD Serono) - Vial, click.easy®
	ᵗ**Serostim®** (somatropin) (EMD Serono) - Vial
	ᵗ**Skytrofa®** (lonapegsomatropin-tcgd) (Ascendis) - Cartridge
	ᵗ**Sogroya®** (somapacitan-beco) (Novo Nordisk) - Pen
	Zomacton® and Zoma-Jet® (somatropin) (Ferring) - Vial, Injection Device
	ᵗ**Zorbtive®** (somatropin) (EMD Serono) - Vial

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Supplementally rebated product(s)
ᵗAdditional approval criteria applies.

Ngenla® (Somatrogon-ghla) Approval Criteria:

1. Member must have a confirmed diagnosis of growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; and
2. Member must be 3 years of age or older; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
4. Prescriber must verify the member has been counseled on proper administration and storage of Ngenla®; and
5. Initial approvals will be for the 0.66mg/kg dose recommended in package labeling; and

6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year; and
    e. Prescriber must verify member still has open epiphyses; and
7. Ngenla® will not be approved following epiphyseal closure. Ngenla® is contraindicated in children with closed epiphyses.

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

Sogroya® (Somapacitan-beco) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
    a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting all the "Initial Approval" criteria for the member's specific diagnosis; or
    b. Adult GHD confirmed by 1 of the following:
        i. Insulin tolerance test (ITT) or glucagon test with a peak growth hormone (GH) response <3ng/mL; or
        ii. ≥3 pituitary hormone deficiencies and insulin like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and
2. Member must be ~~18~~ 2.5 years of age or older; and
3. Sogroya® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member's baseline IGF-1 level and SDS must be provided; and
5. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
6. Prescriber must verify the member does not have active malignancy or active proliferative or severe non-proliferative diabetic retinopathy; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Sogroya®; and
8. Approval quantity will be based on the FDA approved dosing in accordance with the package labeling; and
9. Initial approvals will be for the duration of 6 months. For additional approval consideration:
    a. Dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. Growth velocity should not be <2.5cm/year if not on adult dosing; and

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

10. A maximum approved dose of 8mg per week will apply for members with adult GHD.

Voxzogo® (Vosoritide) Approval Criteria:

1. Member must have an FDA approved indication of achondroplasia; and
   a. Diagnosis must be confirmed by genetic testing identifying a pathogenic mutation in the *FGFR3* gene; and
2. ~~Member must be 5 years of age or older; and~~
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height and growth velocity (GV) must be provided; and
5. Voxzogo® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and
6. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
7. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Voxzogo®, including the need for adequate food and fluid intake prior to each dose; and
8. A quantity limit of 30 vials per 30 days will apply; and
9. Initial and subsequent approvals will be for the duration of 6 months. For additional approval consideration:
   a. Member's current height must be provided and must demonstrate an improvement in GV from baseline; and
   b. Member's recent weight must be provided and dosing must be appropriate; and
   c. Member should be compliant; and
   d. Prescriber must verify member still has open epiphyses; and
10. Voxzogo® will not be approved following epiphyseal closure.

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

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

1. Initial Approval:
   a. ~~Member must be 2 years of age or older; and~~
   b. Member must have a chromosome analysis confirming the diagnosis of PWS; and

c. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
d. ~~Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and~~
e. ~~Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and~~
f. ~~Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and~~
g. Member's growth chart and parental heights must be provided; and
    i. If the form is completed, a growth chart is not required; and
    ii. Parental heights are not always available.

2. Approval Length: 6 months if criteria met, compliant, and not needing to transition to adult dosing.
3. Dosing:
    a. Pediatric Dosing: 0.5-1mg/m^2/day or 0.24mg/kg/week. Treatment should continue until 1 of the following:
        i. Epiphyseal closure; or
        ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
        iii. GV <2.5cm/year; and
    b. Adult Dosing: After attainment of adult height, adults with PWS may be considered for adult dosing if evidence is submitted documenting adult growth hormone deficiency [e.g., low insulin-like growth factor 1 (IGF-1) level and GH stimulation testing].
4. Continuation Approval:
    a. Medications and dosing should be appropriate; and
    b. Member should have had a recent office visit with new information regarding heights provided; and
    c. Member should be compliant; and
    d. GV should not be <2.5cm/year; and
    e. For members on adult dosing, recent IGF-1 level and standard deviation score (SDS) should be submitted and SDS should be between -2 and +2.

Recommendation 4: Vote to Prior Authorize Ryzneuta® (Efbemalenograstim Alfa-vuxw) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends adding Ryzneuta® (efbemalenograstim alfa-vuxw) to the current prior authorization criteria for Rolvedon® (eflapegrastim-xnst) and updating the current criteria based on net costs and to be consistent with clinical practice (changes shown in red):

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

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

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

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), ~~Granix® (tbo-filgrastim), Neupogen® (filgrastim), Zarxio® (filgrastim-sndz)~~, Neulasta® Onpro® (pegfilgrastim), or Ziextenzo® (pegfilgrastim-bmez) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
3. Neulasta® Onpro® (pegfilgrastim) will be covered as a medical only benefit without prior authorization.

Recommendation 5: Vote to Prior Authorize Tyruko® (Natalizumab-sztn) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications

MOTION CARRIED by unanimous approval.

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

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

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, or Crohn's disease in adults; and
2. For a diagnosis of MS, the following criteria will apply:

   a. Prescriber must be a neurologist or an advanced care practitioner with a supervising physician who is a neurologist; and
   b. Approvals will not be granted for concurrent use with other disease-modifying therapies; or
3. For a diagnosis of Crohn's disease, the following criteria will apply:
   a. Treatment with at least 2 different first-line therapeutic categories for Crohn's disease that have failed to yield an adequate clinical response, or a patient-specific, clinically significant reason why the member cannot use all available first- and second-line alternatives must be provided; and
4. For Tyruko®, a patient-specific, clinically significant reason why the member cannot use Tysabri® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
5. For Tyruko®, prescriber, infusion center, and member must enroll in the Tyruko® Risk Evaluation and Mitigation Strategy (REMS) program; and
6. For Tysabri®, prescriber, infusion center, and member must enroll in the TOUCH Prescribing Program; and
7. Compliance will be checked for continued approval every 6 months.

Recommendation 6: Vote to Prior Authorize Aphexda® (Motixafortide) and Update the Approval Criteria for the Stem Cell Mobilizers

MOTION CARRIED by unanimous approval.

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

Aphexda® (Motixafortide) Approval Criteria:

1. An FDA approved indication for use in combination with filgrastim to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in members with multiple myeloma (MM); and
2. Member must have an oncology diagnosis of MM. This medication is not covered for the diagnosis of leukemia; and
3. Aphexda® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and
5. Aphexda® must be given in combination with the granulocyte-colony stimulating factor (G-CSF) filgrastim per package labeling; and
6. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic plerixafor must be provided; and
7. The following dosing restrictions will apply (current body weight in kilograms is required):

a. Recommended dose is 1.25mg/kg actual body weight by subcutaneous injection 10 to 14 hours prior to initiation of apheresis; and
b. A second dose of Aphexda® can be administered 10 to 14 hours prior to a third apheresis if necessary; and

8. Approvals will be for 2 cycles for the duration of 2 months.

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

Mozobil® (Plerixafor) Approval Criteria:

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

Recommendation 7: Vote to Prior Authorize Columvi™ (Glofitamab-gxbm) and Epkinly™ (Epcoritamab-bysp) and Update the Approval Criteria for the Lymphoma Medications

MOTION CARRIED by unanimous approval.

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

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

1. Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including large B-cell lymphoma (LBCL) arising from follicular lymphoma; and
2. Has received ≥2 lines of systemic therapy; and
3. Will receive a single dose of obinutuzumab for pre-treatment purposes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recommendation 8: Calendar Year 2023 Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications

MOTION CARRIED by unanimous approval.

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

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

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

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

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
methylphenidate ER (Ritalin SR®)			methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)Δ
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
+Unique criteria applies for the diagnosis of binge eating disorder (BED).
ΔUnique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 180 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. For ~~Dyanavel® XR oral suspension and~~ Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Kapvay® [Clonidine Extended-Release (ER) Tablet] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
   c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and

3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
4. For Dyanavel® XR oral suspension, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted psychiatrist.
3. For Daytrana® patches, Methylin® oral solution, and Vyvanse® chewable tablet, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
    a. Daytrana® patches and Vyvanse® chewable tablets are brand preferred. Approval of generic methylphenidate transdermal patches or lisdexamfetamine chewable tablets will require a patient-specific, clinically significant reason why brand name Daytrana® or Vyvanse® cannot be used.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
    a. An FDA approved diagnosis of moderate-to-severe BED; and
    b. Member must be 18 years of age or older; and
    c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
    d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
    e. Vyvanse® is brand preferred. Approval of generic lisdexamfetamine will require a patient-specific, clinically significant reason why brand name Vyvanse® cannot be used; and
    f. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and

g. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
   a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
   b. Absence of cataplexy; and
   c. Multiple sleep latency test (MSLT) results showing 1 of the following:
      i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
      ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
   d. At least 1 of the following:
      i. MSLT showing mean sleep latency ≤8 minutes; or
      ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
   e. Insufficient sleep syndrome has been ruled out; and
   f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and
2. Diagnosis must be confirmed by a sleep specialist; and
~~3. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and~~
   ~~a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and~~
~~4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and~~
5. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
   a. Tier-1 stimulant; or
   b. Tier-2 stimulant; or
   c. Nuvigil® (armodafinil); or
   d. Provigil® (modafinil); or
   e. Clarithromycin; and

6. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
7. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. ~~Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and~~
    a. ~~Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or~~
3. ~~Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or~~
4. Use of Lumryz™ (sodium oxybate), Sunosi® (solriamfetol), Wakix® (pitolisant), Xyrem® (sodium oxybate), or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with Tier-1 and Tier-2 stimulants from different chemical categories, Provigil® (modafinil), and Nuvigil® (armodafinil), unless contraindicated, that did not yield adequate results; and
    a. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
5. Additionally, use of Lumryz™ (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided; and
6. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Recommendation 9: Calendar Year 2023 Annual Review of Phenylketonuria (PKU) Medications

MOTION CARRIED by unanimous approval.

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

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

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

≤600micromol/L, approvals may be granted for the 60mg once daily dosing for an additional 16 weeks of treatment; or

c. If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L, subsequent approvals will be for the duration of 1 year; and

10. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600micromol/L after at least 16 weeks of continuous treatment with the maximum dosage of ~~40~~ 60mg once daily will not be approved for subsequent approvals; and
11. Subsequent approvals will be for the duration of 1 year; and
12. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

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

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

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

the member did not respond to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and

8. Subsequent approvals will be for the duration of 1 year; and
9. Reauthorization will require the following:
   a. Documentation of active management with a phenylalanine restricted diet; and
   b. Verification from the prescriber of continued response to therapy.

Recommendation 10: Calendar Year 2023 Annual Review of Ileal Bile Acid Transporter (IBAT) Inhibitors

MOTION CARRIED by unanimous approval.

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

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

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

international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
9. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

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

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

international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

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

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

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying ~~mutations~~ a pathogenic variant in the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be ~~1 year~~ 3 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:
    a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
    b. Conjugated bilirubin >1mg/dL; or
    c. Fat soluble vitamin deficiency otherwise unexplainable; or
    d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
    e. Intractable pruritus explainable only by liver disease; and
6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and

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

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

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

1. An FDA approved indication for the treatment of pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying ~~mutations~~ biallelic pathogenic variants in the *ATP8B1, ABCB11, or ABCB4* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and

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

Recommendation 11: Calendar Year 2023 Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Augtyro™ (Repotrectinib) and Pemrydi RTU® (Pemetrexed)

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

Recommendation 12: Calendar Year 2023 Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Glipizide 2.5mg Tablet, Inpefa® (Sotagliflozin), Lantidra™ (Donislecel-jujn), Metformin 625mg Tablet, Zituvio™ (Sitagliptin), and Zituvimet™ (Sitagliptin/Metformin)

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

Recommendation 13: Calendar Year 2023 Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Izervay™ (Avacincaptad Pegol)

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

Recommendation 14: Calendar Year 2023 Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin), Voquezna® (Vonoprazan), Voquezna® Dual Pak® (Vonoprazan/Amoxicillin), and Voquezna® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin)

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

Recommendation 15: Calendar Year 2023 Annual Review of Systemic Antifungal Medications and 30-Day Notice to Prior Authorize Rezzayo™ (Rezafungin Injection)

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

Recommendation 16: Calendar Year 2023 Annual Review of Filspari® (Sparsentan)

NO ACTION REQUIRED.

Recommendation 21: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

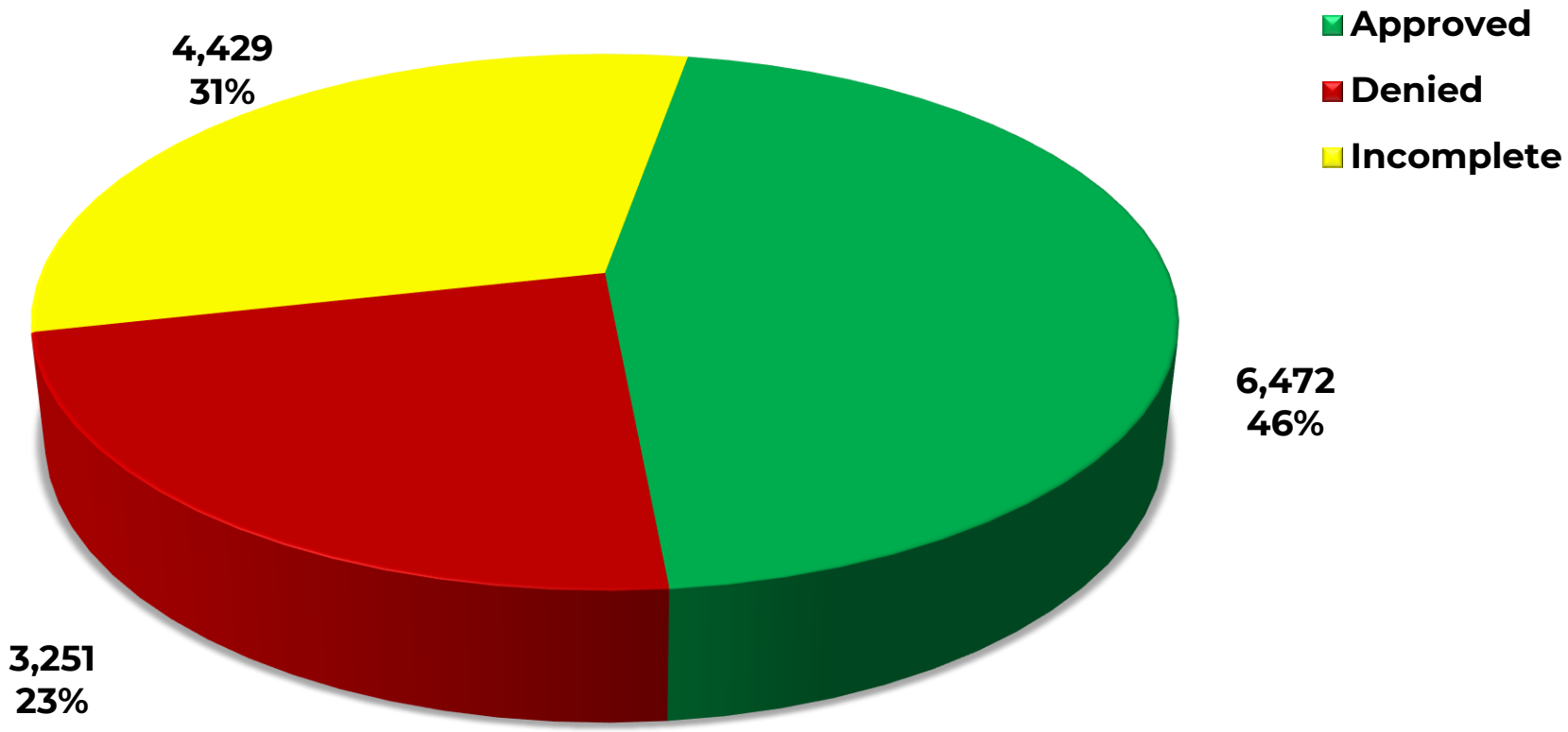
Recommendation 22: Future Business

No DUR Board meeting is scheduled for May 2024.

NO ACTION REQUIRED.

Appendix B

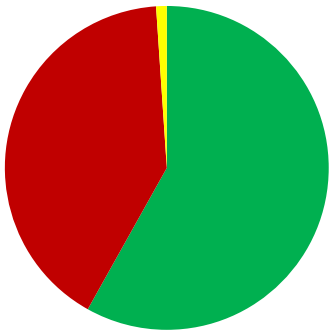
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: APRIL 2024



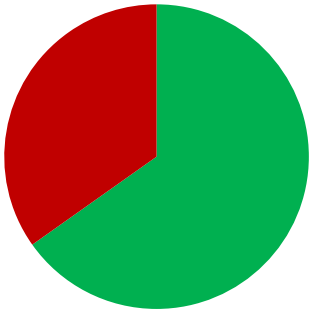
SoonerCare FFS

SoonerSelect Aetna

SoonerSelect Humana

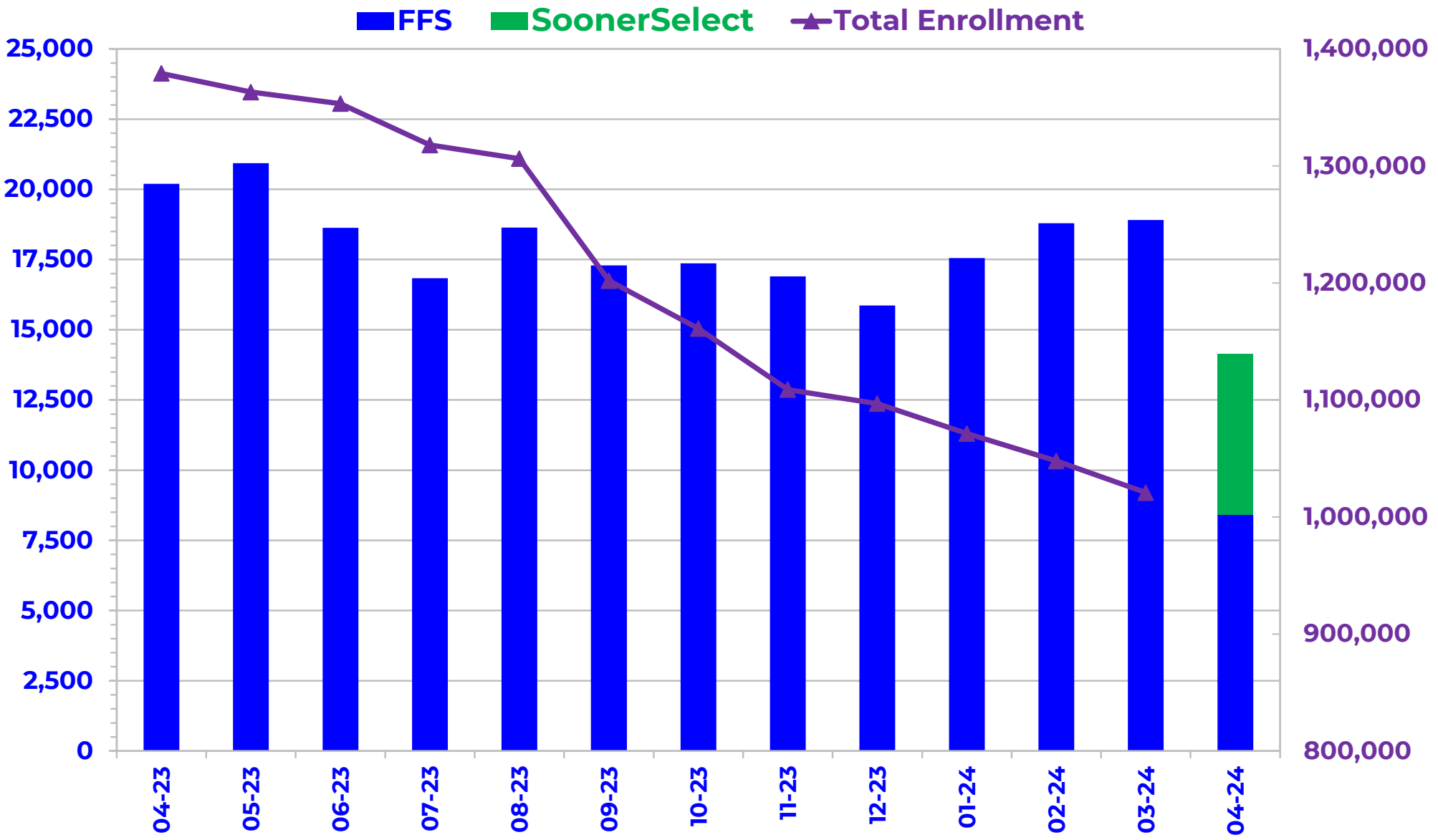


SoonerSelect OK Complete Health



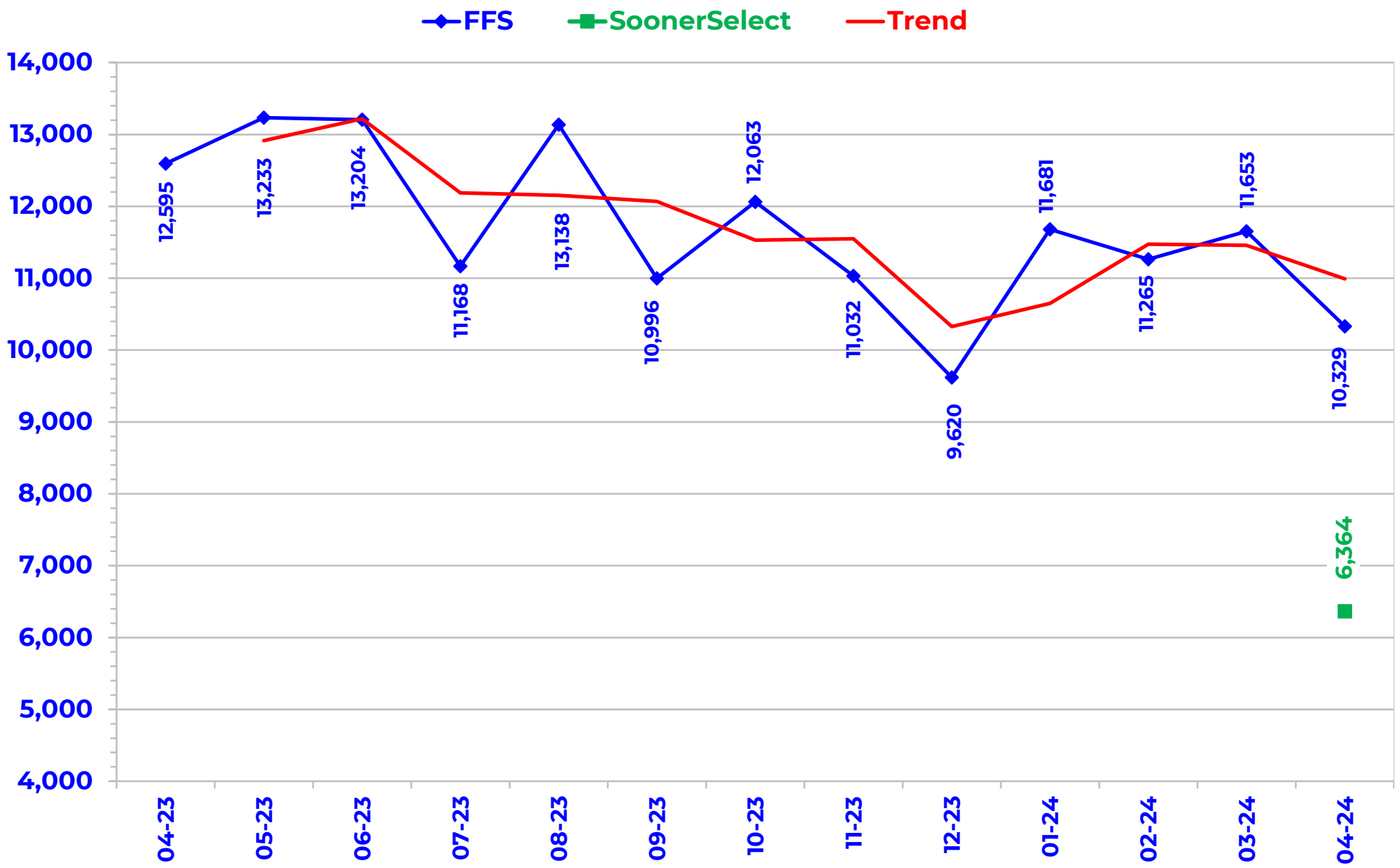
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: APRIL 2023 – APRIL 2024



SoonerCare FFS Prior Authorization Activity

4/1/2024 Through 4/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	136	46	11	79	352
Analgesic, Narcotic	236	105	26	105	125
Antiasthma	63	18	14	31	274
Antibiotic	20	6	0	14	358
Anticonvulsant	178	95	3	80	310
Antidepressant	184	28	32	124	276
Antidiabetic	1,268	454	276	538	353
Antihistamine	25	8	4	13	359
Antimigraine	289	62	104	123	263
Antineoplastic	162	107	6	49	176
Antiobesity	26	0	25	1	0
Antiparasitic	14	2	5	7	18
Antiulcers	32	6	5	21	95
Anxiolytic	17	1	0	16	360
Atypical Antipsychotics	348	138	37	173	354
Biologics	195	83	27	85	309
Bladder Control	104	14	27	63	343
Blood Thinners	26	1	1	24	358
Botox	35	25	7	3	358
Buprenorphine Medications	38	10	5	23	118
Calcium Channel Blockers	10	4	1	5	290
Cardiovascular	75	39	10	26	312
Chronic Obstructive Pulmonary Disease	217	30	55	132	328
Constipation/Diarrhea Medications	162	29	53	80	191
Contraceptive	33	16	3	14	341
Corticosteroid	15	2	6	7	359
Dermatological	277	91	72	114	238
Diabetic Supplies	212	68	32	112	217
Endocrine & Metabolic Drugs	41	16	5	20	230
Erythropoietin Stimulating Agents	22	10	6	6	112
Fibromyalgia	13	0	5	8	0
Fish Oils	11	2	2	7	359
Gastrointestinal Agents	93	22	15	56	176
Glaucoma	16	2	3	11	73
Growth Hormones	91	50	5	36	137
Hematopoietic Agents	12	5	2	5	135
Hepatitis C	25	13	2	10	8
HFA Rescue Inhalers	19	0	2	17	0
Insomnia	47	1	7	39	361
Insulin	331	164	29	138	349

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Miscellaneous Antibiotics	17	1	2	14	23
Multiple Sclerosis	57	26	5	26	239
Muscle Relaxant	44	4	18	22	190
Nasal Allergy	19	1	6	12	86
Neurological Agents	113	29	22	62	188
Neuromuscular Agents	14	10	0	4	272
NSAIDs	28	1	9	18	362
Ophthalmic Anti-infectives	18	4	2	12	13
Ophthalmic Corticosteroid	15	3	2	10	360
Osteoporosis	30	12	3	15	359
Other*	309	77	63	169	277
Otic Antibiotic	54	5	5	44	8
Pediculicide	10	3	0	7	18
Respiratory Agents	20	13	0	7	344
Statins	28	6	10	12	126
Stimulant	948	525	48	375	339
Testosterone	68	11	22	35	352
Topical Antifungal	30	3	8	19	242
Topical Corticosteroids	19	0	5	14	0
Vitamin	70	9	45	16	180
Pharmacotherapy	77	76	1	0	310
Emergency PAs	0	0	0	0	
Total	**7,106**	**2,592**	**1,206**	**3,308**	

Overrides					
Brand	18	11	0	7	272
Compound	18	13	2	3	15
Diabetic Supplies	1	1	0	0	358
Dosage Change	191	180	1	10	17
Ingredient Duplication	3	3	0	0	22
Lost/Broken Rx	75	66	4	5	16
MAT Override	116	84	0	32	87
NDC vs Age	192	130	19	43	271
NDC vs Sex	17	10	2	5	281
Nursing Home Issue	81	68	0	13	16
Opioid MME Limit	77	19	5	53	136
Opioid Quantity	29	20	0	9	150
Other	23	20	1	2	26
Quantity vs Days Supply	401	237	14	150	247
STBS/STBSM	19	11	2	6	85
Step Therapy Exception	13	6	2	5	358

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Stolen	6	6	0	0	16
Third Brand Request	39	19	1	19	19
Overrides Total	**1,319**	**904**	**53**	**362**	
Total Regular PAs + Overrides	**8,425**	**3,496**	**1,259**	**3,670**	

Denial Reasons	
Unable to verify required trials.	3,034
Does not meet established criteria.	1,295
Lack required information to process request.	606
Other PA Activity	
Duplicate Requests	774
Letters	30,454
No Process	0
Changes to existing PAs	594
Helpdesk Initiated Prior Authorizations	477
PAs Missing Information	398

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

SoonerSelect OK Complete Health Prior Authorization Activity

4/1/2024 Through 4/30/2024

	Total	Approved	Denied	Incomplete
ACE Inhibitors	1	0	1	0
Advair/Symbicort/Dulera	32	16	16	0
Analgesic - NonNarcotic	1	0	1	0
Analgesic, Narcotic	152	91	61	0
Anorectal	3	0	3	0
Antiasthma	20	10	10	0
Antibiotic	6	5	1	0
Anticoagulant	1	1	0	0
Anticonvulsant	33	27	6	0
Antidepressant	20	6	14	0
Antidiabetic	111	65	46	0
Antifungal	1	1	0	0
Antigout	2	1	1	0
Antihistamine	5	2	3	0
Anti-inflammatory	2	0	2	0
Antimigraine	37	13	24	0
Antineoplastic	41	33	8	0
Antiobesity	20	0	20	0
Antiparkinsons	3	2	1	0
Antipsychotic	1	1	0	0
Antiulcers	7	2	5	0
Antiviral	4	3	1	0
Anxiolytic	29	25	4	0
Atypical Antipsychotics	42	24	18	0
Biologics	170	146	24	0
Bladder Control	7	6	1	0
Blood Thinners	6	4	2	0
Botox	1	1	0	0
Buprenorphine Medications	62	26	36	0
Calcium Channel Blockers	5	2	3	0
Cardiovascular	37	29	8	0
Chronic Obstructive Pulmonary Disease	6	4	2	0
Constipation/Diarrhea Medications	6	2	4	0
Contraceptive	5	5	0	0
Corticosteroid	2	2	0	0
Cough/Cold/Allergy	2	1	1	0
Dermatological	116	65	51	0

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

	Total	Approved	Denied	Incomplete
Diabetic Supplies	67	51	16	0
Diuretic	4	4	0	0
Ear/Nose/Throat	1	1	0	0
Endocrine & Metabolic Drugs	8	4	4	0
Estrogen Derivative	1	1	0	0
Fibromyalgia	3	2	1	0
Fish Oils	1	1	0	0
Gastrointestinal Agents	24	18	6	0
Genitourinary Agents	4	0	4	0
Glaucoma	2	1	1	0
Gonadotropin-releasing Hormone Agonist	9	8	1	0
Growth Hormones	37	24	13	0
Hematopoietic Agents	5	4	1	0
Hepatitis C	21	16	5	0
HFA Rescue Inhalers	8	7	1	0
Insomnia	4	1	3	0
Insulin	38	30	8	0
Miscellaneous Antibiotics	1	1	0	0
Multiple Sclerosis	4	2	2	0
Muscle Relaxant	1	1	0	0
Nasal Allergy	1	0	1	0
Neurological Agents	11	5	6	0
Neuromuscular Agents	1	0	1	0
Non-Classified	16	12	4	0
NSAIDs	2	2	0	0
Ophthalmic	3	2	1	0
Ophthalmic Anti-infectives	1	1	0	0
Osteoporosis	2	2	0	0
Passive Immunizing Agents	2	1	1	0
Prenatal Vitamins	2	0	2	0
Respiratory Agents	27	20	7	0
Smoking Cess.	1	1	0	0
Statins	11	5	6	0
Stimulant	97	73	24	0
Testosterone	10	5	5	0
Thyroid	6	4	2	0
Topical Antifungal	1	0	1	0
Topical Corticosteroids	7	6	1	0
Vitamin	8	6	2	0
Total	**1,451**	**943**	**508**	**0**

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

Denial Reasons	
Benefit	83
Medical Necessity	429

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

SoonerSelect Humana Prior Authorization Activity

4/1/2024 Through 4/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	13	0	13	0	15
Analgesic, Narcotic	50	17	32	1	145
Antiasthma	20	8	10	2	140
Antibiotic	2	1	1	0	365
Anticonvulsant	12	7	5	0	215
Antidepressant	4	0	4	0	290
Antidiabetic	24	6	18	0	160
Antigout	1	0	1	0	90
Antihemophilic Factor	2	2	0	0	274
Antimigraine	37	14	23	0	156
Antineoplastic	80	63	17	0	287
Antiobesity	1	0	1	0	72
Antiulcers	1	0	1	0	0
Benign Prostatic Hypertrophy	2	0	2	0	38
Biologics	112	90	22	0	261
Bladder Control	3	0	2	1	0
Botox	10	5	5	0	129
Buprenorphine Medications	8	3	5	0	74
Calcium Channel Blockers	2	2	0	0	365
Cardiovascular	33	18	15	0	222
Chronic Obstructive Pulmonary Disease	14	1	13	0	123
Constipation/Diarrhea Medications	13	6	7	0	161
Contraceptive	4	2	2	0	200
Corticosteroid	1	0	1	0	365
Dermatological	65	40	23	2	143
Diabetic Supplies	67	50	16	1	349
Endocrine & Metabolic Drugs	10	7	3	0	244
Erythropoietin Stimulating Agents	5	2	3	0	102
Estrogen Derivative	3	1	2	0	183
Fibromyalgia	1	1	0	0	365
Fish Oils	1	0	1	0	365
Gastrointestinal Agents	15	5	10	0	179
Genitourinary Agents	1	1	0	0	365
Glaucoma	1	0	1	0	80
Gonadotropin-releasing Hormone Agonist	4	4	0	0	365
Growth Hormones	9	6	3	0	168
Hematopoietic Agents	8	3	5	0	189
Hepatitis C	4	2	2	0	75
Insomnia	6	1	5	0	73

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Insulin	15	3	12	0	141
Miscellaneous Antibiotics	2	1	1	0	365
Multiple Sclerosis	14	4	10	0	195
Muscle Relaxant	13	13	0	0	365
Nasal Allergy	1	0	1	0	0
Neurological Agents	4	2	2	0	203
Neuromuscular Agents	4	4	0	0	244
Non-Classified	14	12	2	0	326
Ophthalmic	6	2	4	0	98
Ophthalmic Corticosteroid	4	1	3	0	91
Osteoporosis	10	9	1	0	266
Respiratory Agents	9	8	1	0	313
Statins	10	2	8	0	81
Stimulant	20	6	14	0	146
Testosterone	18	5	12	1	108
Thyroid	1	0	1	0	90
Topical Corticosteroids	2	1	1	0	183
Vitamin	17	2	15	0	129
Totals	**813**	**443**	**362**	**8**	
Overrides					
Ingredient Duplication	28	17	9	2	286
MAT Override	19	10	9	0	261
NDC vs Age	214	165	47	2	280
Opioid MME Limit	13	8	4	1	260
Opioid Quantity	264	192	72	0	232
Other	168	66	100	2	137
Quantity vs Days Supply	67	32	35	0	220
STBS/STBSM	15	10	4	1	218
Step Therapy	97	45	50	2	211
Overrides Total	**885**	**545**	**330**	**10**	
Total Regular PAs + Overrides	**1698**	**988**	**692**	**18**	
Denial Reasons					
Benefit					209
Medical Necessity					485

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

SoonerSelect Aetna Prior Authorization Activity

4/1/2024 Through 4/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
ACE Inhibitors	9	0	0	9	0
Advair/Symbicort/Dulera	77	18	32	27	344
Analgesic - NonNarcotic	7	3	2	2	365
Analgesic, Narcotic	136	65	16	55	267
Angiotensin Receptor Antagonist	2	0	0	2	0
Anorectal	2	0	2	0	0
Antiallergic	1	1	0	0	8
Antiasthma	32	12	7	13	298
Antibiotic	17	3	3	11	151
Anticoagulant	1	0	1	0	0
Anticonvulsant	31	15	10	6	339
Antidepressant	126	29	38	59	354
Antidiabetic	261	81	133	47	343
Antidiarrheal	1	0	0	1	0
Antifungal	1	0	1	0	0
Antigout	5	1	4	0	183
Antihemophilic Factor	2	2	0	0	309
Antihistamine	13	3	9	1	281
Antihyperlipidemic	1	1	0	0	365
Antimalarial Agent	1	0	0	1	0
Antimigraine	84	17	50	17	205
Antineoplastic	30	10	2	18	279
Antiobesity	28	0	27	1	0
Antiparasitic	1	0	1	0	0
Antiparkinsons	5	0	1	4	0
Antipsychotic	1	0	0	1	0
Antiulcers	27	4	3	20	318
Antiviral	2	1	0	1	365
Anxiolytic	30	15	5	10	252
Atypical Antipsychotics	115	31	35	49	306
Benign Prostatic Hypertrophy	4	1	3	0	365
Biologics	164	120	32	12	292
Bladder Control	5	0	4	1	0
Blood Thinners	4	1	0	3	365
Botox	2	0	0	2	0
Buprenorphine Medications	82	43	31	8	83
Calcium Channel Blockers	16	2	3	11	228
Cardiovascular	53	13	9	31	282
Chronic Obstructive Pulmonary Disease	27	4	18	5	210

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Constipation/Diarrhea Medications	16	8	8	0	221
Contraceptive	9	3	4	2	365
Corticosteroid	6	0	2	4	0
Cough/Cold/Allergy	2	1	1	0	91
Dermatological	151	69	65	17	239
Diabetic Supplies	46	19	7	20	298
Diuretic	8	0	0	8	0
Ear/Nose/Throat	1	0	0	1	0
Endocrine & Metabolic Drugs	16	4	10	2	219
Estrogen Derivative	4	2	1	1	365
Fibric Acid Derivatives	2	0	1	1	0
Fibromyalgia	21	0	2	19	0
Fish Oils	3	0	0	3	0
Gastrointestinal Agents	23	5	7	11	178
Genitourinary Agents	7	0	1	6	0
Gonadotropin-releasing Hormone Agonist	3	3	0	0	365
Growth Hormones	19	10	9	0	129
Hematopoietic Agents	2	2	0	0	342
Hepatitis C	7	2	2	3	98
HFA Rescue Inhalers	24	0	3	21	0
Insomnia	15	0	4	11	0
Insulin	63	16	18	29	288
Multiple Sclerosis	14	7	4	3	222
Muscle Relaxant	19	1	5	13	30
Nasal Allergy	6	0	3	3	0
Neurological Agents	14	4	9	1	274
Neuromuscular Agents	1	0	0	1	0
Non-Classified	28	14	8	6	304
NSAIDs	17	0	1	16	0
Ocular Allergy	1	0	1	0	0
Ophthalmic	7	0	4	3	0
Ophthalmic Anti-infectives	4	1	1	2	33
Ophthalmic Corticosteroid	1	0	1	0	0
Osteoporosis	1	1	0	0	324
Otic Antibiotic	23	4	17	2	101
Passive Immunizing Agents	1	0	0	1	0
Pediculicide	3	1	1	1	30
Respiratory Agents	18	13	3	2	296
Smoking Cess.	1	0	1	0	0
Statins	29	2	6	21	206
Stimulant	419	319	51	49	327
Testosterone	18	4	14	0	345

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

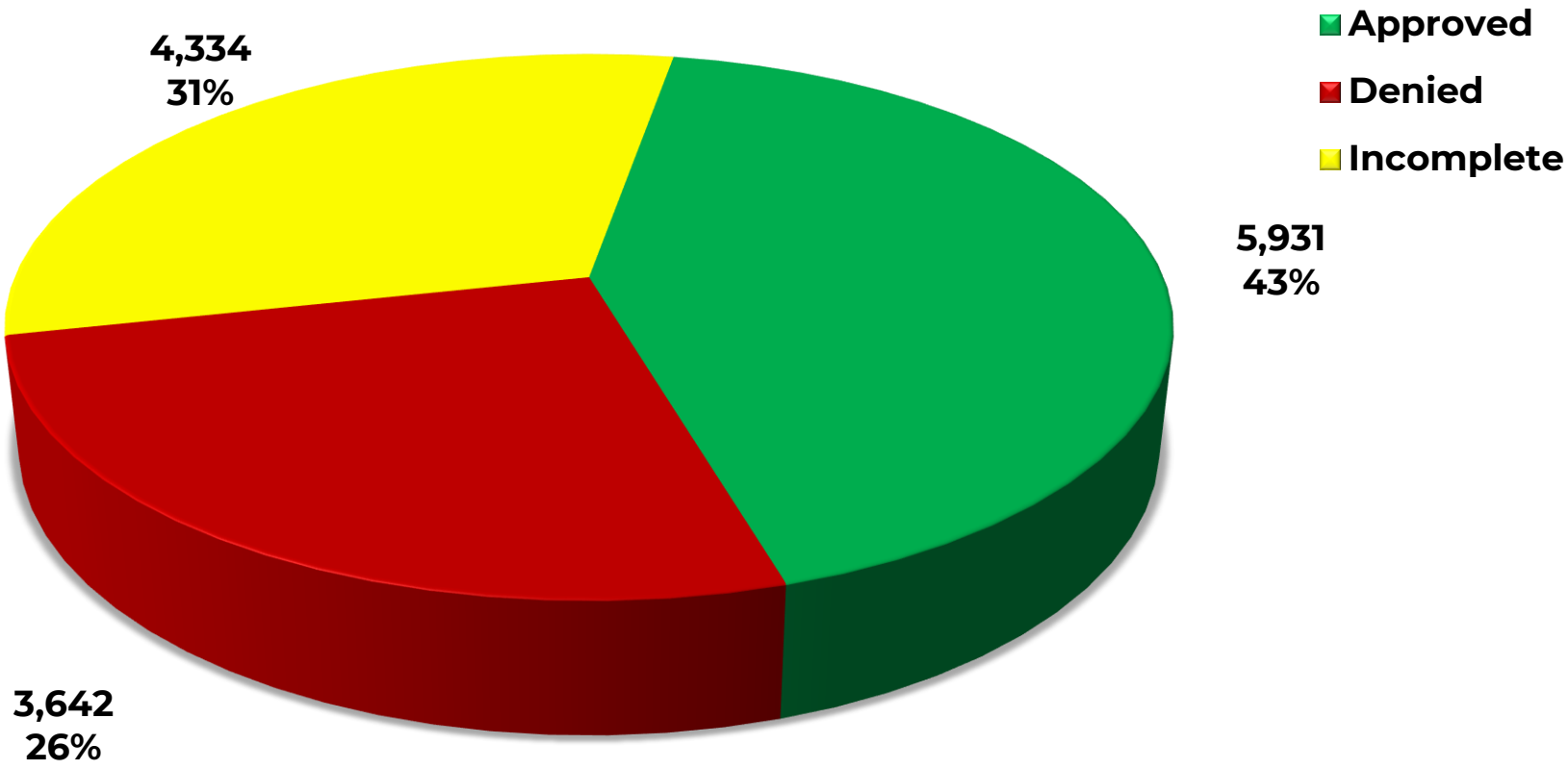
	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Thyroid	2	1	0	1	327
Topical Antibiotic	3	0	0	3	0
Topical Antifungal	6	1	3	2	91
Topical Corticosteroids	7	0	5	2	0
Toradol	2	0	1	1	0
Vitamin	24	9	8	7	265
Totals	**2523**	**1022**	**774**	**727**	

Overrides					
Brand	4	4	0	0	249
Quantity Limit	32	32	0	0	273
Other	1	1	0	0	365
Step Therapy Exception	3	3	0	0	327
Overrides Total	**40**	**40**	**0**	**0**	
Total Regular PAs + Overrides	**2563**	**1062**	**774**	**727**	

Denial Reasons	
Benefit	66
Experimental/Investigational	18
Lack required information to process request	523
Medical Necessity	167
Other	11
Other PA Activity	
Duplicate Requests	21
Letters	2966
No Process	291
Changes to existing PA	81
Helpdesk initiated PA	22
Missing Information	12

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

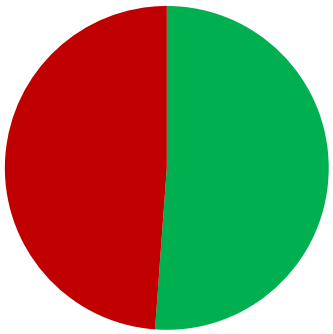
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MAY 2024



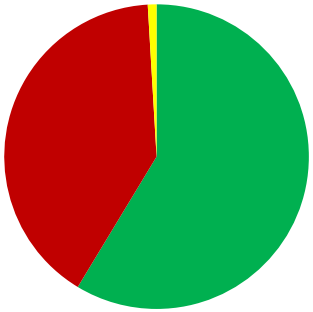
SoonerCare FFS

SoonerSelect Aetna

SoonerSelect Humana

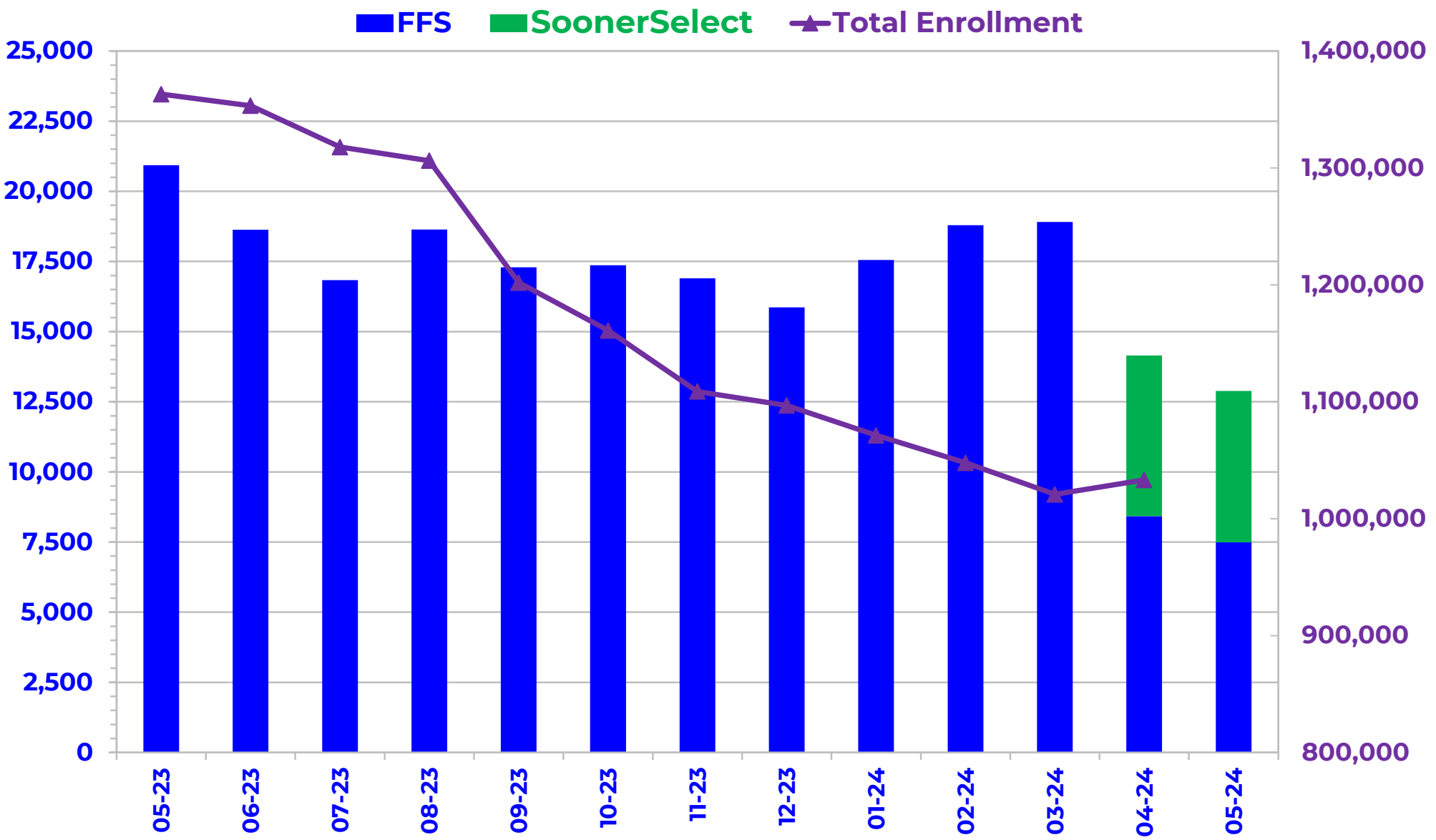


SoonerSelect OK Complete Health



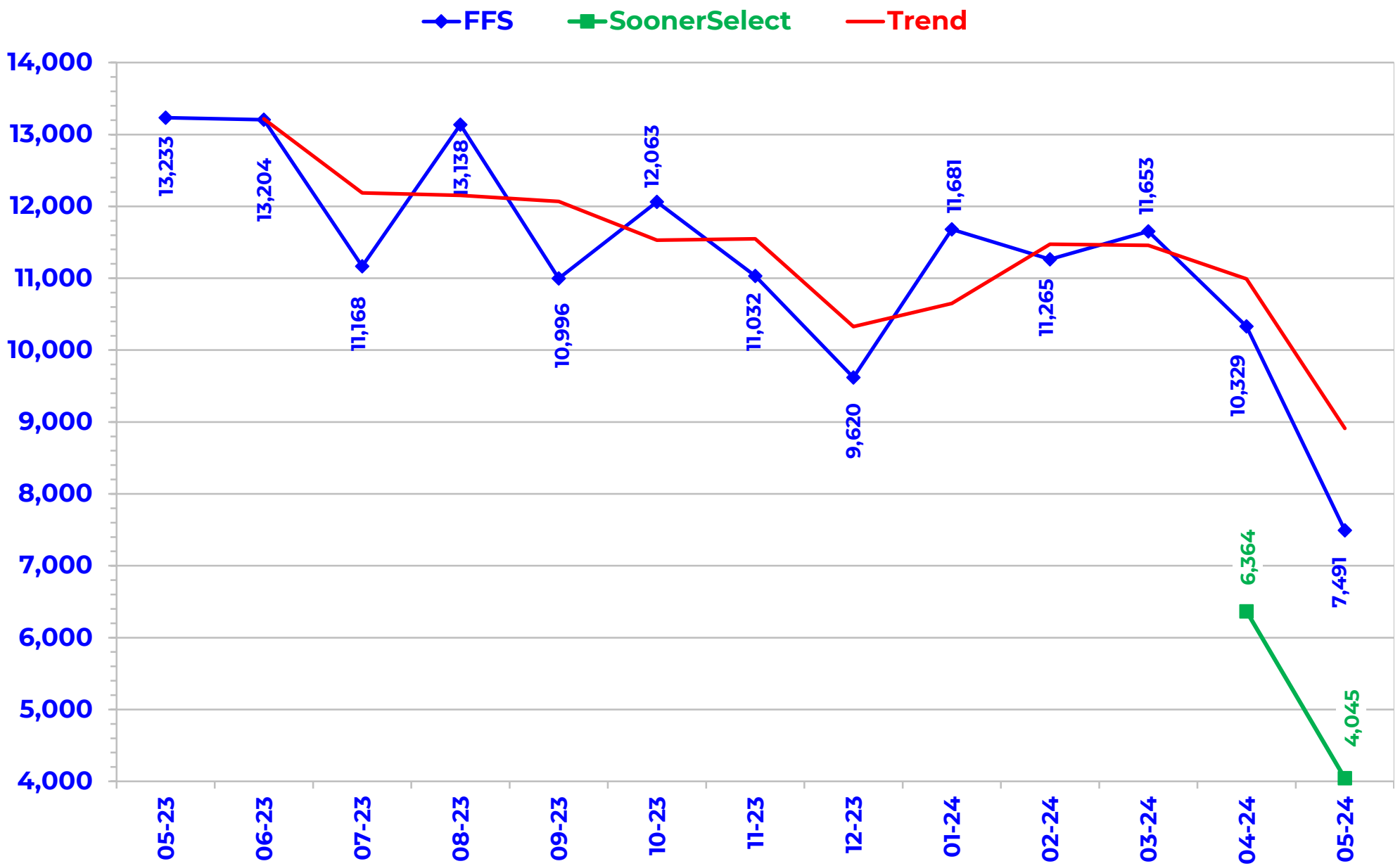
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: MAY 2023 – MAY 2024



SoonerCare FFS Prior Authorization Activity

5/1/2024 Through 5/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	155	53	14	88	360
Analgesic, Narcotic	223	94	18	111	117
Antiasthma	60	25	11	24	272
Antibiotic	19	8	1	10	278
Anticonvulsant	196	85	14	97	329
Antidepressant	171	28	18	125	276
Antidiabetic	1,399	447	318	634	353
Antigout	11	4	1	6	360
Antihistamine	30	6	6	18	359
Antimigraine	245	58	84	103	309
Antineoplastic	152	110	5	37	180
Antiobesity	15	1	13	1	358
Antiulcers	35	6	7	22	109
Anxiolytic	23	1	2	20	175
Atypical Antipsychotics	278	95	25	158	337
Biologics	201	94	17	90	316
Bladder Control	92	16	17	59	333
Blood Thinners	17	0	3	14	0
Botox	51	21	21	9	344
Buprenorphine Medications	49	20	5	24	137
Calcium Channel Blockers	11	2	4	5	222
Cardiovascular	83	54	6	23	338
Chronic Obstructive Pulmonary Disease	252	49	59	144	347
Constipation/Diarrhea Medications	181	44	41	96	205
Contraceptive	35	18	3	14	341
Corticosteroid	10	3	1	6	237
Dermatological	284	78	84	122	219
Diabetic Supplies	238	74	41	123	200
Endocrine & Metabolic Drugs	56	16	7	33	204
Erythropoietin Stimulating Agents	20	10	2	8	116
Gastrointestinal Agents	95	24	24	47	219
Glaucoma	13	3	2	8	360
Gonadotropin-releasing Hormone Agonist	19	16	0	3	358
Growth Hormones	70	49	7	14	149
Hematopoietic Agents	10	3	1	6	155
Hepatitis C	15	5	3	7	7
Insomnia	69	7	12	50	204
Insulin	289	135	20	134	328
Miscellaneous Antibiotics	15	2	3	10	27
Multiple Sclerosis	67	28	8	31	242
Muscle Relaxant	52	5	11	36	239

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Nasal Allergy	35	5	7	23	142
Neurological Agents	188	59	30	99	225
Neuromuscular Agents	12	5	0	7	265
NSAIDs	18	0	6	12	0
Ophthalmic	21	5	4	12	337
Ophthalmic Anti-infectives	17	8	0	9	15
Osteoporosis	2	2	0	0	359
Other*	375	94	73	208	287
Otic Antibiotic	79	6	11	62	12
Respiratory Agents	22	15	0	7	325
Statins	51	13	10	28	194
Stimulant	952	562	46	344	346
Testosterone	80	25	20	35	322
Thyroid	10	3	0	7	360
Topical Antifungal	31	0	9	22	0
Topical Corticosteroids	22	0	11	11	0
Vitamin	53	2	35	16	192
Pharmacotherapy	49	44	1	4	260
Emergency PAs	1	1	0	0	
Total	**7,324**	**2,646**	**1,202**	**3,476**	
Overrides					
Brand	22	17	1	4	270
Compound	13	10	0	3	12
Dosage Change	162	153	0	9	19
High Dose	1	1	0	0	360
Ingredient Duplication	3	2	0	1	24
Lost/Broken Rx	55	51	0	4	22
MAT Override	39	28	2	9	89
NDC vs Age	187	119	25	43	276
NDC vs Sex	13	10	1	2	266
Nursing Home Issue	51	49	0	2	15
Opioid MME Limit	74	20	5	49	139
Opioid Quantity	28	20	1	7	147
Other	59	46	8	5	18
Quantity vs Days Supply	407	252	27	128	269
STBS/STBSM	11	8	2	1	64
Step Therapy Exception	11	8	1	2	243
Stolen	14	14	0	0	13
Third Brand Request	35	20	0	15	18
Overrides Total	**1,185**	**828**	**73**	**284**	
Total Regular PAs + Overrides	**8,509**	**3,474**	**1,275**	**3,760**	

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

Denial Reasons	
Unable to verify required trials.	3,181
Does not meet established criteria.	1,298
Lack required information to process request.	582
Other PA Activity	
Duplicate Requests	836
Letters	30,009
No Process	2
Changes to existing PAs	514
Helpdesk Initiated Prior Authorizations	396
PAs Missing Information	411

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

SoonerSelect OK Complete Health Prior Authorization Activity

5/1/2024 Through 5/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	37	13	24	0	344
Analgesic, Narcotic	140	104	36	0	302
Anorectal	2	0	2	0	0
Antiasthma	12	4	8	0	272
Antibiotic	3	2	1	0	365
Anticonvulsant	39	20	18	1	270
Antidepressant	40	18	22	0	292
Antidiabetic	156	93	59	4	350
Antifungal	2	1	1	0	365
Antihemophilic Factor	1	1	0	0	90
Antihistamine	2	0	2	0	0
Antihyperlipidemic	1	0	1	0	0
Antimigraine	44	12	32	0	251
Antineoplastic	16	13	3	0	269
Antiobesity	29	0	29	0	0
Antiulcers	11	6	5	0	246
Anxiolytic	27	16	11	0	304
Atypical Antipsychotics	45	26	19	0	322
Benign Prostatic Hypertrophy	3	1	2	0	365
Biologics	100	76	23	1	355
Bladder Control	4	3	1	0	365
Blood Thinners	4	4	0	0	291
Buprenorphine Medications	41	21	20	0	205
Calcium Channel Blockers	7	2	5	0	216
Cardiovascular	16	11	4	1	306
Chronic Obstructive Pulmonary Disease	13	7	6	0	273
Constipation/Diarrhea Medications	11	5	6	0	185
Contraceptive	2	1	1	0	224
Cough/Cold/Allergy	1	0	1	0	0
Dermatological	131	68	62	1	270
Diabetic Supplies	63	49	14	0	346
Endocrine & Metabolic Drugs	13	7	6	0	209
Erythropoietin Stimulating Agents	1	0	1	0	0
Estrogen Derivative	4	2	2	0	303
Fibromyalgia	9	5	4	0	253
Fish Oils	1	0	1	0	0
Gastrointestinal Agents	10	4	6	0	365
Genitourinary Agents	1	0	1	0	0
Glaucoma	1	0	1	0	0
Gonadotropin-releasing Hormone Agonist	3	3	0	0	365
Growth Hormones	3	2	1	0	272
Hematopoietic Agents	6	3	3	0	283

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hepatitis C	6	4	2	0	63
HFA Rescue Inhalers	1	1	0	0	225
Insomnia	7	4	3	0	251
Insulin	19	15	4	0	320
Miscellaneous Antibiotics	2	1	1	0	365
Multiple Sclerosis	4	1	3	0	365
Muscle Relaxant	2	1	1	0	365
Nasal Allergy	1	0	1	0	0
Neurological Agents	13	4	9	0	268
Neuromuscular Agents	1	1	0	0	365
Non-Classified	13	10	3	0	351
NSAIDs	2	2	0	0	232
Ocular Allergy	1	0	1	0	0
Ophthalmic	1	0	1	0	0
Ophthalmic Anti-infectives	1	0	0	1	0
OTHER	6	2	4	0	365
Otic Antibiotic	1	1	0	0	365
Passive Immunizing Agents	3	3	0	0	365
Prenatal Vitamins	2	1	1	0	228
Respiratory Agents	6	5	1	0	330
Statins	10	5	5	0	218
Stimulant	110	81	26	3	325
Testosterone	6	2	4	0	365
Thyroid	3	1	2	0	232
Vaccine	1	0	1	0	0
Vitamin	17	11	6	0	353
Totals	**1,294**	**759**	**523**	**12**	

Denial Reasons	
Benefit	74
Medical Necessity	449

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

SoonerSelect Humana Prior Authorization Activity

5/1/2024 Through 5/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	14	0	14	0	14
Analgesic - NonNarcotic	1	0	1	0	0
Analgesic, Narcotic	45	20	25	0	146
Antiasthma	14	6	8	0	165
Antibiotic	6	4	2	0	183
Anticonvulsant	7	5	2	0	340
Antidepressant	15	3	12	0	161
Antidiabetic	122	53	69	0	224
Antihistamine	1	0	1	0	0
Antimigraine	46	13	33	0	122
Antineoplastic	36	33	3	0	252
Antiobesity	33	0	33	0	0
Antiparkinsons	1	1	0	0	365
Antiulcers	2	0	2	0	23
Benign Prostatic Hypertrophy	1	0	1	0	0
Biologics	105	84	21	0	260
Bladder Control	10	2	8	0	137
Botox	28	15	13	0	218
Buprenorphine Medications	15	7	8	0	86
Calcium Channel Blockers	2	1	1	0	183
Cardiovascular	32	19	13	0	279
Chronic Obstructive Pulmonary Disease	31	8	23	0	108
Constipation/Diarrhea Medications	15	7	8	0	141
Contraceptive	14	1	13	0	55
Corticosteroid	2	1	1	0	183
Dermatological	104	64	40	0	184
Diabetic Supplies	137	108	29	0	349
Endocrine & Metabolic Drugs	7	2	5	0	227
Erythropoietin Stimulating Agents	2	2	0	0	122
Estrogen Derivative	6	2	4	0	77
Fish Oils	2	0	2	0	183
Gastrointestinal Agents	17	6	11	0	116
Genitourinary Agents	1	0	1	0	0
Glaucoma	4	2	2	0	274
Gonadotropin-releasing Hormone Agonist	6	6	0	0	345
Growth Hormones	4	3	1	0	192
Hematopoietic Agents	9	3	6	0	94
Hepatitis C	3	1	2	0	21
HFA Rescue Inhalers	1	0	1	0	0
Insomnia	2	0	2	0	0
Insulin	19	4	15	0	87
Multiple Sclerosis	6	4	2	0	236

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Muscle Relaxant	16	12	4	0	232
Neurological Agents	12	4	8	0	95
Non-Classified	19	8	11	0	227
Ophthalmic	5	2	3	0	82
Ophthalmic Anti-infectives	1	0	1	0	0
Ophthalmic Corticosteroid	8	3	5	0	69
Osteoporosis	5	4	1	0	274
Respiratory Agents	5	5	0	0	365
Statins	2	1	1	0	46
Stimulant	23	15	8	0	252
Testosterone	35	8	27	0	134
Thyroid	5	0	5	0	55
Topical Corticosteroids	5	1	4	0	51
Vitamin	45	7	38	0	116
Total	**1114**	**560**	**554**	**0**	
Overrides					
Ingredient Duplication	23	13	10	0	239
MAT Override	16	13	3	0	442
NDC vs Age	175	107	68	0	222
Opioid MME Limit	9	6	3	0	280
Opioid Quantity	28	22	6	0	249
Other	89	21	68	0	83
Quantity vs Days Supply	148	79	69	0	266
STBS/STBSM	32	13	19	0	150
Step Therapy Exception	133	70	63	0	226
Overrides Total	**653**	**344**	**309**	**0**	
Total Regular PAs + Overrides	**1767**	**904**	**863**	**0**	
Denial Reasons					
Benefit					330
Medical Necessity					534

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

SoonerSelect Aetna Prior Authorization Activity

5/1/2024 Through 5/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
ACE Inhibitors	11	0	4	7	0
Advair/Symbicort/Dulera	73	9	30	34	327
Analgesic - NonNarcotic	3	0	3	0	0
Analgesic, Narcotic	110	42	39	29	196
Angiotensin Receptor Antagonist	4	0	2	2	0
Antiasthma	43	9	23	11	261
Antibiotic	10	3	2	5	86
Anticoagulant	1	1	0	0	58
Anticonvulsant	30	9	17	4	365
Antidepressant	157	22	76	59	333
Antidiabetic	282	70	166	46	344
Antidiarrheal	1	0	1	0	0
Antifungal	7	1	3	3	184
Antigout	8	1	4	3	184
Antihemophilic Factor	3	3	0	0	254
Antihistamine	9	3	5	1	365
Antimalarial Agent	1	0	1	0	0
Antimigraine	77	5	63	9	229
Antineoplastic	10	5	1	4	329
Antiobesity	20	0	18	2	0
Antiparasitic	1	1	0	0	7
Antiparkinsons	6	0	3	3	0
Antiulcers	41	2	19	20	365
Antiviral	3	1	0	2	365
Anxiolytic	31	19	8	4	316
Atypical Antipsychotics	90	25	35	30	344
Benign Prostatic Hypertrophy	1	0	1	0	0
Biologics	136	96	27	13	289
Bladder Control	3	0	2	1	0
Blood Thinners	4	1	0	3	365
Botox	1	0	0	1	0
Buprenorphine Medications	57	28	23	6	97
Calcium Channel Blockers	17	4	2	11	365
Cardiovascular	50	6	14	30	365
Chronic Obstructive Pulmonary Disease	23	0	23	0	0
Constipation/Diarrhea Medications	21	9	12	0	176
Contraceptive	10	0	6	4	0
Corticosteroid	4	0	2	2	0
Dermatological	139	67	59	13	252
Diabetic Supplies	51	20	15	16	320
Diuretic	13	0	4	9	0
Endocrine & Metabolic Drugs	10	4	6	0	365
Estrogen Derivative	3	0	1	2	0
Fibric Acid Derivatives	3	0	3	0	0
Fibromyalgia	9	1	3	5	365

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Fish Oils	2	0	0	2	0
Gastrointestinal Agents	27	4	16	7	204
Genitourinary Agents	5	0	1	4	0
Glaucoma	4	0	0	4	0
Gonadotropin-releasing Hormone Agonist	2	1	0	1	184
Growth Hormones	12	4	7	1	214
Hematopoietic Agents	4	2	1	1	275
Hepatitis C	4	2	1	1	84
HFA Rescue Inhalers	23	0	7	16	0
Insomnia	26	1	12	13	365
Insulin	39	11	20	8	320
Miscellaneous Antibiotics	2	0	1	1	0
Multiple Sclerosis	3	0	1	2	0
Muscle Relaxant	23	2	7	14	198
Nasal Allergy	9	0	4	5	0
Neurological Agents	7	1	5	1	365
Neuromuscular Agents	2	0	1	1	0
Non-Classified	34	6	20	8	320
Nsaids	17	2	9	6	365
Ocular Allergy	1	0	1	0	0
Ophthalmic	5	0	2	3	0
Ophthalmic Anti-infectives	5	3	0	2	146
Ophthalmic Corticosteroid	1	0	1	0	0
Osteoporosis	1	0	1	0	0
Otic Antibiotic	5	0	5	0	0
Pediculicide	4	0	4	0	0
Prenatal Vitamins	1	0	1	0	0
Respiratory Agents	2	1	1	0	365
Smoking Cess.	1	0	1	0	0
Statins	21	0	10	11	0
Stimulant	382	270	76	36	360
Testosterone	31	7	23	1	350
Thyroid	3	2	0	1	365
Topical Antibiotic	1	0	1	0	0
Topical Antifungal	2	0	1	1	0
Topical Corticosteroids	5	0	4	1	0
Toradol	1	0	1	0	0
Vitamin	18	7	7	4	320
Total	**2322**	**793**	**979**	**550**	
Overrides					
Quantity Limit	36	36	0	0	286
Step Therapy Exception	1	1	0	0	365
Vacation Override	1	1	0	0	7
Overrides Total	**38**	**38**	**0**	**0**	
Total Regular PAs + Overrides	**2360**	**831**	**979**	**550**	

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

Denial Reasons	
Benefit	71
Experimenta/Investigational	76
Lack required information to process request	354
Medical Necessity	288
Other	190
Other PA Activity	
Duplicate Requests	18
Letters	2443
No Process	268
Changes to exisitng PAs	64
Helpdesk initiated PA	8
Missing information	18

**SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.*

Concomitant Use of Opioids and Gabapentinoids Mailing Update

Oklahoma Health Care Authority
June 2024

Introduction[1,2]

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

While overall overdose deaths remained similar among SUDORS reporting jurisdictions between 2021 and 2022, Oklahoma saw a 28% increase. Of the deaths recorded in Oklahoma, opioids were involved in 748 cases in 2022, a 71% increase from 2021. Gabapentin was cited as a contributing factor to opioid related deaths in 4,297 cases nationwide and 59 cases in Oklahoma, which is an increase from 43 cases in 2021. Since 2019, several warnings and recommendations have been published regarding concomitant use of opioids and gabapentin and the increased risk of respiratory depression. Limiting the concomitant use of opioids and gabapentin may prevent adverse events or death.

Concomitant Opioid and Gabapentinoid Utilization Summary[3,4,5,6]

The U.S. Food and Drug Administration (FDA) issued a safety alert in December 2019 stating that the use of gabapentinoids (pregabalin or gabapentin) concomitantly with opioids and other central nervous system (CNS) depressants puts patients at a higher risk of respiratory depression. The safety alert was issued after 49 cases of respiratory depression, of which 12 patients died, due to gabapentinoids were reported to the FDA from 2012 to 2017. The 12 patients who died were found to have additional risk factors including concurrent opioid or CNS depressant use and lung function-reducing disease such as chronic obstructive pulmonary disease (COPD).

Prescribing for gabapentin has doubled since 2004, reaching 45 million prescriptions in 2019. One study determined that 1 in 5 adults with chronic pain were given a gabapentinoid in 2018, but also determined that rates of

opioid prescribing decreased by around 5%. The increased utilization of gabapentinoids is most commonly an attempt at decreasing the duration or overall use of opioids. While gabapentin is not designated federally as a controlled dangerous substance, pregabalin is considered a controlled medication with a C-V, the lowest control tier, designation. Pregabalin's controlled substance status communicates that these medications are considered less likely to become habit forming than opioid medications, which are typically considered C-II, the highest control tier that is available for legal use. However, misuse of gabapentinoids is rising due to its availability and the similar effects it exhibits to opioids when misused. Gabapentinoids can produce a feeling of euphoria and can increase the euphoria experienced when taking opioids.

Prescriber Mailing: Concomitant Opioid and Gabapentinoid Prescribing

In September 2023, a concomitant opioid and gabapentinoid use retrospective drug utilization review (retroDUR) mailing was sent to prescribers of adult SoonerCare members who were prescribed both opioids and gabapentinoids (pregabalin or gabapentin) concomitantly for at least 30 days within a predetermined 90-day period. While concurrent use of opioids and gabapentinoids is not restricted by SoonerCare, there is evidence to suggest that taking both medications together may be harmful to patients. Members with an oncology diagnosis were not included in our mailings but members with hemophilia and sickle cell diagnoses were included despite being excluded from select SoonerCare opioid edits. The purpose of this mailing was to decrease the concurrent use of gabapentinoids and opioids in SoonerCare members as clinically appropriate.

Prescribers were selected to receive letters if their members met the inclusion criteria for the mailing module. Selection was based on the most recent claim submitted for an opioid and/or a gabapentinoid for a SoonerCare member within the past 90 days. For this mailing module, 2 mailings were sent out to SoonerCare providers, the first in September 2023 and the second in January 2024. For the first mailing, all members who met the inclusion criteria were included in the mailing list to their assigned providers. The second mailing targeted only those members who met inclusion criteria and had utilization of at least 80 continuous days with both medication classes to target those with a higher utilization. The mailings were sent at the end of the month and included a prescriber summary of their SoonerCare members who utilized opioids and gabapentinoids concomitantly for at least 30 days during the 90-day evaluation period.

Prescriber Mailing: Trends

The table below includes a summary of the opioid and gabapentinoid retroDUR mailings sent thus far, which includes the number of providers who received a mailing each month and the number of members who met inclusion criteria and were included in the provider letters. The number of members who, based on claims data, had at least 80 continuous days, decreased across the 3 time periods; however, the number of provider letters between the 2 mailings increased.

The following table shows the changes observed from the first mailing in September 2023, the second mailing in January 2024, and the final data from April 2024.

Dates	Members Included	Members with ≥80 Continuous Days	Prescriber Letters
09-2023	4,827	1,653	131
01-2024	4,417	1,565	162
04-2024	4,418	1,557	n/a

n/a = not applicable

Prescriber Mailing: Results[7]

There were 7,150 unique members who had at least 30 days of concomitant use of an opioid and a gabapentinoid in a 90-day period from September 2023 to April 2024. Some members from the first mailing were included in the second mailing and appeared on the final data pulled in April 2024. A total of 5,423 unique members were included in at least one mailing. Letters were sent to a total of 237 unique prescribers between the September and January mailings, with 56 providers being included in both mailings. Of the 5,423 unique members included in the mailings, 3,313 still had concomitant use of an opioid and a gabapentinoid in the final data pulled in April 2024, which is a 39% decrease (improvement).

The number of unduplicated members included in the September mailing was 4,827 and decreased by approximately 400 members by the final data pull in April 2024. A total of 1,955 unique providers were identified in September 2023 as having members with concomitant use of opioids and gabapentinoids for at least 30 days prior to the first mailing. By April 2024, 1,860 providers were identified, a decrease of 95 providers. The number of members who were receiving prescriptions from multiple prescribers decreased significantly from September 2023 to April 2024 with around 2,000 members who previously received care from multiple providers, now only receiving prescriptions from 1 provider. While this is a positive change, there are a few additional considerations to this decrease. Providers who were prescribing under a physician (i.e., physicians assistants, nurse practitioners)

were considered separate providers and patients could have been seeing an alternate provider due to scheduling. Members who received large quantities of medications following discharge from an acute care or long-term care facility were included if those quantities were at or above 30 days. Members could have received medications from multiple providers following procedures or for a short duration of time, and they could have discontinued use or their primary care provider could have continued both medications moving forward.

The number of members with 80 or more continuous days also decreased from the first mailing by 96 members. The second mailing in January 2024 specifically targeted members with 80 or more continuous days to address those members who were using concomitant gabapentinoids and opioids for a longer duration. The decrease in the number of members with 80 or more continuous days of use could be due to the ending of the Public Health Emergency (PHE) and subsequent disenrollment of SoonerCare members who no longer qualified for Medicaid. The PHE was put into place during the COVID-19 pandemic and prevented state Medicaid agencies from discontinuing services for members who no longer qualified, during this time period. After the end of the PHE, agencies were able to discontinue coverage of members who no longer qualified, resulting in a loss of total members covered and a potential decrease in members using concomitant opioids and gabapentinoids.

Prescriber Mailing: Conclusion

This mailing provided education on the dangers of respiratory depression due to concomitant utilization of opioids and gabapentinoids, with the goal of decreasing the number of SoonerCare members using both medications for long durations, where appropriate. While some members may require concomitant use, the benefits may not outweigh the increase risk of respiratory depression for most members. The overall number of unduplicated members with concomitant use decreased from the first mailing in September 2023 to April 2024. The number of providers included also decreased, but by a smaller margin. In addition to a decrease in the number of members with at least 30 days of concomitant use, the number of members who had ≥80 continuous days of concomitant utilization of opioids and gabapentinoids also decreased. Continued education via targeted mailings or other means is needed to continue to decline in the number of members who are using gabapentinoids and opioids concomitantly.

[1] Centers for Disease Control and Prevention (CDC). SUDORS Dashboard: Fatal Overdose Data. Available online at: https://www.cdc.gov/overdose-prevention/data-research/facts-stats/sudors-dashboard-fatal-overdose-data.html. Last revised 02/26/2024. Last accessed 06/05/2024.
[2] CDC. State Unintentional Drug Overdose Reporting System (SUDORS) Fact Sheet. Available online at: https://www.cdc.gov/overdose-prevention/media/pdfs/2024/04/SUDORS-Fact-Sheet.pdf. Last accessed 05/25/2024.
[3] U.S. Food and Drug Administration (FDA). FDA in Brief: FDA Requires New Warnings for Gabapentinoids About Risk of Respiratory Depression. Available online at: https://www.fda.gov/news-events/fda-brief/fda-brief-fda-requires-new-warnings-gabapentinoids-about-risk-respiratory-depression. Last revised 12/19/2019. Last accessed 05/15/2024.
[4] U.S. FDA. FDA Warns About Serious Breathing Problems with Seizure and Nerve Pain Medicines Gabapentin (Neurontin®, Gralise®, Horizant®) and Pregabalin (Lyrica®, Lyrica® CR). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentin-neurontin. Last revised 01/30/2020. Last accessed 06/05/2024.
[5] Kuehn B. Growing Role of Gabapentin in Opioid-Related Overdoses Highlights Misuse Potential and Off-Label Prescribing Practices. *JAMA* 2022; 328(13):1283-1285. doi: 10.1001/jama.2022.13659.
[6] Gorfinkel L, Hasin D, Saxon A, et al. Trends in Prescriptions for Non-opioid Pain Medications Among U.S. Adults with Moderate or Severe Pain, 2014-2018. *J Pain* 2022; 23(7):1187-1195. doi: 10.1016/j.jpain.2022.01.006.
[7] U.S. Department of Health and Human Services (HHS). Covid-19 Public Health Emergency (PHE). Available online at: https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html. Last revised 12/15/2023. Last accessed 05/15/2024.

Appendix C

Vote to Prior Authorize Glipizide 2.5mg Tablet, Inpefa® (Sotagliflozin), Lantidra™ (Donislecel-jujn), Metformin 625mg Tablet, Zituvio™ (Sitagliptin), and Zituvimet™ (Sitagliptin/Metformin) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone)

Oklahoma Health Care Authority
June 2024

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

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

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

News:

- **February 2022:** The FDA approved generic formulations of dapagliflozin in a 5mg and 10mg dose. However, due to patent

protection on Farxiga®, the generic formulations were not launched until January 3, 2024. An authorized generic of Xigduo® XR (dapagliflozin/metformin) has also been launched.

- **September 2022:** Novo Nordisk announced the launch of an unbranded version of Tresiba® (insulin degludec) for use in patients 1 year of age or older with diabetes. The unbranded version was originally FDA approved in July 2022.
- **March 2023:** Sanofi launched insulin glargine U-300, which is an unbranded version of Toujeo® (insulin glargine U-300). The unbranded version will have the same manufacturing and inactive ingredients as Toujeo®.
- **March 2023:** AstraZeneca has permanently discontinued brand name Onglyza® (saxagliptin) and Kombiglyze® XR (saxagliptin/metformin) due to business decisions and stated that it was not due to any safety or efficacy related concerns. Generic formulations of saxagliptin and saxagliptin/metformin were launched in August 2023 and remain available.
- **July 2023:** Metformin 625mg tablets were launched. Metformin was previously only available as 500mg, 850mg, and 1,000mg tablets in the immediate-release formulation.
- **October 2023:** A new strength of glipizide 2.5mg immediate-release tablets was launched and is now available from TruPharma, LLC.
- **November 2023:** Novo Nordisk announced the discontinuation of Levemir® (insulin detemir) due to manufacturing issues and available alternatives. The FlexPen® will be discontinued by April 1, 2024 and the vials will be discontinued by December 31, 2024.

Inpefa® (Sotagliflozin) Product Summary[15]

Therapeutic Class: SGLT-2 inhibitor

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

How Supplied: 200mg and 400mg tablets

Dosing and Administration:

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

Cost Comparison: SGLT-2 Inhibitors

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

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

Lantidra™ (Donislecel-jujn) Product Summary[16]

Therapeutic Class: Allogenic pancreatic islet cellular therapy

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

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

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

Dosing and Administration:

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

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

Cost Comparison: Biguanides

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year*
metformin 625mg (generic)	**$32.68⁺**	**$1,960.80**	**$23,529.60**
metformin 500mg (generic)	$0.01	$0.60	$7.20
metformin 1,000mg (generic)	$0.02	$1.20	$14.40

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

Cost Comparison: DPP-4 Inhibitors

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year*
Zituvio™ (sitagliptin) 100mg	**$18.15**	**$544.50**	**$6,534.00**
Januvia® (sitagliptin) 100mg	$18.32	$549.60	$6,595.20
Tradjenta® (linagliptin) 5mg	$16.75	$502.50	$6,030.00

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

Cost Comparison: Sulfonylureas

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year*
glipizide 2.5mg (generic)	**$1.16**	**$34.80**	**$417.60**
glipizide 5mg (generic)	$0.03	$0.45	$5.40

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

Recommendations

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

Lantidra™ (Donislecel-jujn) Approval Criteria:

1. An FDA approved diagnosis of type 1 diabetes mellitus (T1DM); and
2. Member must be 18 years of age or older; and

3. Must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member must have had T1DM for ≥5 years and has been receiving intensive insulin management defined as:
    a. Self-monitoring of blood glucose levels at least 3 times per day on average; and
    b. Using insulin pump therapy or using at least 3 insulin injections per day; and
    c. Under the care of a diabetes specialist with at least 3 evaluations in the past 12 months; and
5. Member is exhibiting 1 of the following despite intensive insulin management efforts:
    a. Hypoglycemic unawareness; or
    b. Two or more episodes of severe hypoglycemia, defined as an event with symptoms consistent with hypoglycemia in which the patient requires the assistance of another person and which is associated with a blood glucose level <54mg/dL; or
    c. Two or more hospital visits (inpatient and/or emergency department) for diabetic ketoacidosis over the last year; or
    d. Progressive secondary complications of diabetes as defined by retinopathy, nephropathy, or neuropathy despite efforts at optimal glucose control; and
6. Member must receive concomitant immunosuppression. Lantidra™ is contraindicated in adults who have a contraindication to immunosuppression; and
7. Member is T- and B-cell crossmatch assay negative; and
8. Member must not have any of the following:
    a. Severe cardiac disease defined by 1 of the following:
        i. Recent, within the past 6 months, myocardial infarction; or
        ii. Angiographic evidence of non-correctable coronary artery disease; or
        iii. Evidence of ischemia on functional cardiac exam (with a stress echo test recommended for members with a history of ischemic disease); or
        iv. Heart failure > New York Heart Association (NYHA) II; or
        v. History of stroke within the past 6 months; and
    b. No active infections, including hepatitis C, hepatitis B, human immunodeficiency virus (HIV), or tuberculosis; and
    c. No history of malignancy except squamous or basal skin cancer; and
    d. No concomitant disease or condition that contradicts the procedure or immunosuppression; and

    e. No history of liver disease or renal failure and has not been the recipient of a renal transplant; and
    f. No history of a prior portal vein thrombosis excluding thrombosis limited to second- or third-order portal vein branches; and
    g. C-peptide ≥0.3ng/mL following a 5g arginine intravenous (IV) infusion challenge; and
    h. Insulin requirements >0.7 IU/kg/day; and
    i. Recent hemoglobin A1C (HbA1c) >12%; and
9. Female members of reproductive potential must not be pregnant or breastfeeding and must agree to use effective contraception prior to initiation of immunosuppression and thereafter; and
10. Initial approvals will be for 12 months. Reauthorization may be granted if the prescriber documents the member has not achieved independence from exogenous insulin within 1 year of infusion or may be granted within 1 year after losing independence from exogenous insulin after a previous infusion; and
    a. Prescriber must verify the member is still receiving concomitant immunosuppression; and
11. Lantidra™ must be administered at a manufacturer approved transplant center; and
12. Approvals will be for a maximum of 3 infusions per member per lifetime.

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

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

8. Moving generic saxagliptin and saxagliptin/metformin to Special PA Tier based on net costs and the discontinuation of the brand formulations.

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/ glipizide (Metaglip®)			metformin ER susp (Riomet ER™)
metformin/ glyburide (Glucovance®)			**metformin 625mg tab**
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	**saxagliptin (Onglyza®)**
	linagliptin/ metformin (Jentadueto®)	alogliptin/ metformin (Kazano®)	**saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)**
	linagliptin/ metformin ER (Jentadueto® XR)	alogliptin/ pioglitazone (Oseni®)	**sitagliptin (Zituvio™)***
	~~**saxagliptin (Onglyza®)**~~		**sitagliptin/metformin (Zituvimet™)***
	~~**saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)**~~		
	sitagliptin (Januvia®)		
	sitagliptin/ metformin (Janumet®)		
	sitagliptin/ metformin ER (Janumet XR®)		
DPP-4 Inhibitors/SGLT-2 Inhibitors			

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

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	(Synjardy®)		
	empagliflozin/ metformin ER (Synjardy® XR)		ertugliflozin/ metformin (Segluromet®)
	dapagliflozin/ metformin ER (Xigduo® XR)		**sotagliflozin (Inpefa®)***
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)
Sulfonylureas			
glimepiride (Amaryl®)			**glipizide 2.5mg immediate-release tablet***
glipizide (Glucotrol®)			
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

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

Anti-Diabetic Medications Special PA Approval Criteria:

1. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and

~~2. Use of Invokamet XR [canagliflozin/metformin extended-release (ER)] will require a patient-specific, clinically significant reason why the member cannot take the immediate-release formulation(s); and~~

3. Use of Adlyxin® (lixisenatide) or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide 1 receptor agonists (GLP-1 agonists); and
4. Use of generic dapagliflozin or dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why they member cannot use brand name Farxiga® (dapagliflozin) or Xigduo® XR (dapagliflozin/metformin ER) and all available lower-tiered sodium-glucose cotransporter-2 (SGLT-2) inhibitors; and
5. Use of glipizide 2.5mg immediate-release tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a glipizide 5mg tablet to achieve a 2.5mg dose; and
6. Use of Zituvio™ (sitagliptin) and Zituvimet™ (sitagliptin/metformin) will require a patient-specific, clinically significant reason why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors).

Inpefa® (Sotagliflozin) Approval Criteria:

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

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

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

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

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

1. An FDA approved diagnosis of diabetes mellitus; and

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

Finally, the College of Pharmacy recommends the following changes to the Basaglar® (insulin glargine), Rezvoglar™ (insulin glargine-aglr), Ryzodeg® (insulin degludec/insulin aspart), Soliqua® 100/33 (insulin glargine/ lixisenatide), Toujeo® (insulin glargine), Tresiba® (insulin degludec), and Xultophy® 100/3.6 (insulin degludec/liraglutide) approval criteria based the discontinuation of Levemir® (insulin detemir) and removing the prior authorization of generic Semglee® (insulin glargine-ygfn) due to net costs (changes shown in red):

Basaglar® (Insulin Glargine) Approval Criteria:

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

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

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or ~~Levemir® (insulin detemir)~~ insulin glargine-yfgn (generic Semglee®) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

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

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

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

Semglee®) with an alternative glucagon-like peptide 1 (GLP-1) receptor agonist must be provided; and
3. Current Tier-3 criteria will apply.

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

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

Xultophy® 100/3.6 (Insulin Degludec/Liraglutide) Approval Criteria:
1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or insulin glargine-yfgn (generic Semglee®) with Victoza® (liraglutide) must be provided; and
3. Current Tier-3 criteria will apply.

[1] Lexicon Pharmaceuticals. Lexicon Announces FDA Approval of Inpefa™ (Sotagliflozin) for Treatment of Heart Failure. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2023/05/26/2677371/0/en/Lexicon-Announces-FDA-Approval-of-INPEFA-sotagliflozin-for-Treatment-of-Heart-Failure.html. Issued 05/26/2023. Last accessed 05/14/2024.
[2] U.S. Food and Drug Administration (FDA). FDA Approves First Cellular Therapy to Treat Patients with Type 1 Diabetes. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellular-therapy-treat-patients-type-1-diabetes. Issued 06/29/2023. Last accessed 05/14/2024.
[3] Zydus Lifesciences Limited. Zydus Receives USFDA Approval for Zituvio™ to Treat Adult Patients with Type 2 Diabetes Mellitus. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/zydus-receives-usfda-approval-for-zituvio-to-treat-adult-patients-with-type-2-diabetes-mellitus-301963298.html. Issued 10/20/2023. Last accessed 05/14/2024.
[4] Zituvimet™ (Sitagliptin/Metformin) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_zituvimet_2023-1107.pdf. Issued 11/03/2023. Last accessed 05/14/2024.
[5] Zoler M. FDA Moves Generic Dapagliflozin a Step Closer to US Sales. *Medscape*. Available online at: https://www.medscape.com/viewarticle/969050. Issued 02/23/2022. Last accessed 05/14/2024.
[6] Novo Nordisk. Novo Nordisk Launches Unbranded Biologic of Tresiba® Analog Insulin to Expand Affordability Options for Patients. Available online at: https://www.novonordisk-us.com/media/news-archive/news-details.html?id=133808. Issued 09/08/2022. Last accessed 05/14/2024.
[7] Toujeo®. FROM THE MAKERS OF TOUJEO®. Available online at: https://www.toujeo.com/real-patient-stories/unbranded-toujeo. Last accessed 05/14/2024.
[8] Toujeo® U-300 (Insulin Glargine) Prescribing Information. Sanofi. Available online at: https://products.sanofi.us/toujeo/toujeo.pdf. Last revised 03/2023. Last accessed 05/14/2024.
[9] Ernst D. Diabetes Drugs Onglyza®, Kombiglyze® XR Permanently Discontinued. *Medical Professionals Reference*. Available online at: https://www.empr.com/home/news/diabetes-drugs-onglyza-kombiglyze-xr-permanently-discontinued/. Issued 03/22/2023. Last accessed 05/14/2024.
[10] Aurobindo Pharma. Aurobindo Pharma Receives USFDA Approval for Saxagliptin Tablets, 2.5 mg and 5 mg. Available online at: https://www.aurobindo.com/api/uploads/corporateannouncements/Fy24_SAXAGLIPTIN%20TAB%20APPROVAL.pdf. Issued 08/01/2023. Last accessed 05/14/2024.
[11] Dr. Reddy's Laboratories Ltd. Dr. Reddy's Laboratories Announces its Launch of Saxagliptin and Metformin Hydrochloride Extended-Release Tablets in the U.S. Available online at: https://www.drreddys.com/cms/cms/sites/default/files/2023-08/Dr.%20Reddy%27s%20press%20release%20-%20saxagliptin%20%20metformin%20XR%20tablet%20%28002%29.pdf. Issued 08/10/2023. Last accessed 05/14/2024.
[12] Metformin 625mg Prescribing Information. LifSa Drugs, LLC. Available online at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a2385bcd-0943-4411-8658-c22b50360385&type=display. Last revised 04/2022. Last accessed 05/14/2024.
[13] TruPharma. TruPharma Launces the First Glipizide 2.5mg Tablet Product on a TruPharma Label. Available online at: https://www.trupharma.com/news/trupharma-launches-the-first-glipizide-2-5mg-tablet-product-on-a-trupharma-label/. Issued 10/2023. Last accessed 05/14/2024.
[14] Pediatric Endocrine Society. Levemir®, Discontinued. Available online at: https://pedsendo.org/drug-alerts/levemir-discontinued/. Issued 11/27/2023. Last accessed 05/14/2024.
[15] Inpefa® (Sotagliflozin) Prescribing Information. Lexicon Pharmaceuticals. Available online at: https://www.lexpharma.com/inpefa-US-PI.pdf. Last revised 01/2024. Last accessed 05/14/2024.
[16] Lantidra™ (Donislecel-jujn) Prescribing Information. CellTrans. Available online at: https://www.fda.gov/media/169920/download. Last revised 06/2023. Last accessed 05/14/2024.

Appendix D

Vote to Prior Authorize Izervay™ (Avacincaptad Pegol) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications

Oklahoma Health Care Authority
June 2024

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

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

- **August 2023:** The FDA approved Eylea® HD (aflibercept) 8mg injection for the treatment of wet AMD, diabetic macular edema (DME), and diabetic retinopathy (DR) based on the PULSAR and PHOTON studies. Both studies met their primary endpoint, with Eylea® HD demonstrating non-inferior and clinically equivalent vision gains at 48 weeks when compared to Eylea®. Eylea® HD is a higher dose of the already commercially available Eylea® 2mg injection that allows for less frequent injections with the potential to dose every 16 weeks after the initial 3 monthly doses. The Wholesale Acquisition Cost (WAC) for Eylea® HD is $2,625 per vial resulting in a cost per year of $21,000 for the FDA approved maximum dosing for 1 eye compared to Eylea® whose WAC is $1,850 per vial resulting in a cost per year of $24,050 for the FDA approved maximum dosing for 1 eye.
- **August 2023:** The FDA approved Izervay™ (avacincaptad pegol) for the treatment of geographic atrophy (GA) secondary to AMD.
- **October 2023:** The FDA approved an expanded indication for Vabysmo® (faricimab-svoa) for the treatment of macular edema following retinal vein occlusion (RVO). It was previously FDA approved for wet AMD and DME only.

Izervay™ (Avacincaptad Pegol) Product Summary[6]

Therapeutic Class: Complement inhibitor

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

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

Dosing and Administration:

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

Cost Comparison: Complement Inhibitors

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

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).,
Please note: The cost per dose is based on treatment of 1 eye, and the cost per year is based on the maximum number of doses needed for the treatment of 1 eye.
*Cost is based on 0.1mL every 4 weeks.
inj = injection

Recommendations

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

Izervay™ (Avacincaptad Pegol) Approval Criteria:

1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Izervay™ must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescribers must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and neovascular (wet) AMD; and
5. A patient specific, clinically significant reason why the member cannot use Syfovre® (pegcetacoplan) must be provided; and
6. A quantity limit of (1) 0.1mL single-dose vial per eye once monthly for up to 12 months will apply.

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

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

~~1. An FDA approved diagnosis; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use Byooviz™ (ranibizumab-nuna intravitreal injection) or Cimerli® (ranibizumab-eqrn intravitreal injection) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.~~

Susvimo™ (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of neovascular (wet) age-related macular degeneration (AMD) in adults; and
2. Member must have previously responded to ≥2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Susvimo™ must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal surgery; and
5. Prescriber must verify the member will be monitored for endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs; and
6. A patient-specific, clinically significant reason why the member cannot use ranibizumab intravitreal injection or other VEGF inhibitor injection products (appropriate to disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab)] must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

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

Vabysmo® (Faricimab-svoa Intravitreal Injection) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Neovascular (wet) age-related macular degeneration (AMD); or
   b. Diabetic macular edema (DME); ~~and~~ or
   c. Macular edema following retinal vein occlusion (RVO); and
2. Member must be 18 years of age or older; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Vabysmo® must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal injections; and
5. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and arterial thromboembolic events, and
6. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use

effective contraception during treatment and for 3 months after the final dose of Vabysmo®; and

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

---

[1] Regeneron Pharmaceuticals, Inc. Eylea® HD (Aflibercept) Injection 8mg Approved by FDA for Treatment of Wet Age-Related Macular Degeneration (WAMD), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR). Available online at: https://investor.regeneron.com/news-releases/news-release-details/eylea-hd-aflibercept-injection-8-mg-approved-fda-treatment-wet. Issued 08/18/2023. Last accessed 05/07/2024.

[2] Eylea® HD (Aflibercept) Prescribing Information. Regeneron Pharmaceuticals, Inc. Available online at: https://www.regeneron.com/downloads/eyleahd_fpi.pdf. Last revised 12/2023. Last accessed 05/07/2024.

[3] Astellas Pharma, Inc. Iveric Bio Receives U.S. FDA Approval for Izervay™ (Avacincaptad Pegol Intravitreal Solution), a New Treatment for Geographic Atrophy. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/iveric-bio-receives-us-fda-approval-for-izervay-avacincaptad-pegol-intravitreal-solution-a-new-treatment-for-geographic-atrophy-301894042.html. Issued 08/04/2023. Last accessed 05/07/2024.

[4] Genentech, Inc. FDA Approves Genentech's Vabysmo® for the Treatment of Retinal Vein Occlusion (RVO). Available online at: https://www.gene.com/media/press-releases/15009/2023-10-26/fda-approves-genentechs-vabysmo-for-the-. Issued 10/26/2023. Last accessed 05/07/2024.

[5] Vabysmo® (Faricimab-svoa) Prescribing Information. Genentech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761235s003lbl.pdf. Last revised 10/2023. Last accessed 05/07/2024.

[6] Izervay™ (Avacincaptad Pegol Intravitreal Injection) Prescribing Information. Iveric bio, Inc. Available online at: https://ivericbio.com/wp-content/uploads/IZERVAY-avacincaptad-pegol-intravitreal-solution-PI_Final_8.4.23.pdf. Last revised 08/2023. Last accessed 05/07/2024.

Appendix E

Vote to Prior Authorize Rezzayo™ (Rezafungin Injection)

Oklahoma Health Care Authority
June 2024

Market News and Updates[1]

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

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

Rezzayo™ (Rezafungin Injection) Product Summary[2]

Therapeutic Class: Echinocandin antifungal

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

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

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

Dosing and Administration:

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

Cost Comparison: Echinocandin Antifungal Medications

Medication	Cost Per Vial*	Cost Per Treatment†
Rezzayo™ (rezafungin) 200mg	**$1,950.00**	**$9,750.00**
Eraxis® (anidulafungin) 100mg	$190.89	$5,535.81
micafungin 100mg (generic)	$187.00[α]	$5,236.00
caspofungin 50mg (generic)	$66.29	$1,922.41

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

[α]Cost per vial varies per NDC

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

Recommendations

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

Rezzayo™ (Rezafungin Injection) Approval Criteria:

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

---

[1] Gallagher A. FDA Approves Rezafungin Injection for the Treatment of Candidemia, Invasive Candidiasis. *Pharmacy Times*. Available online at: https://www.pharmacytimes.com/view/fda-approves-rezafungin-injection-for-the-treatment-of-candidemia-invasive-candidiasis. Issued 03/24/2023. Last accessed 05/24/2024.

[2] Rezzayo™ (Rezafungin) Prescribing Information. Cidara Therapeutics Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217417s000lbl.pdf. Last revised 03/2023. Last accessed 05/24/2024.

Appendix F

Vote to Prior Authorize PrevPac® (Lansoprazole/ Amoxicillin/Clarithromycin), Voquezna® (Vonoprazan), Voquezna® Dual Pak® (Vonoprazan/Amoxicillin), and Voquezna® Triple Pak® (Vonoprazan/Amoxicillin/ Clarithromycin) and Update the Approval Criteria for the Anti-Ulcer Medications

Oklahoma Health Care Authority
June 2024

Market News and Updates[1,2,3]

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

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

Voquezna® (Vonoprazan) Product Summary[4]

Therapeutic Class: Potassium-competitive acid blocker

Indication(s):

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

How Supplied: 10mg and 20mg tablets

Dosing and Administration:

- Healing of erosive esophagitis: 20mg once daily for 8 weeks
- Maintenance of healed erosive esophagitis: 10mg once daily for up to 6 months

- Treatment of *H. pylori*: 20mg twice daily in combination with amoxicillin ± clarithromycin

Cost Comparison: Anti-Ulcer Medications

Product	Cost Per Unit	Cost Per 8-Week Course*
Voquezna® (vonoprazan) 20mg tablet	**$20.71**	**$1,159.76**
esomeprazole 40mg capsule (generic)	$0.13	$7.28
pantoprazole 40mg tablet (generic)	$0.05	$2.80
omeprazole 20mg capsule (generic)	$0.03	$1.68

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet or capsule
*Cost per 8-week treatment course is based on the FDA approved dosing for the healing of erosive esophagitis for each product

Voquezna® Dual Pak® (Vonoprazan/Amoxicillin) and Voquezna® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin) Product Summary[5]

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

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

How Supplied: Carton of 14 daily administration packs for morning and evening dosing, each containing the following:
- Voquezna® Dual Pak®: Vonoprazan 20mg tablets and amoxicillin 500mg capsules
- Voquezna® Triple Pak®: Vonoprazan 20mg tablets, amoxicillin 500mg capsules, and clarithromycin 500mg tablets

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

Cost Comparison: *H. Pylori* Treatments

Product	Cost Per Unit	Cost Per Course*
Voquezna® Dual Pak® (vonoprazan/amoxicillin)	**$7.25**	**$812.00**
Voquezna® Triple Pak® (vonoprazan/amoxicillin/ clarithromycin)	**$7.25**	**$812.00**

lansoprazole/amoxicillin/clarithromycin (generic PrevPac®)	**$5.15**	**$576.80**
Talicia® (omeprazole/amoxicillin/rifabutin)	$4.59	$771.12
Pylera® (bismuth/metronidazole/tetracycline)	$2.43	$291.60

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

Recommendations

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

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

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
~~**bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® caps) – Brand Preferred**~~	pantoprazole (Protonix® I.V.)	esomeprazole (Nexium® I.V.)	**bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® caps)**
dexlansoprazole (Dexilant® caps)		esomeprazole strontium caps	cimetidine (Tagamet® tabs)
esomeprazole (Nexium® caps)		omeprazole (Prilosec® susp, powder)	esomeprazole kit (ESOMEP-EZS™)
esomeprazole (Nexium® packet) – **Brand Preferred**		pantoprazole (Protonix® susp)	famotidine (Pepcid® susp)
lansoprazole (Prevacid® caps)		rabeprazole (Aciphex® sprinkles)	glycopyrrolate (Glycate® tabs)

lansoprazole ODT (Prevacid® ODT) – **Brand Preferred**			glycopyrrolate ODT (Dartisla® ODT)
omeprazole (Prilosec® caps)			**lansoprazole/amoxicillin/ clarithromycin (PrevPac®)**
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/amoxicillin/ rifabutin (Talicia® caps)
sucralfate susp (Carafate®)			omeprazole/sodium bicarbonate (Konvomep™ for oral suspension)
			omeprazole/sodium bicarbonate (Zegrid® caps & pack)
			vonoprazan (Voquezna® tabs)
			vonoprazan fumarate/ amoxicillin trihydrate (Voquezna® Dual Pak®)
			vonoprazan fumarate/ amoxicillin trihydrate/ clarithromycin (Voquezna® Triple Pak®)

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

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

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

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

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole,

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

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

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

Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate) and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/ Clarithromycin) Approval Criteria:
1. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/ H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori*

infection (e.g., omeprazole, amoxicillin, and clarithromycin) which are available without prior authorization, must be provided; and

5. A quantity limit of 112 tablets/capsules per 14 days will apply.

---

[1] Phathom Pharmaceuticals. Phathom Pharmaceuticals Announces FDA Approval of Voquezna® Triple Pak® (Vonoprazan, Amoxicillin, Clarithromycin) and Voquezna® Dual Pak® (Vonoprazan, Amoxicillin) for the Treatment of *H. pylori* Infection in Adults. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2022/05/03/2435147/0/en/Phathom-Pharmaceuticals-Announces-FDA-Approval-of-VOQUEZNA-TRIPLE-PAK-vonoprazan-amoxicillin-clarithromycin-and-VOQUEZNA-DUAL-PAK-vonoprazan-amoxicillin-for-the-Treatment-of-H-pylo.html. Issued 05/03/2022. Last accessed 05/14/2024.

[2] Phathom Pharmaceuticals. Phathom Pharmaceuticals Announces FDA Approval of Reformulated Vonoprazan Tablets for Voquezna® Triple Pak® (Vonoprazan, Amoxicillin, Clarithromycin) and Voquezna® Dual Pak® (Vonoprazan, Amoxicillin) for the Treatment of *H. pylori* Infection in Adults. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2023/10/30/2769171/0/en/Phathom-Pharmaceuticals-Announces-FDA-Approval-of-Reformulated-Vonoprazan-Tablets-for-VOQUEZNA-TRIPLE-PAK-vonoprazan-amoxicillin-clarithromycin-and-VOQUEZNA-DUAL-PAK-vonoprazan-amo.html. Issued 10/30/2023. Last accessed 05/14/2024.

[3] Phathom Pharmaceuticals. Phathom Pharmaceuticals Announces FDA Approval of Voquezna® (Vonoprazan) Tablets for the Treatment of Erosive GERD and Relief of Heartburn Associated with Erosive GERD in Adults. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2023/11/01/2771786/0/en/Phathom-Pharmaceuticals-Announces-FDA-Approval-of-VOQUEZNA-vonoprazan-Tablets-for-the-Treatment-of-Erosive-GERD-and-Relief-of-Heartburn-Associated-with-Erosive-GERD-in-Adults.html. Issued 10/30/2023. Last accessed 05/14/2024.

[4] Voquezna® (Vonoprazan) Prescribing Information. Phathom Pharmaceuticals. Available online at: https://www.phathompharma.com/wp-content/uploads/VOQUEZNA-tablets-Prescriber-Information.pdf. Last revised 11/2023. Last accessed 05/14/2024.

[5] Voquezna® Triple Pak® (Vonoprazan/Amoxicillin/Clarithromycin) and Voquezna® Dual Pak® (Vonoprazan/Amoxicillin) Prescribing Information. Phathom Pharmaceuticals. Available online at: https://www.phathompharma.com/wp-content/uploads/VOQUEZNA-TRIPLE-PAK-and-VOQUEZNA-DUAL-PAK-FDA-Final-Label-3.pdf. Last revised 10/2023. Last accessed 05/14/2024.

Appendix G

Vote to Prior Authorize Augtyro™ (Repotrectinib) and Pemrydi RTU® (Pemetrexed) and Update the Approval Criteria for the Lung Cancer Medications

Oklahoma Health Care Authority
June 2024

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

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

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

- **April 2024:** The FDA approved a new indication for Alecensa® (alectinib) for adjuvant treatment of adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive NSCLC (tumors ≥4cm or node positive) as detected by an FDA-approved test.
- **May 2024:** The FDA granted accelerated approval for an age expansion down to 2 years of age for Retevmo® (selpercatinib) for 3 indications: treatment of advanced or metastatic medullary thyroid cancer (MTC) with a rearranged during transfection (RET) gene fusion in patients who require systemic therapy, treatment of advanced or metastatic thyroid cancer with a RET gene fusion in patients who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate), and treatment of locally advanced or metastatic solid tumors with a RET gene fusion in patients who have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

News:

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

Guideline Update(s):

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

Augtyro™ (Repotrectinib) Product Summary[14]

Therapeutic Class: Kinase inhibitor

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

How Supplied: 40mg oral capsule

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

Cost: The Wholesale Acquisition Cost (WAC) is $120.83 per capsule, resulting in a cost of $6,766.48 for the initial 14 days of treatment. Subsequent cost would be $28,999.20 per 30 days or $347,990.40 per year based on the recommended dosing.

Recommendations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Diagnosis of solid tumors; and
2. Member must be older than 1 month ~~12 years~~ of age ~~or older~~; and
3. Neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation; and
4. Metastatic or not a surgical candidate; and
5. Progressed following treatment or have no satisfactory alternative therapy.
6. As a single agent.

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

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

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

1. Diagnosis of NSCLC; and
    a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; ~~or~~ and
    b. As a single agent; or
2. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease; or
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and
    c. As a single agent; or
3. ~~As a single agent; or~~
4. Diagnosis of locally advanced or metastatic non-squamous NSCLC; and
    a. Used as first-line treatment; and
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and
    c. Used in combination with pemetrexed and platinum-based (cisplatin or carboplatin) chemotherapy.

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

Imfinzi® (Durvalumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of unresectable HCC; and
2. Used in combination with tremelimumab-actl; or
3. As a single agent.

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

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

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

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

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

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

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

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

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

[1] Amneal Pharmaceuticals, Inc. Amneal Receives 505(b)(2) NDA Approval from FDA for Pemrydi RTU®, a Ready-to-Use Oncology Injectable. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2023/Amneal-Receives-505b2-NDA-Approval-from-FDA-for-PEMRYDI-RTU-a-Ready-to-Use-Oncology-Injectable/default.aspx. Issued 06/14/2023. Last accessed 05/23/2024.
[2] Pemrydi RTU® (Pemetrexed Injection) Prescribing Information. Amneal Pharmaceuticals, Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=0f006b06-ab85-423d-ba0c-dfc3fc25844e&type=pdf. Last revised 06/2023. Last accessed 05/23/2024.
[3] U.S. FDA. FDA Expands Pediatric Indication for Entrectinib and Approves New Pellet Formulation. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-pediatric-indication-entrectinib-and-approves-new-pellet-formulation. Issued 10/20/2023. Last accessed 05/23/2024.
[4] U.S. FDA. FDA Approves Repotrectinib for ROS1-Positive Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-repotrectinib-ros1-positive-non-small-cell-lung-cancer. Issued 11/15/2023. Last accessed 05/23/2024.
[5] U.S. FDA. FDA Approves Osimertinib with Chemotherapy for EGFR-Mutated Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-osimertinib-chemotherapy-egfr-mutated-non-small-cell-lung-cancer. Issued 02/16/2024. Last accessed 05/23/2024.
[6] U.S. FDA. FDA Approves Amivantamab-vmjw for EGFR Exon 20 Insertion-Mutated Non-Small Cell Lung Cancer Indications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-amivantamab-vmjw-egfr-exon-20-insertion-mutated-non-small-cell-lung-cancer-indications. Issued 03/01/2024. Last accessed 05/23/2024.
[7] U.S. FDA. FDA Approves Alectinib as Adjuvant Treatment for ALK-Positive Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-alectinib-adjuvant-treatment-alk-positive-non-small-cell-lung-cancer. Issued 04/18/2024. Last accessed 05/23/2024.
[8] U.S. FDA. FDA Grants Accelerated Approval to Selpercatinib for Pediatric Patients Two Years and Older with RET-Altered Metastatic Thyroid Cancer or Solid Tumors. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-selpercatinib-pediatric-patients-two-years-and-older-ret-altered. Issued 05/29/2024. Last accessed 05/31/2024.
[9] Genentech. Genentech Provides Update on Gavreto® U.S. Indication for Advanced or Metastatic Medullary Thyroid Cancer. Available online at: https://www.gene.com/media/statements/ps_062923. Issued 6/29/2023. Last accessed 05/23/2024.
[10] Takeda. Takeda Provides Update on Exkivity® (Mobocertinib). Available online at: https://www.takeda.com/newsroom/newsreleases/2023/Takeda-Provides-Update-on-EXKIVITY-mobocertinib/. Issued 10/02/2023. Last accessed 05/23/2024.
[11] National Comprehensive Cancer Network (NCCN). Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Last revised 04/09/2024. Last accessed 05/23/2024.
[12] NCCN. Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Last revised 04/30/2024. Last accessed 05/23/2024.
[13] NCCN. Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Last revised 04/23/2024. Last accessed 05/23/2024.
[14] Augtyro™ (Repotrectinib) Prescribing Information. Bristol-Myers Squibb. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/218213s000lbl.pdf. Last revised 11/2023. Last accessed 05/23/2024.

Appendix H

Calendar Year 2023 Annual Review of Nasal Allergy Medications

Oklahoma Health Care Authority
June 2024

Current Prior Authorization Criteria

Nasal Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
azelastine (Astelin®)	azelastine (Astepro®)	azelastine/fluticasone (Dymista®)
beclomethasone (Beconase® AQ)	mometasone (Nasonex®)	beclomethasone (Qnasl® 80mcg, 40mcg)
fluticasone (Flonase®)		ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®, Nasarel®)
		fluticasone (Veramyst®)
		fluticasone (Xhance®)*
		olopatadine (Patanase®)
		olopatadine/mometasone (Ryaltris®)

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).
*Xhance®: Unique criteria applies.

Nasal Allergy Medications Tier-2 Approval Criteria:

1. Member must have failure with all Tier-1 medications defined as no beneficial response after at least 3 weeks use at the maximum recommended dose; or
2. Documented adverse effect or contraindication to all Tier-1 medications; and
3. For members 2 to 4 years of age, the age-appropriate, lower-tiered generic medications must be tried prior to the approval of higher-tiered medications; and
4. Approvals will be for the duration of 3 months, except for members with chronic diseases such as asthma or chronic obstructive pulmonary disease (COPD), in which case authorizations will be for the duration of 1 year.

Nasal Allergy Medications Tier-3 Approval Criteria:

1. All Tier-2 criteria must be met; and

2. Member must have failure with all available Tier-2 medications defined as no beneficial response after at least 3 weeks use at the maximum recommended dose; or
3. Documented adverse effect or contraindication to all Tier-2 medications; and
4. For members 2 to 4 years of age, the age-appropriate, lower-tiered generic medications must be tried prior to the approval of higher-tiered medications; and
5. Approvals will be for the duration of 3 months, except for members with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of 1 year.

Sinuva® (Mometasone Furoate Sinus Implant) Approval Criteria:

1. An FDA approved indication of nasal polyps in adults 18 years of age and older who have had ethmoid sinus surgery; and
2. Date of ethmoid sinus surgery must be provided; and
3. Sinuva® must be prescribed and implanted by a physician specializing in otolaryngology; and
4. Failure of intranasal corticosteroids after at least a 3-month trial at the maximum recommended dose in combination with a 14-day trial of oral corticosteroids within the last 6 months (if not contraindicated); and
5. Prescriber must confirm the member has recurrent nasal obstruction/congestion symptoms and recurrent bilateral sinusitis or chronic sinusitis due to nasal polyps; and
6. A quantity limit of 2 implants per member will apply.

Xhance® (Fluticasone Propionate Nasal Spray) Approval Criteria:

1. An FDA approved diagnosis of nasal polyps; and
2. A patient-specific, clinically significant reason why the member cannot use intranasal fluticasone, budesonide, mometasone, and/or other cost-effective therapeutic equivalent medication(s) must be provided; and
3. Current Tier structure rules will also apply.

Utilization of Nasal Allergy Medications: Calendar Year 2023

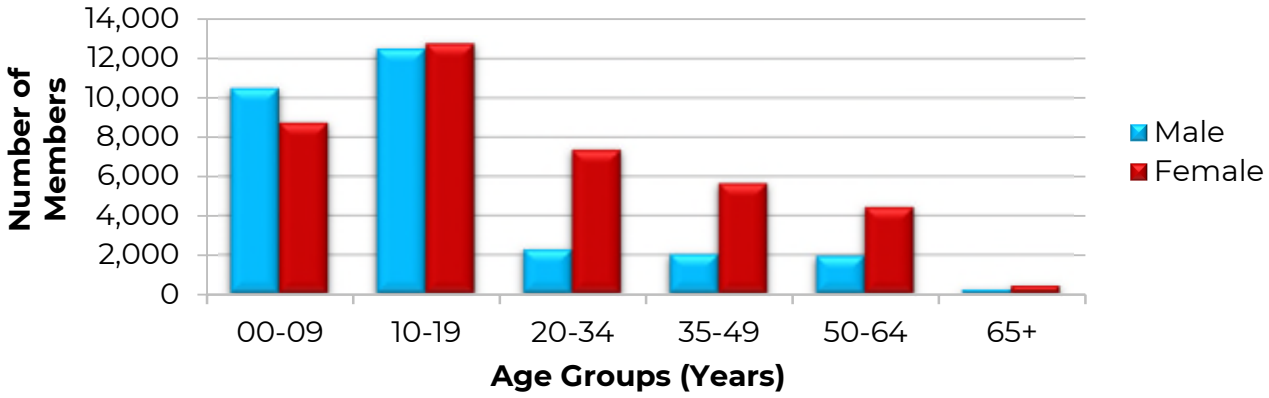
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	62,103	111,705	$2,151,178.62	$19.26	$0.49	1,827,255	4,368,141
2023	68,470	119,762	$2,286,839.73	$19.09	$0.48	1,997,918	4,736,381
% Change	**10.30%**	**7.20%**	**6.30%**	**-0.90%**	**-2.00%**	**9.30%**	**8.40%**
Change	**6,367**	**8,057**	**$135,661.11**	**-$0.17**	**-$0.01**	**170,663**	**368,240**

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

- Aggregate drug rebates collected during calendar year 2023 for the nasal allergy medications totaled $528,517.81.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Nasal Allergy Medications

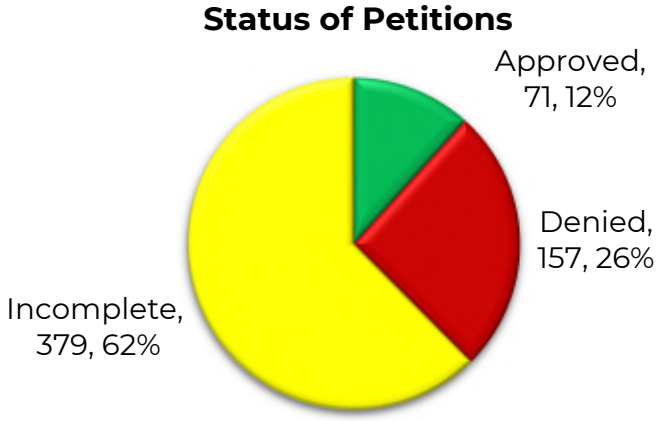


Top Prescriber Specialties of Nasal Allergy Medications by Number of Claims

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

Prior Authorization of Nasal Allergy Medications

There were 607 prior authorization requests submitted for nasal allergy medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



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

Anticipated Patent Expiration(s):

- Dymista® (azelastine/fluticasone): August 2026
- Omnaris® (ciclesonide): February 2028
- Zetonna® (ciclesonide): February 2028
- Astepro® (azelastine): June 2028
- Qnasl® (beclomethasone): October 2031
- Sinuva® (mometasone furoate): November 2034
- Xhance® (fluticasone): February 2036
- Ryaltris® (olopatadine/mometasone): September 2038

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

- **August 2016:** GSK Consumer Healthcare announced the FDA approval of Flonase® Sensimist™ (fluticasone furoate) as an over-the-counter product that was previously available by prescription only as Veramyst® (fluticasone furoate). Flonase® Sensimist™ was launched in February 2017 replacing Veramyst®, which is no longer available.
- **March 2024:** The FDA approved an expanded indication for Xhance® (fluticasone) nasal spray for the treatment of chronic rhinosinusitis without nasal polyps. Previously, Xhance® was only approved for chronic rhinosinusitis with nasal polyps.

News:

- **January 2023:** The FDA updated the term for “nasal polyps” in the package labeling for Sinuva® (mometasone furoate sinus implant) to “chronic rhinosinusitis with nasal polyps”.

Pipeline:

- **LYR-210:** LYR-210 is a bioabsorbable nasal mesh that is administered into the nasal passage during an in-office procedure and delivers mometasone furoate continuously for up to 6 months. It is currently being evaluated for use in patients with chronic rhinosinusitis who have failed current treatments in the Phase 3 clinical program, ENLIGHTEN.

Recommendations

The College of Pharmacy recommends the following change to the Xhance® (fluticasone) nasal spray approval criteria based on the new FDA approved indication (changes shown in red):

Xhance® (Fluticasone Propionate Nasal Spray) Approval Criteria:

1. An FDA approved diagnosis ~~of nasal polyps~~; and
2. A patient-specific, clinically significant reason why the member cannot use intranasal fluticasone, budesonide, mometasone, and/or other cost-effective therapeutic equivalent medication(s) must be provided; and
3. Current Tier structure rules will also apply.

Additionally, the College of Pharmacy recommends the following change to the Sinuva® (mometasone furoate sinus implant) approval criteria to be consistent with the package labeling (changes shown in red):

Sinuva® (Mometasone Furoate Sinus Implant) Approval Criteria:

1. An FDA approved indication of chronic rhinosinusitis with nasal polyps in adults 18 years of age and older who have had ethmoid sinus surgery; and
2. Date of ethmoid sinus surgery must be provided; and
3. Sinuva® must be prescribed and implanted by a physician specializing in otolaryngology; and
4. Failure of intranasal corticosteroids after at least a 3-month trial at the maximum recommended dose in combination with a 14-day trial of oral corticosteroids within the last 6 months (if not contraindicated); and
5. Prescriber must confirm the member has recurrent nasal obstruction/ congestion symptoms and recurrent bilateral sinusitis or chronic sinusitis due to nasal polyps; and
6. A quantity limit of 2 implants per member will apply.

Finally, the College of Pharmacy recommends the following changes to the current Nasal Allergy Medications Product Based Prior Authorization (PBPA) category based on net costs and product availability (changes shown in red):

1. Moving ciclesonide (Omnaris®, Zetonna®) from Tier-3 to Tier-1; and
2. Moving olopatadine (Patanase®) from Tier-3 to Tier-2; and
3. Removing fluticasone (Veramyst®) due to product discontinuation.

Nasal Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
azelastine (Astelin®)	azelastine (Astepro®)	azelastine/fluticasone (Dymista®)
beclomethasone (Beconase® AQ)	mometasone (Nasonex®)	beclomethasone (Qnasl® 80mcg, 40mcg)
ciclesonide (Omnaris®, Zetonna®)	**olopatadine (Patanase®)**	~~**ciclesonide (Omnaris®, Zetonna®)**~~
fluticasone (Flonase®)		flunisolide (Nasalide®, Nasarel®)
		~~**fluticasone (Veramyst®)**~~
		fluticasone (Xhance®)*
		~~**olopatadine (Patanase®)**~~
		olopatadine/mometasone (Ryaltris®)

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).
*Xhance®: Unique criteria applies.

Utilization Details of Nasal Allergy Medications: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
FLUTICASONE SPR 50MCG	113,253	66,411	$1,703,856.69	$15.04	1.71	74.51%
AZELASTINE SPR 0.1%	4,775	3,062	$83,673.66	$17.52	1.56	3.66%
BECONASE AQ SUS 0.042%	1,583	781	$481,438.43	$304.13	2.03	21.05%
SUBTOTAL	**119,611**	**68,448***	**$2,268,968.78**	**$18.97**	**1.75**	**99.22%**
TIER-2 PRODUCTS						
MOMETASONE SPR 50MCG	69	28	$2,825.02	$40.94	2.46	0.12%
AZELASTINE SPR 0.15%	3	3	$80.54	$26.85	1	0.00%
SUBTOTAL	**72**	**31***	**$2,905.56**	**$40.36**	**2.32**	**0.13%**
TIER-3 PRODUCTS						
AZEL/FLUTIC SPR 137/50MCG	46	8	$4,090.11	$88.92	5.75	0.18%
QNASL AER 80MCG	22	4	$6,430.66	$292.30	5.5	0.28%
QNASL CHILD SPR 40MCG	4	3	$1,183.24	$295.81	1.33	0.05%
XHANCE 93MCG	3	3	$2,890.91	$963.64	1	0.13%
OMNARIS SPR 50MCG	2	1	$293.02	$146.51	2	0.01%
OLOPATADINE SPR 0.6%	2	2	$77.45	$38.73	1	0.00%
SUBTOTAL	**79**	**21***	**$14,965.39**	**$189.44**	**3.76**	**0.65%**
TOTAL	**119,762**	**68,470***	**$2,286,839.73**	**$19.09**	**1.75**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AER = aerosol; AQ = aqueous; AZEL/FLUTIC = azelastine/fluticasone; SPR = spray; SUS = suspension

[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 05/2024. Last accessed 05/03/2024.
[2] OptiNose®, Inc. Xhance® Approved by FDA as First and Only Medication Indicated for Treatment of Adults with Chronic Rhinosinusitis without Nasal Polyps. Available online at: https://ir.optinose.com/news-releases/news-release-details/xhance-approved-fda-first-and-only-medication-indicated. Issued 03/15/2024. Last accessed 05/03/2024.
[3] Xhance® Prescribing Information. OptiNose®, Inc. Available online at: https://www.xhance.com/files/XHANCE_Full_Prescribing_Information.pdf. Last revised 03/2024. Last accessed 05/03/2024.
[4] Sinuva® Prescribing Information. Intersect ENT, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209310s006lbl.pdf. Last revised 01/2023. Last accessed 05/24/2024.
[5] GlaxoSmithKline (GSK), PLC. FDA Approves Flonase® Sensimist™ Allergy Relief. Available online at: https://us.gsk.com/en-us/media/press-releases/fda-approves-flonase-sensimist-allergy-relief/. Issued 08/02/2016. Last accessed 05/29/2024.
[6] GSK, PLC. GSK Consumer Healthcare Launches Flonase® Sensimist™ Allergy Relief Nationwide. Available online at: https://us.gsk.com/en-us/media/press-releases/gsk-consumer-healthcare-launches-flonase-sensimist-allergy-relief-nationwide/. Issued 02/08/2017. Last accessed 05/29/2024.
[7] Lyra Therapeutics. Pipeline LYR-210: An Innovative Therapeutic Solution for Chronic Rhinosinusitis (CRS). Available online at: https://lyratherapeutics.com/pipeline/lyr-210/. Last accessed 05/07/2024.

Appendix I

Calendar Year 2023 Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Akeega® (Niraparib/ Abiraterone) and Anktiva® (Nogapendekin Alfa Inbakicept-pmln)

Oklahoma Health Care Authority
June 2024

Current Prior Authorization Criteria

Utilization data for Bavencio® (avelumab), Keytruda® (pembrolizumab), Mekinist® (trametinib), Opdivo® (nivolumab), and Yervoy® (ipilimumab) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the December 2023 DUR Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Talzenna® (talazoparib) and Trodelvy® (sacituzumab govitecan-hziy) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the September 2023 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the breast cancer medications.

Adstiladrin® (Nadofaragene Firadenovec-vncg) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS) with or without papillary tumors; and
2. High-risk disease that was unresponsive to prior Bacillus Calmette-Guérin (BCG) therapy.

Afinitor® (Everolimus) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Hormone receptor (HR) positive; and
4. Used in combination with exemestane, fulvestrant, or tamoxifen; and
5. Member must have failed treatment with, have a contraindication to, or be intolerant to letrozole or anastrozole.

Afinitor® (Everolimus) Approval Criteria [Neuroendocrine Tumors (NET) of Pancreatic (PNET), Gastrointestinal, or Lung Origin Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic NET of pancreatic (PNET), gastrointestinal, or lung origin; and
2. Progressive disease from a previous treatment.

Afinitor® (Everolimus) Approval Criteria [Renal Angiomyolipoma (AML) and Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of renal AML and TSC; and
2. Not requiring immediate surgery; and
3. Used in pediatric and adult members 1 year of age and older.

Afinitor® (Everolimus) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Failure of treatment with sunitinib or sorafenib; and
3. Everolimus may also be approved to be used in combination with lenvatinib for advanced RCC.

Afinitor® (Everolimus) Approval Criteria [Subependymal Giant Cell Astrocytoma (SEGA) with Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of SEGA with TSC; and
2. Requires therapeutic intervention but cannot be curatively resected.

Afinitor® (Everolimus) Approval Criteria [Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures Diagnosis]:

1. Diagnosis of TSC-associated partial-onset seizures; and
2. Initial prescription must be written by a neurologist or neuro-oncologist; and
3. Failure of ≥3 other medications commonly used for seizures; and
4. Must be used as adjunctive treatment; and
5. Member must not be taking any P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin) concurrently with Afinitor®; and
6. Member must not be taking St. John's wort concurrently with Afinitor®; and
7. Prescriber must verify that Afinitor® trough levels and adverse reactions (e.g., non-infectious pneumonitis, stomatitis, hyperglycemia, dyslipidemia, thrombocytopenia, neutropenia, febrile neutropenia) will be monitored and dosing changes or discontinuations will correspond with recommendations in the package labeling; and
8. Prescriber must verify that female members are not pregnant and will use contraception while receiving Afinitor® therapy and for 8 weeks after the last dose of Afinitor® and that male members with female partners of reproductive potential will use contraception while receiving Afinitor® therapy and for 4 weeks after the last dose of Afinitor®; and
9. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and

10. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Balversa® (Erdafitinib) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Tumor positive for *FGFR2* or *FGFR3* genetic mutation; and
3. Used as second-line or greater therapy including:
    a. Following at least 1 line of platinum-containing chemotherapy; and
    b. Within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

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

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

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

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

Cabometyx® (Cabozantinib) Approval Criteria:

1. For cabozantinib monotherapy:
    a. Diagnosis of advanced renal cell carcinoma (RCC); or
    b. Diagnosis of advanced hepatocellular carcinoma (HCC); and
        i. Member has previously received sorafenib; or
    c. Diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) in adults and pediatric members 12 years of age and older; and
        i. Disease has progressed following prior vascular endothelial growth factor (VEGF)-targeted therapy; and
        ii. Disease is radioactive iodine-refractory or member is ineligible for radioactive iodine; or
2. For cabozantinib in combination with nivolumab:
    a. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
    b. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

Camcevi® (Leuprolide) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication].

Elahere™ (Mirvetuximab Soravtansine-gynx) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Tumor is folate receptor alpha (FRα) positive; and
3. Member has received 1 to 3 prior systemic treatment regimens.

Erleada® (Apalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; or
2. Castration-resistant or disease progression while on androgen deprivation therapy (ADT); and
3. Prostate specific antigen doubling time of ≤10 months; and
4. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Erleada® (Apalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Fotivda® (Tivozanib) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or refractory advanced RCC; and
2. Member has received at least 2 prior systemic therapies; and
3. As a single agent.

Jelmyto® (Mitomycin) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of non-metastatic upper urinary tract tumor; and
2. Must be a single, residual, low-grade, low-volume (5 to 15mm) tumor; and
3. Member is not a candidate for nephroureterectomy; and
4. Initial approvals will be for the duration of 6 weeks. With documentation from the prescriber of complete response 3 months after initial treatment, subsequent approvals may be authorized for once monthly use for up to 11 additional instillations.

Jemperli (Dostarlimab-gxly) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Diagnosis of advanced, recurrent, or metastatic endometrial cancer; and
2. Mismatch repair deficient (dMMR) disease; and
3. Disease has progressed on or following prior treatment with a platinum-containing regimen.

Jemperli (Dostarlimab-gxly) Approval Criteria [Mismatch Repair Deficient (dMMR) Solid Tumor Diagnosis]:

1. Diagnosis of recurrent or advanced solid tumors that are dMMR; and
2. Disease has progressed on or following prior treatment; and
3. There are no satisfactory treatment alternatives for the member.

Jevtana® (Cabazitaxel) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Previous treatment with a docetaxel-containing regimen; and
3. Used in combination with prednisone.

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

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

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

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
3. Member is not a candidate for curative surgery or radiation; and
4. Used in 1 of the following settings:
    a. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
    b. As a single agent for advanced endometrial cancer that is MSI-H or dMMR.

Keytruda® (Pembrolizumab) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

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

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

1. Diagnosis of new or recurrent stage 4 clear-cell RCC; and
    a. Member has not received previous systemic therapy for advanced disease; and
    b. Must be used in combination with axitinib or lenvatinib; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

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

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

Lenvima® (Lenvatinib) Approval Criteria [Differentiated Thyroid Cancer (DTC) Diagnosis]:

1. Locally recurrent or metastatic disease; and

2. Disease progression on prior treatment; and
3. Radioactive iodine-refractory disease.

Lenvima® (Lenvatinib) Approval Criteria [Endometrial Carcinoma Diagnosis]:

1. Advanced disease with progression on prior systemic therapy; and
2. Member is not a candidate for curative surgery or radiation; and
3. Disease is mismatch repair proficient (pMMR) or is not microsatellite instability-high (MSI-H); and
4. Used in combination with pembrolizumab.

Lenvima® (Lenvatinib) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Unresectable disease; and
2. First-line treatment.

Lenvima® (Lenvatinib) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
    a. Used in combination with pembrolizumab; or
    b. Following 1 prior anti-angiogenic therapy; and
        i. Used in combination with everolimus.

Lynparza® (Olaparib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy; and
    a. Used in the adjuvant setting; and
    b. Positive test for a germline BRCA-mutation (gBRCAm); and
    c. Maximum treatment duration of 1 year; or
2. Diagnosis of metastatic breast cancer; and
    a. Member must have shown progression on previous chemotherapy; and
    b. Members with hormone receptor positive disease must have failed prior endocrine therapy or are considered to not be a candidate for endocrine therapy.

Lynparza® (Olaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Used in 1 of the following settings:
    a. Member must have failed previous first-line therapy; and
        i. Used as a single agent except for the following:

            1. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
        ii. Disease must be positive for a mutation in a homologous recombination gene; or
    b. Used in combination with abiraterone and prednisone (or prednisolone); and
        i. Disease must be positive for a deleterious or suspected deleterious BRCA mutation.

Lynparza® (Olaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Maintenance treatment of advanced disease:
    a. Disease must be in a complete or partial response to primary chemotherapy; and
        i. Used as a single agent in members with a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) or somatic BRCA-mutated (sBRCAm), advanced ovarian cancer; or
        ii. Used in combination with bevacizumab following a primary therapy regimen that included bevacizumab; or
    b. Complete or partial response to second-line or greater platinum-based chemotherapy (no mutation required); and
    c. A quantity limit based on FDA approved dosing will apply.

Lynparza® (Olaparib) Approval Criteria [Pancreatic Cancer Diagnosis]:

1. Diagnosis of metastatic pancreatic adenocarcinoma with known germline BRCA1/BRCA2 mutation; and
2. Maintenance therapy as a single agent; and
3. In members who have not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

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

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

Nubeqa® (Darolutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Nubeqa® (Darolutamide) Approval Criteria [Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Diagnosis]:

1. Diagnosis of mHSPC in combination with docetaxel; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Opdivo® (Nivolumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)]; and
2. Used in 1 of the following settings:
    a. For nivolumab monotherapy:
        i. Diagnosis of relapsed or surgically unresectable stage IV disease; and
        ii. Failed prior therapy with 1 of the following medications:
            1. Sunitinib; or
            2. Sorafenib; or
            3. Pazopanib; or
            4. Axitinib; or
    b. For nivolumab use in combination with ipilimumab:
        i. Diagnosis of relapsed or surgically unresectable stage IV disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or
    c. For nivolumab use in combination with cabozantinib:
        i. Diagnosis of relapsed or surgically unresectable stage IV disease in the initial treatment of members with advanced RCC; and
        ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and
3. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks thereafter; or
    c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks;

nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

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

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

Orgovyx® (Relugolix) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication]; and
3. A quantity limit of 30 tablets per 30 days will apply. Upon meeting approval criteria, a quantity limit override will be approved for the day 1 loading dose of 360mg.

Padcev® (Enfortumab Vedotin-ejfv) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Used in 1 of the following settings:
    a. As a single agent and member has previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting; or
    b. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or
    c. Used in combination with pembrolizumab and member is ineligible for cisplatin-containing chemotherapy.

Pluvicto® (Lutetium Lu 177 Vipivotide Tetraxetan) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC); and
2. Member must have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy.

Provenge® (Sipuleucel-T) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Asymptomatic or minimally symptomatic; and
3. No hepatic metastases; and
4. Life expectancy of >6 months; and
5. ECOG performance status of 0 or 1; and
6. Approvals will be for the duration of 3 months at which time additional authorization may be granted if the prescriber documents that the member has not shown evidence of progressive disease while on sipuleucel-T therapy.

Rubraca® (Rucaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Member must have failed previous first-line therapy; and
3. Used as a single agent except for the following:
    a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Disease must be positive for a mutation in BRCA1 or BRCA2.

Rubraca® (Rucaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Maintenance treatment of recurrent disease:
    a. Diagnosis of recurrent disease; and
    b. Disease must be in a complete or partial response to platinum-based chemotherapy; and
    c. Positive for a BRCA mutation; and
    d. Used as a single agent.

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.

Tivdak® (Tisotumab Vedotin-tftv) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
2. Disease has progressed on or after chemotherapy.

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

1. Diagnosis of unresectable, locally advanced, or metastatic disease; and
2. Member must have previously received platinum-containing chemotherapy; and

3. Member must have previously received either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

Welireg® (Belzutifan) Approval Criteria [von Hippel-Landau (VHL) Disease Diagnosis]:

1. Diagnosis of VHL disease; and
2. Diagnosis of either renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumor; and
3. Does not require immediate surgery.

Xofigo® (Radium-223 Dichloride) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Symptomatic bone metastases; and
3. No known visceral metastatic disease; and
4. Prescriber must verify radium-223 dichloride will not be used in combination with chemotherapy; and
5. Absolute neutrophil count ≥1.5 x 10^9/L, platelet count ≥100 x 10^9/L, and hemoglobin ≥10g/dL; and
6. Approvals will be for the duration of 6 months at which time additional authorization may be granted if the prescriber documents the following:
    a. The member has not shown evidence of progressive disease while on radium-223 dichloride therapy; and
    b. Member must have an absolute neutrophil count ≥1 x 10^9/L, platelet count ≥100 x 10^9/L (radium-223 dichloride should be delayed 6 to 8 weeks otherwise).

Xtandi® (Enzalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of CRPC.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC.

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

1. Diagnosis of relapsed or surgically unresectable stage IV disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; and
2. Used in combination with nivolumab; and
3. Member has not previously failed programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and

4. Dose as follows: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks.

Yonsa® (Abiraterone Acetate) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Zejula® (Niraparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Maintenance treatment of advanced disease:
    a. Diagnosis of advanced or recurrent disease; and
    b. Disease must be in a complete or partial response to platinum chemotherapy; and
    c. If used for maintenance following recurrence:
        i. Must be positive for a BRCA mutation (this does not apply if used after first-line therapy); and
    d. Used as a single agent.

Zytiga® (Abiraterone) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Zytiga® (Abiraterone) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and

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

Utilization of Genitourinary and Gynecologic Cancer Medications: Calendar Year 2023

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

Calendar Year Comparison: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	126	662	$11,578,854.53	$17,490.72	$585.20	49,621	19,786
2023	164	924	$12,292,598.13	$13,303.68	$449.73	73,687	27,333
% Change	**30.20%**	**39.60%**	**6.20%**	**-23.90%**	**-23.10%**	**48.50%**	**38.10%**
Change	**38**	**262**	**$713,743.60**	**-$4,187.04**	**-$135.47**	**24,066**	**7,547**

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

Calendar Year Comparison: Medical Claims

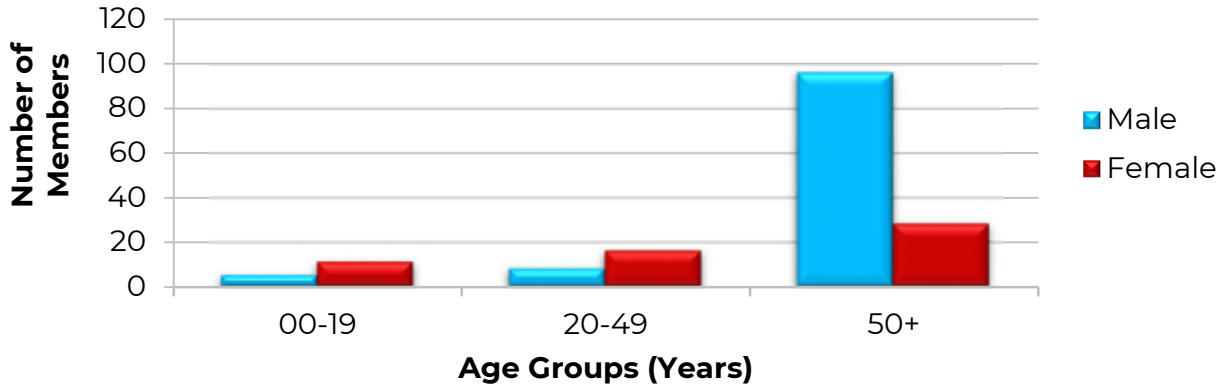
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	11	35	$430,758.38	$12,307.38	3.18
2023	18	69	$1,120,208.77	$16,234.91	3.83
% Change	**63.64%**	**97.14%**	**160.06%**	**31.91%**	**20.44%**
Change	**7**	**34**	**$689,450.39**	**$3,927.53**	**0.65**

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

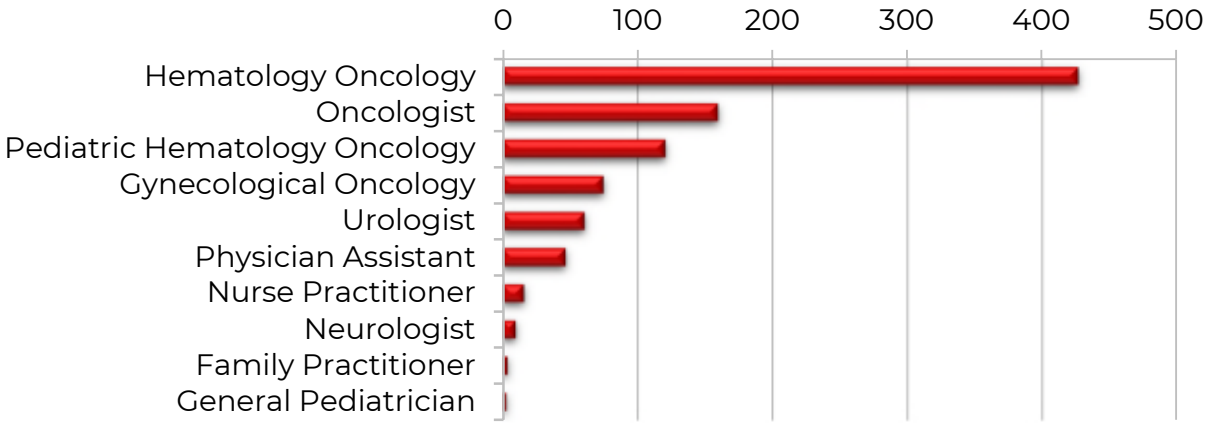
- Aggregate drug rebates collected during calendar year 2023 for genotourinary and gynecologic cancer medications totaled $3,928,290.13.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Genitourinary and Gynecologic Cancer Medications: Pharmacy Claims



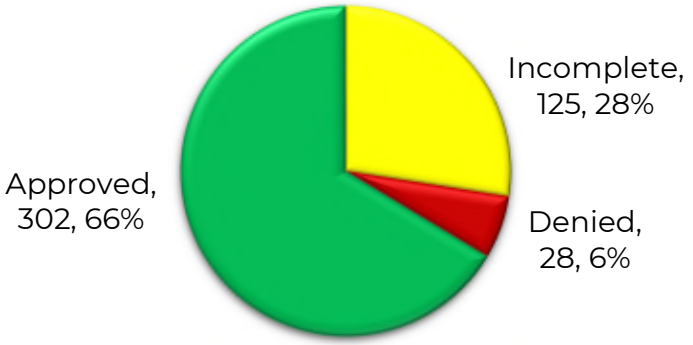
Top Prescriber Specialties of Genitourinary and Gynecologic Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Genitourinary and Gynecologic Cancer Medications

There were 455 prior authorization requests submitted for genitourinary and gynecologic cancer medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Afinitor® (everolimus): July 2028
- Jelmyto® (mitomycin): January 2031
- Jevtana® (cabazitaxel): April 2031
- Lynparza® (olaparib): August 2031
- Cabometyx® (cabozantinib): July 2033
- Xtandi® (enzalutamide): September 2033
- Yonsa® (abiraterone acetate): May 2034
- Welireg® (belzutifan): September 2034
- Pluvicto® (lutetium lu-177 vipivotide tetraxetan): October 2034
- Rubraca® (rucaparib): August 2035
- Lenvima® (lenvatinib): August 2036
- Orgovyx® (relugolix): September 2037
- Balversa® (erdafitinib): February 2038
- Nubeqa® (darolutamide): February 2038
- Akeega® (niraparib/abiraterone): March 2038
- Zejula® (niraparib): January 2039
- Camcevi® (leuprolide mesylate): January 2039
- Fotivda® (tivozanib): November 2039
- Erleada® (apalutamide): January 2040

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

- **July 2023:** The FDA approved Jemperli (dostarlimab-gxly) for a new indication, in combination with carboplatin and paclitaxel, followed by single-agent dostarlimab-gxly, for primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).
- **August 2023:** The FDA approved Akeega® (niraparib/abiraterone), in combination with prednisone, for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration resistant prostate cancer (CRPC). Patients should be selected for therapy based on an FDA-approved test for Akeega®.
- **November 2023:** The FDA approved Xtandi® (enzalutamide) for a new indication for the treatment of non-metastatic castration-sensitive prostate cancer (CSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR).
- **December 2023:** The FDA approved Welireg® (belzutifan) for a new indication for patients with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).

- **December 2023:** The FDA approved Padcev® (enfortumab vedotin-ejfv) for an expanded indication, in combination with Keytruda® (pembrolizumab), for patients with locally advanced or metastatic urothelial cancer. This removes the previous requirement that the patient must be ineligible for cisplatin-containing chemotherapy.
- **January 2024:** The FDA approved Balversa® (erdafitinib) for an updated indication for adult patients with locally advanced or metastatic urothelial carcinoma with susceptible *FGFR3* genetic alterations, as determined by an FDA-approved companion diagnostic test, whose disease has progressed on or after at least 1 line of prior systemic therapy.
- **April 2024:** The FDA approved Anktiva® (nogapendekin alfa inbakicept-pmln), in combination with Bacillus Calmette-Guérin (BCG), for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Akeega® (Niraparib/Abiraterone) Product Summary[9]

Therapeutic Class: Combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor

Indication(s): Treatment, in combination with prednisone, of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic CRPC

How Supplied: Oral tablets containing niraparib/abiraterone in 2 fixed-dose combinations - 50mg/500mg and 100mg/500mg

Dosing and Administration: Niraparib/abiraterone 200mg/1,000mg [using (2) 100mg/500mg tablets] once daily in combination with prednisone 10mg until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) is $312.50 per tablet, resulting in a cost of $18,750 per 30 days or $225,000 per year based on the recommended dose of niraparib/abiraterone 200mg/1,000mg once daily.

Anktiva® (Nogapendekin Alfa Inbakicept-pmln) Product Summary[10]

Therapeutic Class: Interleukin-15 (IL-15) receptor agonist

Indication(s): Treatment, in combination with BCG, of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors

How Supplied: 400mcg/0.4mL solution in a single-dose vial (SDV) for intravesical instillation after dilution

Dosing and Administration:

- Induction: 400mcg administered intravesically with BCG once weekly for 6 weeks
  - A second induction course may be administered if complete response is not achieved at month 3.
- Maintenance: 400mcg administered intravesically with BCG once weekly for 3 weeks at months 4, 7, 10, 13, and 19 (for a total of 15 doses)
  - For patients with an ongoing complete response at month 25 and later, additional maintenance instillations with BCG may be administered once weekly for 3 weeks at months 25, 31, and 37 (for a maximum of 9 additional instillations).
- The recommended duration of treatment is until disease persistence after second induction, disease recurrence or progression, unacceptable toxicity, or a maximum of 37 months.

Cost: The WAC is $35,800 per SDV. This results in an estimated cost of $214,800 per induction course. For a member who requires 2 induction courses and receives the full 37 months of treatment, this results in an estimated cost of $751,800 for the first year of treatment, $214,800 for the second year of treatment, and $322,200 for the third year of treatment.

Recommendations

The College of Pharmacy recommends the prior authorization of Akeega® (niraparib/abiraterone) and Anktiva® (nogapendekin alfa inbakicept-pmln) with the following criteria (listed in red):

Akeega® (Niraparib/Abiraterone Acetate) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Presence of deleterious or suspected deleterious BRCA mutation based upon an FDA-approved test; and
3. Used in conjunction with prednisone; and
4. Used in conjunction with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Anktiva® (Nogapendekin Alfa Inbakicept-pmln) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS); and
2. Cancer is unresponsive to initial Bacillus Calmette-Guerin (BCG) therapy; and
3. Will be used in conjunction with BCG; and
4. Initial approval will be for 6 induction doses; and
5. Subsequent requests must indicate if the member has had a complete response to induction dosing; and

a. A second induction course (6 doses) may be approved if a complete response is not achieved at month 3; and

6. If complete response is achieved, maintenance dosing may be approved in 6-month intervals up to a maximum of 37 months of treatment.

Next, the College of Pharmacy recommends updating the approval criteria for Balversa® (erdafitinib), Jemperli (dostarlimab-gxly), Padcev® (enfortumab vedotin-ejfv), Welireg® (belzutifan), and Xtandi® (enzalutamide) based on recent FDA approvals (changes and new criteria noted in red):

Balversa® (Erdafitinib) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Tumor positive for ~~*FGFR2 or*~~ *FGFR3* genetic mutation; and
3. Disease has progressed on or after at least 1 line of systemic therapy.
4. ~~Use in second-line or greater treatments including:~~
   a. ~~Following at least 1 line of platinum-containing chemotherapy; and~~
   b. ~~Within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.~~

Jemperli (Dostarlimab-gxly) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Used as a single agent; and
   a. Diagnosis of advanced, recurrent, or metastatic endometrial cancer; and
   b. Mismatch repair deficient (dMMR) disease; and
   c. Disease has progressed on or following prior treatment with a platinum-containing regimen; or
2. Used in combination with carboplatin and paclitaxel; and
   a. Diagnosis of primary advanced or recurrent endometrial cancer; and
   b. Mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease.

Padcev® (Enfortumab Vedotin-ejfv) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Used in 1 of the following settings:
   a. As a single agent and member has previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting; or
   b. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or

c. Used in combination with pembrolizumab ~~and member is ineligible for cisplatin-containing chemotherapy~~.

Welireg® (Belzutifan) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Member has received at least 2 lines of systemic therapy, including a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI); and
3. As a single agent.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC; or
2. Diagnosis of non-metastatic CSPC with biochemical recurrence at high risk for metastasis (high-risk BCR).

Lastly, the College of Pharmacy recommends updating the Provenge® (sipuleucel-T) approval criteria to be more consistent with the FDA approved dosing (changes shown in red):

Provenge® (Sipuleucel-T) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Asymptomatic or minimally symptomatic; and
3. No hepatic metastases; and
4. Life expectancy of >6 months; and
5. ECOG performance status of 0 or 1; and
6. ~~Approvals will be for the duration of 3 months at which time additional authorization may be granted if the prescriber documents that the member has not shown evidence of progressive disease while on sipuleucel-T therapy.~~
7. Approvals will be for 1 treatment course (3 doses) per member per lifetime.

Utilization Details of Genitourinary and Gynecologic Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
EVEROLIMUS PRODUCTS						
EVEROLIMUS TAB 5MG	40	8	$166,663.84	$4,166.60	5	1.36%
EVEROLIMUS TAB 5MG	31	6	$908,569.55	$29,308.70	5.17	7.39%
AFINITOR DIS TAB 5MG	30	4	$832,448.55	$27,748.29	7.5	6.77%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
EVEROLIMUS TAB 10MG	22	8	$112,176.14	$5,098.92	2.75	0.91%
EVEROLIMUS TAB 3MG	17	5	$443,014.73	$26,059.69	3.4	3.60%
EVEROLIMUS TAB 2MG	15	3	$206,490.83	$13,766.06	5	1.68%
AFINITOR DIS TAB 2MG	15	2	$377,932.32	$25,195.49	7.5	3.07%
EVEROLIMUS TAB 7.5MG	12	4	$67,917.93	$5,659.83	3	0.55%
AFINITOR DIS TAB 3MG	9	2	$156,831.12	$17,425.68	4.5	1.28%
SUBTOTAL	**191**	**42**	**$3,272,045.01**	**$17,131.13**	**4.55**	**26.62%**
ABIRATERONE PRODUCTS						
ABIRATERONE TAB 250MG	153	25	$26,429.42	$172.74	6.12	0.22%
ABIRATERONE TAB 500MG	30	6	$129,673.86	$4,322.46	5	1.05%
ZYTIGA TAB 500MG	1	1	$10,894.43	$10,894.43	1	0.09%
SUBTOTAL	**184**	**32**	**$166,997.71**	**$907.60**	**5.75**	**1.36%**
ENZALUTAMIDE PRODUCTS						
XTANDI CAP 40MG	88	17	$1,146,408.48	$13,027.37	5.18	9.33%
XTANDI TAB 80MG	48	8	$655,076.24	$13,647.42	6	5.33%
XTANDI TAB 40MG	33	8	$450,773.54	$13,659.80	4.13	3.67%
SUBTOTAL	**169**	**33**	**$2,252,258.26**	**$13,326.97**	**5.12**	**18.32%**
OLAPARIB PRODUCTS						
LYNPARZA TAB 150MG	64	15	$977,599.82	$15,275.00	4.27	7.95%
LYNPARZA TAB 100MG	26	4	$381,530.74	$14,674.26	6.5	3.10%
SUBTOTAL	**90**	**19**	**$1,359,130.56**	**$15,101.45**	**4.74**	**11.06%**
CABOZANTINIB PRODUCTS						
CABOMETYX TAB 40MG	49	13	$1,177,074.40	$24,021.93	3.77	9.58%
CABOMETYX TAB 60MG	19	8	$467,495.43	$24,605.02	2.38	3.80%
CABOMETYX TAB 20MG	11	5	$275,488.28	$25,044.39	2.2	2.24%
SUBTOTAL	**79**	**26**	**$1,920,058.11**	**$24,304.53**	**3.04**	**15.62%**
APALUTAMIDE PRODUCTS						
ERLEADA TAB 60MG	78	11	$1,034,466.24	$13,262.39	7.09	8.42%
SUBTOTAL	**78**	**11**	**$1,034,466.24**	**$13,262.39**	**7.09**	**8.42%**
LENVATINIB PRODUCTS						
LENVIMA CAP 10MG	15	6	$342,084.65	$22,805.64	2.5	2.78%
LENVIMA CAP 20MG	11	7	$244,009.51	$22,182.68	1.57	1.99%
LENVIMA CAP 18MG	9	2	$204,132.69	$22,681.41	4.5	1.66%
LENVIMA CAP 14MG	9	1	$202,746.69	$22,527.41	9	1.65%
LENVIMA CAP 12MG	9	4	$177,963.90	$19,773.77	2.25	1.45%
LENVIMA CAP 8MG	2	2	$45,520.82	$22,760.41	1	0.37%
LENVIMA CAP 4MG	2	2	$44,772.32	$22,386.16	1	0.36%
SUBTOTAL	**57**	**24**	**$1,261,230.58**	**$22,126.85**	**2.38**	**10.26%**
NIRAPARIB PRODUCTS						
ZEJULA CAP 100MG	10	4	$129,771.85	$12,977.19	2.5	1.06%
ZEJULA TAB 100MG	5	2	$103,781.90	$20,756.38	2.5	0.84%
ZEJULA TAB 200MG	5	2	$86,495.55	$17,299.11	2.5	0.70%
ZEJULA TAB 300MG	2	1	$34,593.42	$17,296.71	2	0.28%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**22**	**9**	**$354,642.72**	**$16,120.12**	**2.44**	**2.89%**
RELUGOLIX PRODUCTS						
ORGOVYX TAB 120MG	22	4	$57,514.62	$2,614.30	5.5	0.47%
SUBTOTAL	**22**	**4**	**$57,514.62**	**$2,614.30**	**5.5**	**0.47%**
DAROLUTAMIDE PRODUCTS						
NUBEQA TAB 300MG	17	6	$218,871.27	$12,874.78	2.83	1.78%
SUBTOTAL	**17**	**6**	**$218,871.27**	**$12,874.78**	**2.83**	**1.78%**
BELZUTIFAN PRODUCTS						
WELIREG TAB 40MG	14	2	$367,375.64	$26,241.12	7	2.99%
SUBTOTAL	**14**	**2**	**$367,375.64**	**$26,241.12**	**7**	**2.99%**
TIVOZANIB PRODUCTS						
FOTIVDA CAP 0.89MG	1	1	$28,007.41	$28,007.41	1	0.23%
SUBTOTAL	**1**	**1**	**$28,007.41**	**$28,007.41**	**1**	**0.23%**
TOTAL	**924**	**164***	**$12,292,598.13**	**$13,303.68**	**5.63**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DIS = Disperz (oral tablet for suspension); TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PADCEV J9177	19	7	$194,344.00	$10,228.63	2.71
TIVDAK J9273	18	3	$328,610.48	$18,256.14	6
JEVTANA J9043	16	5	$180,690.18	$11,293.14	3.2
ELAHERE J9063	7	1	$167,416.75	$23,916.68	7
XOFIGO A9606	6	1	$87,202.98	$14,533.83	6
PROVENGE Q2043	3	1	$161,944.38	$53,981.46	3
TOTAL	**69**	**18**	**$1,120,208.77**	**$16,234.91**	**3.83**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 05/2024. Last accessed 05/02/2024.
[2] U.S. FDA. FDA Approves Dostarlimab-Gxly with Chemotherapy for Endometrial Cancer. Available online at: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-dostarlimab-gxly-chemotherapy-endometrial-cancer. Issued 07/31/2023. Last accessed 05/02/2024.
[3] U.S. FDA. FDA Approves Niraparib and Abiraterone Acetate Plus Prednisone for BRCA-Mutated Metastatic Castration-Resistant Prostate Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-niraparib-and-abiraterone-acetate-plus-prednisone-brca-mutated-metastatic-castration. Issued 08/11/2023. Last accessed 05/02/2024.
[4] U.S. FDA. FDA Approves Enzalutamide for Non-Metastatic Castration-Sensitive Prostate Cancer with Biochemical Recurrence. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-enzalutamide-non-metastatic-castration-sensitive-prostate-cancer-biochemical-recurrence. Issued 11/16/2023. Last accessed 05/02/2024.
[5] U.S. FDA. FDA Approves Belzutifan for Advanced Renal Cell Carcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-belzutifan-advanced-renal-cell-carcinoma. Issued 12/14/2023. Last accessed 05/02/2024.
[6] U.S. FDA. FDA Approves Enfortumab Vedotin-ejfv with Pembrolizumab for Locally Advanced or Metastatic Urothelial Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-enfortumab-vedotin-ejfv-pembrolizumab-locally-advanced-or-metastatic-urothelial-cancer. Issued 12/15/2023. Last accessed 05/02/2024.
[7] U.S. FDA. FDA Approves Erdafitinib for Locally Advanced or Metastatic Urothelial Carcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-erdafitinib-locally-advanced-or-metastatic-urothelial-carcinoma. Issued 01/19/2024. Last accessed 05/02/2024.
[8] U.S. FDA. FDA Approves Nogapendekin Alfa Inbakicept-pmln for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nogapendekin-alfa-inbakicept-pmln-bcg-unresponsive-non-muscle-invasive-bladder-cancer. Issued 04/22/2024. Last accessed 05/02/2024.
[9] Akeega® (Niraparib/Abiraterone) Prescribing Information. Janssen Biotech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216793s000lbl.pdf. Last revised 08/2023. Last accessed 05/02/2024.
[10] Anktiva® (Nogapendekin Alfa Inbakicept-pmln) Prescribing Information. ImmunityBio, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf. Last revised 04/2024. Last accessed 05/02/2024.

Appendix J

Calendar Year 2023 Annual Review of the SoonerCare Pharmacy Benefit

Oklahoma Health Care Authority
June 2024

Summary[1]

During calendar year (CY) 2023, prescription drugs accounted for $1.2 billion of the approximately $8.93 billion in total SoonerCare spending. In July 2021, the SoonerCare benefit expanded across the state to include the Healthy Adult Program (HAP). The expanded population is included in the CY 2021, CY 2022, and CY 2023 data. The average monthly enrollment remained steady from CY 2022 to CY 2023 (0.25% increase), which can be attributed at least partly to a combination of adding the expanded population and the unwinding process that allowed state Medicaid agencies to disenroll members who no longer qualified for services but were enrolled during the public health emergency (PHE). The PHE ended in May 2023, and the unwinding process was completed by December 2023. Despite a negligible increase in enrollment, the number of utilizers (SoonerCare members utilizing the pharmacy benefit) and total claims increased by approximately 6% and 6.5%, respectively, from CY 2022 to CY 2023. Comparing SoonerCare pharmacy data from CY 2022, the total reimbursement increased approximately 21% from CY 2022 to CY 2023. The annual pharmacy cost per member increased from $783.23 in CY 2022 to $942.86 in CY 2023, which is a 20% increase. Additionally, the specialty pharmaceutical products total pharmacy reimbursement continues to be on the incline as a result of orphan drug approvals for rare diseases, as well as numerous new oncology medications and the high costs associated with these therapies.

Indian Health Service (IHS) reimbursement was updated in 2017 to the Federal Office of Management and Budget encounter rate; therefore, to more accurately compare CY 2023 with previous years, IHS data was excluded from this analysis. Additionally, costs in this report do not reflect the federal and state supplemental rebates that are provided by medication manufacturers. The coverage and prior authorization criteria of many medications, particularly the anti-infective, attention-deficit/hyperactivity disorder (ADHD), antipsychotic, anti-diabetic agents, and analgesic classes, are significantly influenced by supplemental rebates, and net costs are lower than the total reimbursement to pharmacies included in this analysis.

Total Pharmacy Calendar Year (CY) Comparison							
CY	Claims	Members†	Utilizers*	Reimbursement	Cost/ Claim	Cost/ Member	Cost/ Day
2021	6,000,394	1,067,537	587,744	$696,139,037.71	$116.02	$652.10	$3.91
2022	7,803,484	1,277,220	712,019	$1,000,361,351.12	$128.19	$783.23	$4.18
2023	8,312,160	1,280,428	754,460	$1,207,266,389.49	$145.24	$942.86	$4.60

†Average monthly enrollment as obtained from OHCA Fast Facts reports.
*Total number of unduplicated utilizers.
Reimbursement does not reflect rebated costs or net costs.

The per member per year (PMPY) value reflects the total pharmacy cost divided by the unduplicated number of members (total enrollees) for each period. To reflect an accurate PMPY value, average monthly enrollment was used in place of annual enrollment, and dual eligible (members eligible for Medicare and Medicaid) and IHS members were excluded. The PMPY value is used across benefit plans with similar populations to accurately assess health care spending. The following table contains the overall PMPY values for the past few years.

Overall PMPY CY Comparison			
Calendar Year (CY)	CY 2021¥	CY 2022	CY 2023
Overall PMPY Value†	$835.32	$984.33	$1,203.00

PMPY = per member per year
†PMPY value calculated using average monthly enrollment, excluding dual eligible and IHS members.
¥Oklahoma Medicaid expansion became effective 07/01/2021.

During calendar year 2023, Oklahoma used a fee-for-service (FFS) pharmacy benefit for the SoonerCare program. Pharmacy benefit managers (PBMs) are used by some states for their FFS pharmacy programs, contracting out services such as claims processing and payment, prior authorization processing, drug utilization review (DUR), and formulary management. Similarly, Medicaid managed care organizations (MCOs) frequently subcontract the management of the pharmacy benefit to a separate PBM. The Oklahoma Health Care Authority (OHCA) currently contracts with Pharmacy Management Consultants (PMC), a department within the University of Oklahoma College of Pharmacy, for many of these services.

As of April 2024, Oklahoma Medicaid transitioned from FFS to a Managed Care Organization (MCO) pharmacy benefit. The majority of SoonerCare members were transitioned to a SoonerSelect health plan of their choosing starting on April 1, 2024. The SoonerSelect health plans provide prescriptions, health services, and behavioral health services with oversight from OHCA. Previously, the prescription drug benefit was carried out exclusively by PMC including managing the formulary and reviewing prior authorizations. Through this change, the MCOs will have the responsibility of reviewing the prior authorizations for their active members but will not have a role in managing

the formulary, which will remain a responsibility of PMC. The 3 MCOs that were awarded contracts with Oklahoma Medicaid include Aetna Better Health of Oklahoma, Humana Healthy Horizons of Oklahoma, and Oklahoma Complete Health which is operated by the Centene Corporation.

SoonerCare prior authorization policies, coupled with quantity limits and monthly prescription limits, yield better than average results while still providing a comprehensive pharmacy benefit for over 1 million SoonerCare members.

Medicaid Drug Rebate Program[2,3,4]

Medicaid coverage of a drug requires the manufacturer to have a federal rebate agreement with the Secretary of Health and Human Services (HHS). Participation in the federal drug rebate program requires Medicaid coverage with limited exceptions (e.g., weight loss medications, cosmetic medications, fertility medications). Rebate amounts are based on the "best price" for each drug. Best price refers to the lowest price paid to a manufacturer for a drug by any commercial payer. Best prices are reported to CMS by the manufacturer but are not publicly available.

If a drug's price increases more quickly than inflation, an additional rebate penalty is included based on the change in price compared with the consumer price index (CPI). The CPI penalty of the federal rebate is designed to keep Medicaid net cost relatively flat despite increases in drug prices. Until the first quarter of 2017, the CPI penalty only applied to brand medications; however, following a Senate vote in October 2015 in response to increasing generic drug prices, the Medicaid CPI penalty was extended to generic drugs with an effective date of January 1, 2017. The cost increases found in this report do not reflect net cost increases.

Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. In CY 2023, OHCA collected over $731 million in federal and state supplemental rebates, resulting in a total increase from CY 2022 of approximately $154 million ($577 million in federal and state supplemental rebates collected in CY 2022). The rebates are collected after reimbursement for the medication and are not reflected in this report.

Alternative Payment Models[5,6,7,8,9]

The introduction of a greater number of costly specialty medications, finite Medicaid budgets, Medicaid policy, and access requirements has resulted in alternative payment arrangements as particularly compelling opportunities. Medicaid programs must provide comprehensive care to vulnerable individuals while operating under limited budgets and regulatory requirements. An alternative payment model (APM) is an agreement between

a payer and manufacturer that is intended to provide improved patient care or increased access to evidence-based therapies while lowering costs or improving health outcomes. In general, there are 2 types of APMs:

- **Financial APM:** Caps or discounts are used to provide predictability or limit spending; these types of contracts are intended to lower costs and expand access. Data collection for financial APMs is minimal, making them easier to administer.
  - Examples: Price volume agreements, market share, patient level utilization caps, manufacturer funded treatment initiation
- **Health Outcome-Based APM:** Payments for medications are tied to clinical outcomes or measurements; these types of contracts are often referred to as "value-based contracts." Health outcome based APMs require additional planning and data collection but do have the potential to increase the quality and value of treatments.
  - Examples: Outcomes guarantee, conditional coverage, PMPY guarantees, event avoidance (e.g., hospitalizations)

Since October 2016, PMC and OHCA have been engaged in negotiations with pharmaceutical manufacturers regarding pharmacy value-based contracts. Oklahoma was the first Medicaid state to receive approval from CMS to participate in value-based payment arrangements in June 2018. Since that time, PMC and OHCA have initiated talks with numerous pharmaceutical manufacturers regarding APMs and have established multiple APM contracts, with 4 APM contracts being active in calendar year 2023. Future considerations include the expectation that initial SoonerCare value-based contracts will set the precedent for further collaboration among manufacturers and state Medicaid agencies.

Overview of Established APM Contracts: Calendar Year 2023	
Manufacturer	**Details**
AbbVie	▪ Treatment patterns in hepatitis C – utilization, treatment duration, and non-responder/re-treatment/ treatment failures (2022-2024)
AveXis	▪ Spinal muscular atrophy (SMA) medication – utilization (2021-2024)
Pear Therapeutics	▪ Adherence and persistence with prescription digital therapeutics – resource utilization (2022-2023)
Supernus	▪ Adherence and persistence in ADHD – medication possession ratios (2022-2024)

APM = alternative payment model

Drug Approval Trends[10,11,12]

During CY 2023, the U.S. Food and Drug Administration (FDA) approved the first generic product of several key medications that may have a significant impact on SoonerCare reimbursement. Key first-time generics approved by

the FDA in CY 2023 included dabigatran (generic Pradaxa®), lisdexamfetamine (generic Vyvanse®), and tiotropium inhalation powder (generic Spiriva® HandiHaler®).

A total of 55 novel drugs were approved by the FDA during CY 2023. The active ingredient or ingredients in a novel drug have never before been approved in the United States. Select novel drugs approved during CY 2023 that are expected to be highly utilized or have a particular impact in the SoonerCare population are included in the following table.

Select Novel Drugs FDA Approved During Calendar Year 2023			
Drug Name	**Date Approved**	**FDA-Approved Indication**	**Estimated Annual Cost Per Member***
perfluorohexyloctane (Miebo®)	05/18/2023	dry eye disease	$35,586.72[α]
fezolinetant (Veozah®)	05/12/2023	moderate to severe hot flashes caused by menopause	$6,336.00[¥]
somatrogon-ghla (Ngenla™)	06/27/2023	growth hormone deficiency	$74,700.00[Δ]
zuranolone (Zurzuvae™)	08/04/2023	postpartum depression	$15,900.08[†]
etrasimod (Velsipity®)	10/12/2023	ulcerative colitis	$73,972.56[‡]

*Costs do not include rebated or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
[α]Based on a maximum quantity of 12mL per month and a dose of 1 drop per affected eye 4 times daily
[¥]Based on an FDA approved once daily dose
[Δ]Based on an FDA approved once weekly dose of 0.66mg/kg in a member weighing 25kg
[†]Based on a maximum FDA approved dose of 50mg once daily for 14 days
[‡]Based on a maximum FDA approved dose of 2mg once daily

Traditional Versus Specialty Pharmacy Products

Traditional pharmaceuticals include products that are typically non-injectable, do not require special transportation, storage, or administration, and are not typically indicated for rare diseases requiring unique management. These products treat many common chronic diseases such as diabetes, hypertension, and chronic obstructive pulmonary disease. Traditional pharmaceuticals carried the bulk of the reimbursement costs, accounting for 68% of the total pharmacy reimbursement and more than 99% of utilizers, in CY 2023.

Specialty products, in contrast, are typically injectable, require special handling such as refrigerated transport and special administration techniques, or are indicated for rare diseases requiring unique management. These products include treatments for cystic fibrosis (CF), hemophilia, rheumatoid arthritis, and genetic deficiencies. Specialty pharmaceuticals have become a larger part of reimbursement over the last 10 years. Specifically, specialty pharmaceuticals

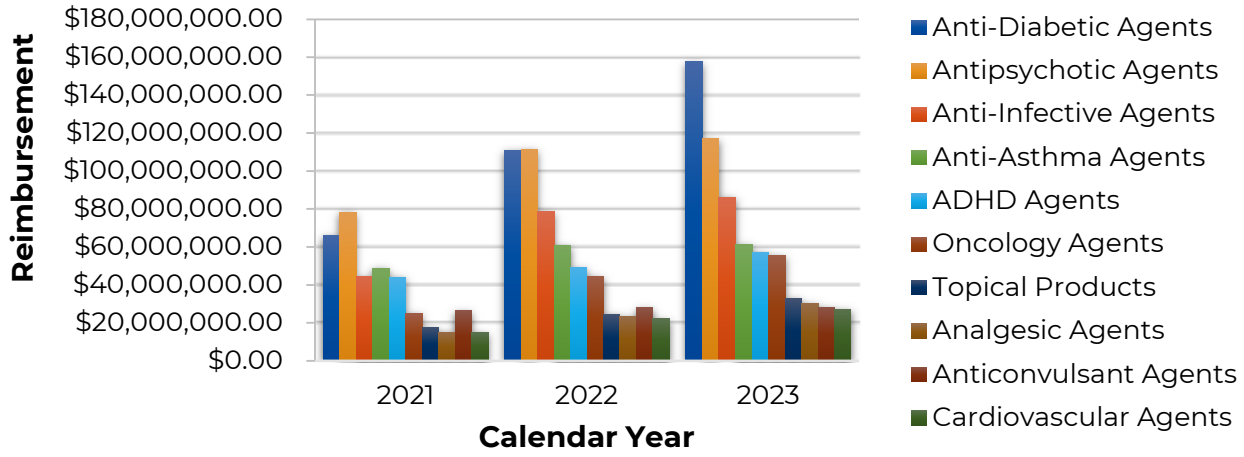
accounted for 32% of the total pharmacy reimbursement in CY 2023 and approximately 1% of utilizers.

Top 10 Traditional Therapeutic Classes by Reimbursement: CY 2023

Costs in this report do not reflect the federal and state supplemental rebates that are provided by medication manufacturers. Many branded agents, particularly anti-infective, ADHD, antipsychotic, anti-diabetic agents, and analgesic medications are significantly influenced by supplemental rebates, and net costs are substantially lower than the total reimbursement paid to pharmacies included in this analysis.

2021	2022	2023	Therapeutic Class
$66,068,136.96	$111,055,684.25	**$157,538,919.35**	**Anti-Diabetic Agents**
$78,516,118.92	$111,520,874.56	**$117,191,957.10**	**Antipsychotic Agents**
$44,551,521.98	$78,642,836.44	**$86,435,060.14**	**Anti-Infective Agents**
$48,998,641.36	$60,883,505.15	**$61,555,196.18**	**Anti-Asthma Agents**
$44,219,801.91	$49,045,427.21	**$57,285,980.16**	**ADHD Agents**
$25,084,839.10	$44,560,656.67	**$55,535,114.43**	**Oncology Agents**
$17,578,926.94	$24,570,761.49	**$33,060,869.20**	**Topical Products**
$15,266,630.82	$23,390,966.62	**$30,153,747.05**	**Analgesic Agents**
$26,266,628.59	$27,988,964.57	**$28,257,689.33**	**Anticonvulsant Agents**
$15,085,427.73	$22,052,375.92	**$27,186,338.14**	**Cardiovascular Agents**

ADHD = attention-deficit/hyperactivity disorder
Reimbursement does not reflect rebated prices or net costs.



The top 10 traditional pharmaceutical classes that showed the most significant change from CY 2022 to 2023 were anti-diabetic agents and oncology agents. Other traditional classes saw minor fluctuations.

- Anti-diabetic agents' reimbursement increased by $46 million in CY 2023. The increase in reimbursement in this class can be accounted for by increased utilization of glucagon-like peptide 1 (GLP-1) inhibitors, such

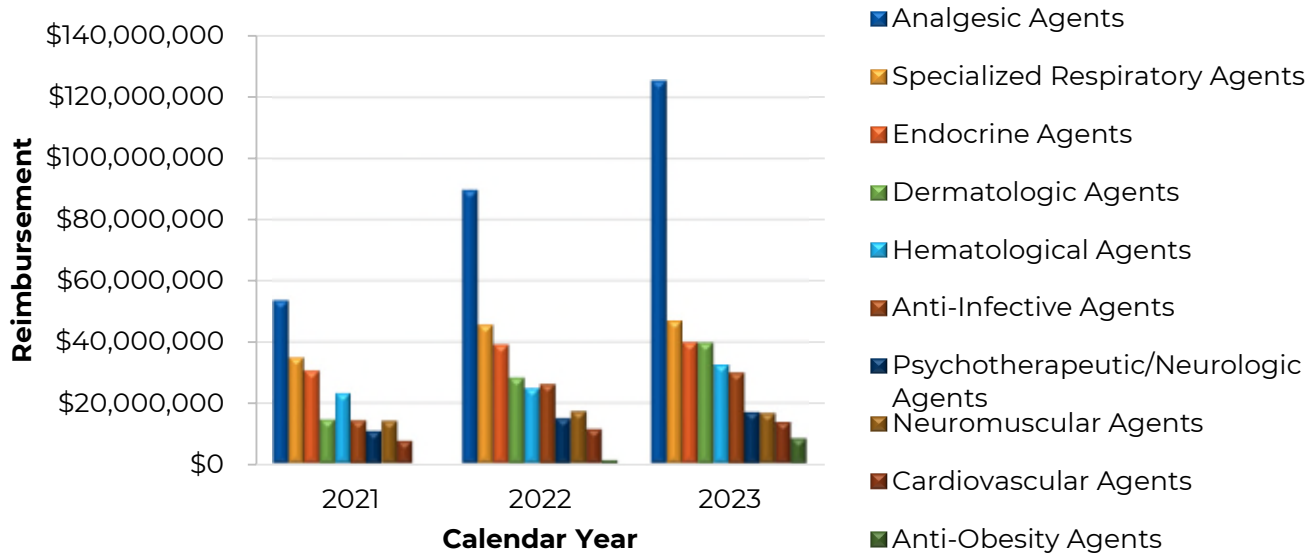
as Trulicity® (dulaglutide) and Ozempic® (semaglutide). It is important to note that many anti-diabetic agents have supplemental rebates in place with Oklahoma Medicaid, and net cost increases are not reflected in this analysis.

- CY 2023 reimbursement increased by approximately $11 million in the oncology agents. The overall number of claims increased by around 3,000 with an additional 800 utilizing members compared to CY 2022. Oncology agents utilization among SoonerCare members has been steadily increasing since 2021 and could be at least partially due to the expansion population, as well the sustained growth of new FDA approved oncology agents and new indications.

Top 10 Specialty Therapeutic Classes by Reimbursement: CY 2023

2021	2022	2023	Therapeutic Class
$53,429,945.30	$89,631,077.43	**$125,454,998.43**	**Analgesic Agents**
$34,804,839.95	$45,499,309.92	**$46,940,653.02**	**Specialized Respiratory Agents**
$30,491,144.37	$39,101,470.27	**$39,755,441.49**	**Endocrine Agents**
$14,546,228.68	$28,169,889.43	**$39,715,091.82**	**Dermatologic Agents**
$23,118,617.96	$24,761,074.33	**$32,523,066.60**	**Hematological Agents**
$14,215,017.63	$26,114,825.89	**$29,814,254.81**	**Anti-Infective Agents**
$10,660,813.68	$14,817,174.77	**$16,802,504.90**	**Psychotherapeutic/Neurologic Agents**
$13,994,765.56	$17,107,588.45	**$16,487,552.18**	**Neuromuscular Agents**
$7,364,280.07	$11,226,948.72	**$13,559,937.51**	**Cardiovascular Agents**
N/A	$1,099,368.01	**$8,282,763.05**	**Anti-Obesity Agents**

Reimbursement does not reflect rebated prices or net costs.
N/A = not applicable



The cost of specialty therapeutic products is high, largely in part due to the targeted immunomodulator agents and therapies focused on rare diseases, including CF, hemophilia, and spinal muscular atrophy (SMA). The increasing number of new FDA approvals and subsequent increase in utilizers make the management of specialty therapeutic products challenging; however, continuous review and management of these products has promoted minimal reimbursement increases, other than expected yearly price increases by product manufacturers and the rising cost of newly approved products.

- The cost of specialty analgesic agents increased significantly this year, with a $33 million increase in anti-inflammatory agents. Reimbursement in this class is largely attributed to targeted immunomodulator agents such as Humira® (adalimumab), Enbrel® (etanercept), Ilaris® (canakinumab), Orencia® (abatacept), Simponi® (golimumab), Xeljanz® (tofacitinib), Otezla® (apremilast), and Kineret® (anakinra). Most of the utilization was seen in Humira® and Enbrel®, both of which are Tier-2 medications based on supplemental rebate participation. The supplementally rebated prices and net costs are not reflected in this analysis.
- Dermatologic products also saw a significant increase of $11 million from calendar year 2022, along with an increase in claims and utilizers. This class includes specialty medications used for dermatologic conditions, such as psoriasis and atopic dermatitis, such as Dupixent® (dupilumab), Stelara® (ustekinumab), Taltz® (ixekizumab), Skyrizi® (risankizumab), and Adbry® (tralokinumab), among other targeted immunomodulators, though many of these medications are FDA approved for multiple indications.

Top 10 Medications by Reimbursement: CY 2023

Many of the top 10 medications by reimbursement are still branded at this time and not available in a generic formulation. The top products typically come from highly utilized classes such as autoimmune, atypical antipsychotics, and ADHD therapies. Top drug reimbursement rankings only slightly change from year to year for several reasons: high use, broad use between age demographics, and high costs of therapies for rare diseases such as those indicated for CF. Other high-cost medications were included in this list of medications for this year, including hepatitis C and human immunodeficiency virus (HIV) medications. Dupilumab was included this year after utilization increased due to several new FDA approved indications.

Top 10 Medications by Reimbursement			
Rank	**2021**	**2022**	**2023**
1	adalimumab inj	adalimumab inj	adalimumab inj
2	paliperidone inj	paliperidone inj	paliperidone inj
3	lisdexamfetamine	elexacaftor/tezacaftor/ ivacaftor	dulaglutide inj
4	elexacaftor/tezacaftor/ ivacaftor	lisdexamfetamine	elexacaftor/tezacaftor/ ivacaftor
5	lurasidone	lurasidone	lisdexamfetamine
6	somatropin inj	dulaglutide inj	bictegravir/emtricitabine/ tenofovir
7	insulin glargine inj	bictegravir/emtricitabine/ tenofovir	etanercept inj
8	albuterol	etanercept inj	glecaprevir/pibrentasvir
9	etanercept inj	insulin glargine inj	dupilumab inj
10	dexmethylphenidate	somatropin inj	insulin glargine inj

*Includes brand and generic where applicable.
Rank does not reflect rebated prices or net costs.
Medications are listed by generic name but may include both generic and brand formulations.
inj = injection

Cost Per Claim

The SoonerCare cost per claim of traditional medications increased by 12.1% in CY 2023 in comparison to CY 2022, and the cost per specialty medication claim increased by 4.6%. As mentioned previously, specialty costs are largely driven by the significant cost associated with medications for rare diseases.

Cost Per Claim			
Drug Class	**CY 2021**	**CY 2022**	**CY 2023**
Traditional	$79.71	$88.08	$98.73
Specialty	$7,126.40	$7,672.82	$8,025.00

CY = calendar year
Reimbursement does not reflected rebated costs or net costs.

Market Projections[10,11,13,14]

Specialty medications made up approximately 1% of the utilizers for CY 2023 but generated approximately 32% of the cost. The top 2 drugs by cost have been identical the past 3 years and are led by specialty products. Zurzuvae™ (zuranolone), an antidepressant that is a gamma-aminobutyric acid (GABA) A receptor positive modulator, was approved by the FDA in August 2023 for the treatment of postpartum depression, and Bimzelx® (bimekizumab-bkzx) was approved by the FDA in October 2023 for the treatment of moderate-to-severe plaque psoriasis. These 2 new products have the potential to make a substantial impact on reimbursement in the upcoming year. Oncology

medications made up about 29% of drug approvals in 2023 for various indications, as shown in the following table. With new oncology agents continually entering the market, assessment of the oncology medication classes will need frequent reevaluation. In addition to specialty medications and oncologic medications, 5 gene therapies were approved in 2023 with more expected to be approved by the end of 2024. Gene therapies have been developed for rare genetic diseases such as Elevidys (delandistrogene moxeparvovec-rokl) for the treatment of Duchenne muscular dystrophy (DMD) in patients ages 4 to 5 and those for sickle cell disease such as Casgevy™ (exagamglogene autotemcel). The cost of these therapies is of concern considering they are typically priced in the millions for a single dose or course of therapy. Gene therapies are going to continue to be FDA approved and launched with increasing cost associated with them and will require ongoing reevaluation.

Oncology Medications FDA Approved in Calendar Year 2023			
Brand	**Generic**	**Indication(s)**	**Approval Date**
Orserdu®	elacestrant	breast cancer	01/27/2023
Jaypirca®	pirtobrutinib	mantle cell lymphoma	01/27/2023
Zynyz®	retifanlimab-dlwr	Merkel cell carcinoma	03/22/2023
Epkinly™	epcoritamab-bysp	diffuse large B-cell lymphoma	05/19/2023
Columvi™	glofitamab-gxbm	diffuse large B-cell lymphoma	06/15/2023
Vanflyta®	quizartinib	acute myeloid leukemia	07/20/2023
Talvey®	talquetamab-tgvs	multiple myeloma	08/09/2023
Akeega™	niraparib/abiraterone	prostate cancer	08/11/2023
Elrexfio™	elranatamab-bcmm	multiple myeloma	08/14/2023
Hepzato™	melphalan	uveal melanoma	08/14/2023
Loqtorzi™	toripalimab-tpzi	nasopharyngeal carcinoma	10/27/2023
Fruzaqla®	fruquintinib	colorectal cancer	11/08/2023
Augtyro™	repotrectinib	non-small cell lung cancer	11/15/2023
Trugap™	capivasertib	breast cancer	11/16/2023
Ogsiveo®	nirogacestat	desmoid tumors	11/27/2023
Iwilfin™	eflornithine	neuroblastoma	12/13/2023

FDA = U.S. Food and Drug Administration

Conclusion

New prior authorization categories and continuous evaluation of categories such as oncology and hemophilia medications, along with new respiratory and anti-diabetic medications that continue to be FDA approved, ensure the most clinically appropriate, cost-effective measures are taken. Modifications to Tier

structures and other generic categories reduced elevated spending on high-priced generic products. When new drugs are FDA approved and become available on the market, a cost-effectiveness analysis is performed to minimize spending while ensuring appropriate clinical care. The goal of the SoonerCare program is to provide SoonerCare members with the most appropriate health care in a fiscally responsible manner. For the pharmacy benefit, this is accomplished through DUR services, using prior authorization criteria, quantity limits, monthly total prescription limits and brand name prescription limits for non-institutionalized adult members, continuous product pricing maintenance, and provider outreach and education. Constant market review and response to changes, including evolving gene therapies, growth of the specialty market, and introduction of biosimilars, is necessary. SoonerCare will continue to strive to bring value-based pharmacy services to its members.

Top 50 Reimbursed Drugs by Calendar Year

Generic	Brand	CY 2023		CY 2022	
		Rank	Amount Paid	Rank	Amount Paid
adalimumab	Humira®	**1**	**$83,536,912**	1	$61,254,156
paliperidone inj	Various	**2**	**$57,289,287**	2	$46,036,947
dulaglutide	Trulicity®	**3**	**$46,170,169**	6	$23,814,678
elexacaftor/tezacaftor/ ivacaftor	Trikafta®	**4**	**$38,546,827**	3	$33,439,856
lisdexamfetamine	Vyvanse®	**5**	**$32,152,426**	4	$27,822,986
bictegravir/emtricitabine/ tenofovir alafenamide	Biktarvy®	**6**	**$27,967,772**	7	$22,021,118
etanercept	Enbrel®	**7**	**$27,030,739**	8	$18,174,839
glecaprevir/pibrentasvir	Mavyret®	**8**	**$26,033,676**	11	$15,847,031
dupilumab	Dupixent®	**9**	**$21,226,075**	13	$12,939,368
insulin glargine	Various	**10**	**$19,140,764**	9	$17,523,869
empagliflozin	Jardiance®	**11**	**$17,326,075**	19	$10,299,283
aripiprazole	Abilify®	**12**	**$17,105,309**	12	$14,148,498
somatropin	Various	**13**	**$15,623,204**	10	$16,190,582
emicizumab-kxwh	Hemlibra®	**14**	**$15,391,894**	16	$11,208,545
cariprazine	Vraylar®	**15**	**$13,371,839**	27	$8,003,511
ustekinumab	Stelara®	**16**	**$13,246,385**	17	$11,139,960
dexmethylphenidate	Focalin XR®	**17**	**$13,050,822**	15	$11,250,068
apixaban	Eliquis®	**18**	**$12,103,737**	25	$8,450,916
fluticasone/salmeterol	Various	**19**	**$11,160,351**	18	$11,060,215
insulin lispro	Various	**20**	**$10,976,002**	20	$9,645,801
albuterol	Various	**21**	**$10,689,363**	14	$12,632,143
tiotropium	Spiriva®	**22**	**$10,199,814**	24	$8,507,913
insulin aspart	Novolog®	**23**	**$10,115,805**	21	$9,519,979
budesonide/formoterol	Symbicort®	**24**	**$9,979,929**	23	$8,858,238

Generic	Brand	CY 2023		CY 2022	
		Rank	Amount Paid	Rank	Amount Paid
dapagliflozin	Farxiga®	**25**	**$8,505,306**	49	$4,292,458
setmelanotide	Imcivree®	**26**	**$8,282,763**	n/a	$1,099,368
fluticasone propionate HFA	Various	**27**	**$8,238,942**	22	$9,332,132
aripiprazole lauroxil inj	Aristada®	**28**	**$7,731,620**	28	$7,212,214
semaglutide tab	Rybelsus®	**29**	**$7,568,198**	52	$4,116,486
pancrelipase	Zenpep®	**30**	**$7,479,110**	29	$7,106,872
lurasidone	Latuda®	**31**	**$7,416,017**	5	$24,286,117
buprenorphine	Various	**32**	**$6,889,639**	51	$4,171,161
sacubitril/valsartan	Entresto®	**33**	**$6,646,016**	42	$4,697,528
insulin detemir	Levemir®	**34**	**$6,468,280**	30	$7,098,604
rifaximin	Xifaxan®	**35**	**$6,428,161**	44	$4,530,941
valbenazine	Ingrezza®	**36**	**$6,251,223**	46	$4,402,312
dornase alfa	Pulmozyme®	**37**	**$5,655,390**	34	$5,372,403
secukinumab	Cosentyx®	**38**	**$5,585,035**	50	$4,218,732
deutetrabenazine	Austedo®	**39**	**$5,488,374**	58	$3,699,087
upadacitinib	Rinvoq®	**40**	**$5,445,775**	92	$2,005,979
cannabidiol	Epidiolex®	**41**	**$5,391,323**	40	$4,816,082
liraglutide	Victoza®	**42**	**$5,388,664**	36	$5,215,348
methylphenidate	Various	**43**	**$5,330,495**	45	$4,439,267
dasatinib	Sprycel®	**44**	**$5,244,089**	48	$4,362,182
darunavir/cobicistat/ emtricitabine/tenofovir alafenamide	Symtuza®	**45**	**$5,200,581**	33	$5,399,178
ixekizumab	Taltz®	**46**	**$5,189,484**	72	$2,695,011
casimersen	Amondys 45	**47**	**$5,113,965**	35	$5,230,777
tirzepatide	Mounjaro®	**48**	**$5,019,409**	n/a	$652,229
sitagliptin	Januvia®	**49**	**$5,016,036**	41	$4,739,666
risankizumab-rzaa	Skyrizi®	**50**	**$4,920,185**	88	$2,118,657

Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.
CY = calendar year; HFA = hydrofluoroalkane, INJ = injection; n/a = not applicable
Please note: Medications with "n/a" for the CY 2022 rank were not included in the top 100 medications by reimbursement for CY 2022; therefore, the CY 2022 reimbursement ranking is not available.

Top 50 Medications by Total Number of Claims: Calendar Year 2023

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/ Day**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
1	albuterol	282,724	122,670	$10,689,362.61	1.81	2.3	$37.81	8.55%
2	amoxicillin	275,286	203,158	$3,477,950.58	11.1	1.36	$12.63	2.78%
3	cetirizine	184,397	86,845	$2,265,302.03	2.85	2.12	$12.28	1.81%
4	hydrocodone/APAP	155,453	68,406	$2,514,937.79	3.79	2.27	$16.18	2.01%

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/ Day**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
5	gabapentin	154,150	40,691	$2,623,048.14	2.93	3.79	$17.02	2.10%
6	ondansetron	127,653	92,553	$1,751,875.56	2.37	1.38	$13.72	1.4%
7	sertraline	121,650	34,745	$1,542,759.50	1.16	3.5	$12.68	1.23%
8	fluticasone propionate	113,256	66,413	$1,706,747.60	0.4	1.71	$15.07	1.36%
9	ibuprofen	109,705	75,653	$1,282,324.49	3.01	1.45	$11.69	1.03%
10	azithromycin	109,112	86,791	$1,630,079.60	2.59	1.26	$14.94	1.3%
11	trazodone	108,030	29,531	$1,229,919.41	1.21	3.66	$11.38	0.98%
12	prednisone	106,908	78,161	$1,051,268.45	1.78	1.37	$9.83	0.84%
13	amoxicillin & K clavulanate	100,148	84,297	$1,987,230.87	6.84	1.19	$19.84	1.59%
14	fluoxetine	97,963	26,520	$1,185,987.99	1.21	3.69	$12.11	0.95%
15	montelukast	97,176	34,612	$1,382,987.43	1	2.81	$14.23	1.11%
16	omeprazole	94,915	36,161	$1,161,685.28	1.19	2.62	$12.24	0.93%
17	lisdexamfetamine	94,201	17,779	$32,152,426.20	1	5.3	$341.32	25.70%
18	lisinopril	92,828	32,157	$1,000,904.86	1.08	2.89	$10.78	0.8%
19	atorvastatin	91,837	32,373	$1,161,717.63	1	2.84	$12.65	0.93%
20	escitalopram	90,092	27,417	$1,178,294.86	1.05	3.29	$13.08	0.94%
21	clonidine	89,648	18,779	$992,375.97	1.48	4.77	$11.07	0.79%
22	levothyroxine	82,807	21,725	$1,505,282.35	1	3.81	$18.18	1.2%
23	cephalexin	79,347	68,407	$1,284,132.68	8.45	1.16	$16.18	1.03%
24	metformin	78,714	28,098	$813,909.03	2.02	2.8	$10.34	0.65%
25	bupropion	78,089	23,109	$1,311,961.03	1.18	3.38	$16.80	1.05%
26	hydroxyzine	77,699	31,118	$991,833.79	2.82	2.5	$12.77	0.79%
27	cefdinir	77,428	61,648	$1,637,579.18	6.29	1.26	$21.15	1.31%
28	aripiprazole	77,288	18,895	$17,105,309.17	0.94	4.09	$221.32	13.67%
29	methylphenidate	72,205	12,739	$5,330,494.77	1.4	5.67	$73.82	4.26%
30	buspirone	71,874	22,805	$986,021.97	2.19	3.15	$13.72	0.79%
31	quetiapine	69,530	15,905	$973,980.29	1.36	4.37	$14.01	0.78%
32	cyclobenzaprine	68,842	33,141	$716,617.47	2.24	2.08	$10.41	0.57%
33	amlodipine	65,943	23,031	$679,466.90	1.04	2.86	$10.30	0.54%
34	pantoprazole	65,577	25,705	$865,867.74	1.15	2.55	$13.20	0.69%
35	duloxetine	60,470	17,021	$958,947.02	1.27	3.55	$15.86	0.77%
36	guanfacine	57,387	10,346	$1,063,473.79	1	5.55	$18.53	0.85%
37	triamcinolone	55,140	40,713	$801,446.83	4.67	1.35	$14.53	0.64%
38	meloxicam	54,962	27,322	$559,618.87	1.06	2.01	$10.18	0.45%
39	oxycodone/APAP	54,685	22,069	$996,144.02	3.72	2.48	$18.22	0.8%
40	amphetamine/ dextroamphetamine	52,813	10,497	$1,425,597.25	1.42	5.03	$26.99	1.14%
41	alprazolam	52,293	9,404	$572,331.25	2.2	5.56	$10.94	0.46%
42	prednisolone	52,256	38,537	$854,689.82	6.52	1.36	$16.36	0.68%

Top 50 Medications by Total Number of Claims								
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Units/ Day**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
43	methylprednisolone	51,723	44,610	$674,233.24	3.44	1.16	$13.04	0.54%
44	mupirocin	51,345	43,902	$794,737.84	2.15	1.17	$15.48	0.64%
45	lamotrigine	51,032	11,181	$1,026,683.68	1.74	4.56	$20.12	0.82%
46	hydroxyzine	47,916	19,268	$782,728.04	2.47	2.49	$16.34	0.63%
47	tizanidine	46,974	16,223	$564,333.25	2.68	2.9	$12.01	0.45%
48	famotidine	45,931	21,416	$1,033,211.96	1.61	2.14	$22.49	0.83%
49	buprenorphine/naloxone	45,557	6,104	$2,842,183.28	1.97	7.46	$62.39	2.27%
50	dexmethylphenidate	44,988	7,169	$13,050,821.93	1.11	6.28	$290.10	26.8%

APAP = acetaminophen; K = potassium
Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.

Top 10 Traditional and Specialty Therapeutic Categories by Calendar Year

Traditional Therapeutic Category	2023 Total Claims	2023 Total Cost	2023 Cost/ Member	2022 Total Claims	2022 Total Cost	2022 Cost/ Member
	CALENDAR YEAR 2023			CALENDAR YEAR 2022		
ANTI-DIABETIC AGENTS						
Anti-Diabetics	292,979	$157,538,919.35	$3,436.71	239,894	$111,054,477.35	$2,954.36
Total	**292,979**	**$157,538,919.35**	**$3,436.71**	**239,894**	**$111,054,477.35**	**$2,954.36**
ANTIPSYCHOTICS						
Antipsychotics	328,564	$117,191,957.10	$2,125.01	309,674	$111,520,874.56	$2,236.50
Total	**328,564**	**$117,191,957.10**	**$2,125.01**	**309,674**	**$111,520,874.56**	**$2,236.50**
ANTI-INFECTIVE AGENTS						
Antivirals	66,571	$60,588,932.95	$1,739.51	98,539	$54,776,802.03	$803.71
Misc. Anti-Infectives	144,845	$9,930,062.74	$99.95	140,929	$8,466,525.14	$88.26
Penicillins	384,968	$6,043,262.74	$22.95	326,452	$5,110,274.25	$22.23
Cephalosporins	164,553	$3,422,056.87	$26.97	150,883	$3,240,170.67	$27.46
Macrolide Antibiotics	112,671	$2,556,826.28	$28.74	118,881	$2,712,422.75	$29.36
Antifungals	47,989	$1,427,566.26	$44.17	44,969	$2,135,581.20	$71.47
Tetracyclines	53,198	$1,114,573.32	$28.34	47,940	$1,025,273.35	$29.37
Antimalarial	16,944	$403,244.71	$92.28	12,675	$335,193.50	$103.07
Aminoglycosides	523	$391,130.47	$1,481.55	594	$378,683.21	$1,387.12
Fluoroquinolones	25,727	$356,269.28	$17.05	24,042	$335,090.09	$17.27
Antimycobacterial Agents	625	$99,001.22	$352.32	598	$35,801.54	$140.95
Anthelmintic	2,014	$87,005.70	$50.03	1,657	$109,629.63	$74.78
Sulfonamides	14	$15,127.82	$3,781.96	2	$2,583.51	$1,291.76
Amebicides	0	0	0	1	$283.36	$283.36
Total	**1,020,642**	**$86,435,060.14**	**$121.31**	**968,162**	**$78,664,314.23**	**$113.39**

Traditional Therapeutic Category	2023 Total Claims	2023 Total Cost	2023 Cost/ Member	2022 Total Claims	2022 Total Cost	2022 Cost/ Member
ANTI-ASTHMA AGENTS						
Antiasthmatic & Bronchodilatory Agents	542,246	$61,555,196.18	$421.03	530,781	$60,892,110.34	$419.62
Total	**542,246**	**$61,555,196.18**	**$421.03**	**530,781**	**$60,892,110.34**	**$419.62**
ADHD AGENTS						
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiants	367,394	$57,285,980.16	$1,115.75	356,428	$49,047,287.54	$1,065.60
Total	**367,394**	**$57,285,980.16**	**$1,115.75**	**356,428**	**$49,047,287.54**	**$1,065.60**
ONCOLOGY AGENTS						
Oncology Agents	20,083	$55,535,114.43	$10,659.33	17,384	$44,560,656.67	$10,088.44
Total	**20,083**	**$55,535,114.43**	**$10,659.33**	**17,384**	**$44,560,656.67**	**$10,088.44**
TOPICAL PRODUCTS						
Dermatological	247,240	$23,837,101.93	$172.79	223,563	$15,447,327.63	$123.44
Otic	33,785	$4,917,785.35	$176.53	32,104	$4,809,368.32	$180.55
Ophthalmic	94,256	$3,593,335.98	$54.60	79,361	$3,646,475.83	$67.62
Mouth/Throat/Dental Agents	32,812	$483,054.42	$17.94	33,452	$496,357.67	$18.07
Anorectal	2,732	$229,591.52	$99.91	2,314	$171,801.36	$88.97
Total	**410,825**	**$33,060,869.20**	**$126.74**	**295,479**	**$17,579,241.32**	**$94.43**
ANALGESIC AGENTS						
Analgesics – Narcotic	371,592	$14,363,463.20	$123.23	353,763	$13,233,125.14	$121.03
Analgesics – Anti-Inflammatory	262,583	$13,268,993.67	$97.65	241,147	$8,290,355.60	$66.47
Migraine Products	26,280	$2,245,149.37	$190.98	21,923	$1,607,013.74	$162.54
Gout	10,447	$146,948.90	$46.99	9,190	$134,970.47	$50.59
Analgesics – NonNarcotic	7,665	$125,407.15	$36.65	6,191	$124,001.82	$52.30
Local Anesthetics – Parenteral	194	$3,784.76	$25.57	135	$2,251.31	$19.75
Total	**678,761**	**$30,153,747.05**	**$111.31**	**632,349**	**$23,391,718.08**	**$93.91**
ANTICONVULSANT PRODUCTS						
Anticonvulsants	470,518	$28,257,689.33	$334.03	443,224	$27,989,301.56	$369.96
Total	**470,518**	**$28,257,689.33**	**$334.03**	**443,224**	**$27,989,301.56**	**$369.96**
CARDIOVASCULAR AGENTS						
Misc Cardiovascular	12,476	$9,824,806.44	$4,061.52	8,710	$5,690,640.36	$3,279.91
Antihypertensive	335,811	$5,202,498.95	$59.76	317,705	$5,027,123.17	$64.98
Vasopressors	14,717	$3,254,971.28	$311.81	12,582	$2,894,049.88	$317.30
Beta Blockers	153,331	$2,518,004.13	$52.57	140,439	$2,449,920.07	$58.76
Antihyperlipidemic	157,093	$2,455,034.53	$48.34	140,911	$2,246,776.25	$51.63
Diuretics	108,432	$2,129,890.09	$64.84	101,076	$2,059,411.01	$69.80

Traditional Therapeutic Category	2023 Total Claims	2023 Total Cost	2023 Cost/ Member	2022 Total Claims	2022 Total Cost	2022 Cost/ Member
Calcium Blockers	80,098	$1,130,222.76	$40.92	72,870	$1,042,470.81	$43.49
Antianginal Agents	11,808	$282,619.22	$64.76	10,921	$264,553.12	$64.49
Antiarrhythmic	5,501	$253,051.67	$172.97	4,848	$211,171.90	$164.46
Cardiotonics	2,742	$135,239.07	$188.88	3,086	$166,259.35	$217.90
Total	**882,009**	**$27,186,338.14**	**$102.36**	**813,148**	**$22,052,375.92**	**$94.63**

Table is not an all-inclusive list.
Reimbursement does not reflect rebated costs or net costs.

Specialty Therapeutic Category	2023 Total Claims	2023 Total Cost	2023 Cost/ Member	2022 Total Claims	2022 Total Cost	2022 Cost/ Member
	CALENDAR YEAR 2023			CALENDAR YEAR 2022		
ANALGESIC AGENTS						
Analgesic – Anti-Inflammatory	16,436	$120,363,794.74	$44,105.46	12,601	$86,931,982.47	$43,078.29
Analgesic – Narcotics	1,742	$3,305,489.24	$7,814.40	715	$1,299,747.25	$6,840.78
Migraine Products	2,666	$1,782,723.74	$3,448.21	2,154	$1,395,441.62	$3,370.63
Local Anesthetics – Parenteral	133	$2,990.71	$29.91	161	$3,906.09	$36.51
Total	**20,977**	**$125,454,998.43**	**$33,286.02**	**15,631**	**$89,631,077.43**	**$32,843.93**
SPECIALIZED RESPIRATORY AGENTS						
Misc. Respiratory	3,229	$46,940,653.02	$174,500.57	3,193	$45,499,309.92	$183,464.96
Total	**3,229**	**$46,940,653.02**	**$174,500.57**	**3,193**	**$45,499,309.92**	**$183,464.96**
ENDOCRINE AGENTS						
Misc. Endocrine	4,368	$39,199,851.88	$66,666.41	4,503	$36,487,384.94	$69,499.78
Progestins	221	$555,589.61	$5,342.21	1,050	$2,614,085.33	$7,780.02
Total	**4,589**	**$39,755,441.49**	**$57,450.06**	**5,553**	**$39,101,470.27**	**$45,414.02**
DERMATOLOGIC AGENTS						
Dermatological	5,161	$39,290,080.41	$40,969.84	3,909	$28,169,889.43	$41,609.88
Ophthalmic	1	$425,011.41	$425,011.41	0	$0	$0
Total	**5,162**	**$39,715,091.82**	**$41,369.89**	**3,909**	**$28,169,889.43**	**$41,609.88**
HEMATOLOGICAL AGENTS						
Misc. Hematological	1,078	$27,896,641.37	$200,695.26	958	$21,820,175.49	$180,332.03
Hematopoietic Agents	615	$4,626,425.23	$33,283.63	408	$2,954,742.83	$26,381.63
Total	**1,693**	**$32,523,066.60**	**$116,989.45**	**1,366**	**$24,774,918.32**	**$106,330.12**
ANTI-INFECTIVE AGENTS						
Antiviral	2,241	$28,211,974.55	$24,341.65	2,252	$24,363,182.87	$23,745.79
Aminoglycosides	400	$898,591.87	$6,559.06	479	$1,043,423.40	$6,864.63
Misc. Anti-Infectives	57	$644,148.05	$40,259.25	59	$598,289.05	$35,193.47

Specialty Therapeutic Category	2023 Total Claims	2023 Total Cost	2023 Cost/ Member	2022 Total Claims	2022 Total Cost	2022 Cost/ Member
Antifungals	10	$59,540.34	$11,908.07	19	$109,930.57	$27,482.64
Total	**2,708**	**$29,814,254.81**	**$22,638.01**	**2,809**	**$26,114,825.89**	**$21,780.51**
PSYCHOTHERAPEUTIC/NEUROLOGIC AGENTS						
Misc. Psychotherapeutic and Neurologic Agents	2,182	$16,802,504.90	$51,227.15	2,014	$14,836,282.79	$47,400.26
Total	**2,182**	**$16,802,504.90**	**$51,227.15**	**2,014**	**$14,836,282.79**	**$47,400.26**
NEUROMUSCULAR AGENTS						
Neuromuscular Agents	275	$15,492,313.88	$469,464.06	302	$16,596,625.52	$488,136.04
Antimyasthenic Agents	26	$995,238.30	$331,746.10	16	$510,962.93	$255,481.47
Total	**301**	**$16,487,552.18**	**$457,987.56**	**318**	**$17,107,588.45**	**$475,210.79**
CARDIOVASCULAR AGENTS						
Misc. Cardiovascular	2,379	$13,317,554.22	$49,878.45	2,152	$11,116,468.23	$40,131.65
Antihyperlipidemic	452	$242,392.29	$3,068.26	219	$110,480.49	$2,350.65
Total	**2,831**	**$13,559,937.51**	**$39,190.57**	**2,371**	**$11,226,948.72**	**$34,651.08**
ANTI-OBESITY AGENTS						
Anti-Obesity	310	$8,282,763.05	$145,311.63	46	$1,099,368.01	$84,566.77
Total	**310**	**$8,282,763.05**	**$145,311.63**	**46**	**$1,099,368.01**	**$84,566.77**

Table is not an all-inclusive list.
Reimbursement does not reflect rebated costs or net costs.

Calendar Year Age Group Comparison

Traditional Pharmacy Reimbursement by Age Group			
Age Group (Years)	**CY 2021**	**CY 2022**	**CY 2023**
Age 0 to 2	$9,532,924.41	$13,482,145.72	$12,387,768.65
Age 3 to 5	$13,527,628.37	$14,843,542.44	$17,944,610.25
Age 6 to 9	$35,434,408.54	$54,183,962.23	$41,900,607.74
Age 10 to 14	$55,895,238.33	$61,404,103.33	$64,076,364.57
Age 15 to 18	$43,025,682.56	$51,515,924.56	$52,023,143.94
Age 19 to 25	$37,531,719.25	$54,614,719.34	$65,013,840.85
Age 26 to 34	$51,993,217.13	$83,507,877.87	$100,563,591.21
Age 35 to 54	$135,037,231.80	$214,782,989.26	$271,807,367.35
Age 55 to 64	$81,805,886.61	$132,632,580.98	$166,728,141.16
Age 65+	$12,054,896.85	$16,896,738.31	$23,430,399.79
Total (All Ages)	**$475,838,833.85**	**$697,864,584.04**	**$815,875,835.51**

Reimbursement does not reflect rebated costs or net costs.

Specialty Pharmacy Reimbursement by Age Group			
Age Group (Years)	**CY 2021**	**CY 2022**	**CY 2023**
Age 0 to 2	$10,367,579.60	$6,637,359.68	$5,634,829.23
Age 3 to 5	$7,926,890.19	$10,133,008.36	$10,485,189.78
Age 6 to 9	$24,703,074.37	$34,840,379.11	$27,676,602.60
Age 10 to 14	$35,510,944.43	$44,945,876.11	$48,220,328.06
Age 15 to 18	$31,966,869.23	$38,240,635.55	$38,160,770.01
Age 19 to 25	$20,940,101.65	$35,312,897.03	$39,366,522.46
Age 26 to 34	$22,181,230.98	$36,705,618.73	$53,656,849.92
Age 35 to 54	$44,500,345.61	$79,071,179.22	$114,346,860.06
Age 55 to 64	$20,232,692.31	$36,439,010.26	$49,470,472.79
Age 65+	$1,961,427.44	$3,216,228.33	$4,368,756.33
Total (All Ages)	**$220,291,155.81**	**$325,542,192.50**	**$391,387,181.24**

Reimbursement does not reflect rebated costs or net costs.

Total Enrollment by Age Group Comparison by Calendar Year				
Age Group (Years)	**2021**	**2022**	**2023**	**% Change (2022 vs. 2023)**
Age 0 to 2	100,587	101,858	105,073	3.16%
Age 3 to 5	99,914	104,301	111,321	6.73%
Age 6 to 9	130,688	138,788	147,685	6.41%
Age 10 to 14	159,970	167,227	176,556	5.58%
Age 15 to 18	111,921	124,031	136,809	10.30%
Age 19 to 25	85,544	130,046	167,595	28.87%
Age 26 to 34	93,505	133,136	167,072	25.49%
Age 35 to 54	132,007	204,810	261,482	27.67%
Age 55 to 64	59,272	85,377	104,354	22.23%
Age 65+	69,298	77,569	92,630	19.42%
Total (All Ages)	**1,042,706**	**1,267,142**	**1,470,577**	**16.05%**

The sum of each age group does not add up to the total average per year from enrollment.
Average monthly enrollment as obtained from OHCA Fast Facts reports.

[1] U.S. Department of Health and Human Services (HHS). Covid-19 Public Health Emergency (PHE). Available online at: https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html. Last revised 12/15/2023. Last accessed 05/30/2024.
[2] Dolan R. Understanding the Medicaid Prescription Drug Rebate Program. *Kaiser Family Foundation (KFF)*. https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/. Issued 11/12/2019. Last accessed 05/30/2024.
[3] Office of Inspector General (OIG): Department of Health and Human Services (HHS). States' Collection of Offset and Supplemental Medicaid Rebates. Available online at: http://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf. Issued 12/2014. Last accessed 05/30/2024.
[4] Gibbons DC, Kirschenbaum AM. Bipartisan Budget Bill Extends Medicaid Drug Rebate Program Price Increase Penalty to Generic Drugs. *FDA Law Blog*. Available online at: http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2015/11/bipartisan-budget-bill-extends-medicaid-drug-rebate-program-price-increase-penalty-to-generic-drugs.html. Issued 11/02/2015. Last accessed 05/30/2024.
[5] Social Security Administration. Payment for Covered Outpatient Drugs. Available online at: https://www.ssa.gov/OP_Home/ssact/title19/1927.htm. Last accessed 05/30/2024.
[6] National Association of Medicaid Directors (NAMD). The Role of State Medicaid Programs in Improving the Value of the Health Care System. *Bailit Health*. Available online at: https://medicaiddirectors.org/wp-content/uploads/2022/02/Report-Role-of-State-Medicaid-Programs-in-Improving-the-Value-of-the-Healthcare-System.pdf. Issued 03/22/2016. Last accessed 05/30/2024.
[7] Goodman C, Daniel R, Balch A, Doyle J. Value-Based Health Care for Patients, Providers & Payers – Summary from AMCP Foundation Research Symposium Highlights Webinar. *AMCP Foundation*. Available online at: https://www.amcp.org/Resource-Center/value-based-care/value-based-health-care-patients-providers-payers-summary-amcp. Webinar recorded 11/30/2017. Last accessed 05/30/2024.
[8] Tichy EM, Hoffman JM, Tadrous M, et al. National Trends in Prescription Drug Expenditures and Projections for 2024. *Am J Health Syst Pharm* 2024; zxae105. doi: 10.1093/ajhp/zxae105. Online ahead of print.
[9] Centers for Medicare and Medicaid Services (CMS). CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers. Available online at: https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers. Issued 06/27/2018. Last accessed 05/30/2024.
[10] U.S. Food and Drug Administration (FDA). First Generic Drug Approvals. Available online at: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/2023-first-generic-drug-approvals. Last revised 03/08/2024. Last accessed 05/30/2024.
[11] U.S. FDA. Novel Drug Approvals for 2023. Available online at: https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2023. Last revised 04/22/2024. Last accessed 05/30/2024.
[12] U.S. 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 05/2024. Last accessed 05/30/2024.
[13] U.S. FDA. Oncology (Cancer) / Hematologic Malignancies Approval Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancer-hematologic-malignancies-approval-notifications. Last revised 05/29/2024. Last accessed 05/30/2024.
[14] Senior M. Fresh from the Biotech Pipeline: Record-Breaking FDA Approvals. *Nature Biotechnology*. Available online at: https://www.nature.com/articles/s41587-024-02166-7. Published 02/26/2024. Last accessed 05/30/2024.

Appendix K

30-Day Notice to Prior Authorize Rezdiffra™ (Resmetirom)

Oklahoma Health Care Authority
June 2024

Introduction[1,2,3,4,5,6,7]

Nonalcoholic fatty liver disease (NAFLD[Δ]) is a common cause of chronic liver disease and is closely associated with obesity, insulin resistance, type 2 diabetes mellitus (T2DM), hypertension (HTN), and atherogenic dyslipidemia. NAFLD occurs when there is evidence of hepatic steatosis on imaging or histology in the absence of secondary causes (e.g., significant alcohol consumption, chronic use of steatogenic medications, certain genetic disorders). NAFLD can be further classified as either nonalcoholic fatty liver (NAFL) or nonalcoholic steatohepatitis (NASH[Δ]). NAFL is defined by hepatic steatosis present in ≥5% of hepatocytes without evidence of hepatocellular injury (e.g., hepatocyte ballooning). NASH is a more aggressive form of NAFLD defined by hepatic steatosis present in ≥5% of hepatocytes with the presence of inflammation and hepatocyte injury, with or without fibrosis. NASH can further progress to advanced liver fibrosis, cirrhosis, or hepatocellular carcinoma, and NASH-related cirrhosis is currently the most common indication for liver transplantation in women and in patients older than 65 years of age.

NAFLD is estimated to affect approximately 25-30% of people globally, of which 12-14% have NASH. The prevalence is even higher among patients with T2DM and obesity, with approximately 25-30% of obese people and 30-40% of people with T2DM having NASH. The prevalence of either form of NAFLD may be as high as 75% among people with T2DM.

According to guidance from the American Association for the Study of Liver Diseases (AASLD), NAFLD can be diagnosed through a combination of non-invasive tests (NITs), including laboratory and imaging techniques, as well as through liver biopsy assessment. However, due to the invasive nature, risk, and costs associated with a liver biopsy, it is typically reserved for specific scenarios, such as patients with indeterminate NITs or diagnostic uncertainty.

[Δ] Please note: The former nomenclature for NAFLD/NASH has been used throughout this report for clarity to align with the FDA approved labeling for Rezdiffra™. The FDA approved labeling does not currently include the updated nomenclature from multinational liver societies, including the AASLD [metabolic dysfunction-associated steatotic liver dysfunction (MASLD)/metabolic dysfunction-associated steatohepatitis (MASH)].

T2DM has been identified as a major driver of disease progression in NAFLD and may result in faster disease progression. Approximately one third of people with NAFLD will progress to NASH, 20% of whom will develop liver fibrosis and have a high risk of extrahepatic complications, cirrhosis, and liver failure. All stages of NAFLD are associated with an increased overall risk of mortality and the mortality risk increases as the severity of liver disease increases. Mortality in NAFLD is due primarily to extrahepatic cancer, cirrhosis, cardiovascular disease (CVD), and hepatocellular carcinoma.

Treatment of NAFLD involves treating the liver disease itself as well as the associated co-morbidities, including obesity, T2DM, HTN, and hyperlipidemia. In March 2024, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Rezdiffra™ (resmetirom), in conjunction with diet and exercise, for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Rezdiffra™ is the first FDA approved medication for the treatment of NASH.

Rezdiffra™ (Resmetirom) Product Summary[8]

Therapeutic Class: Thyroid hormone receptor-beta (THR-beta) agonist

Indication(s): Treatment, in conjunction with diet and exercise, of adults with NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

- **Limitation(s) of Use:** Use should be avoided in patients with decompensated cirrhosis.

How Supplied: 60mg, 80mg, and 100mg oral tablets

Dosing and Administration: May be administered with or without food with the dose based on actual body weight as follows:

- <100kg: 80mg once daily
- ≥100kg: 100mg once daily
- Lower doses required if used concomitantly with a moderate CYP2C8 inhibitor (e.g., clopidogrel)
- Concomitant use is not recommended with strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine)

Cost: The Wholesale Acquisition Cost (WAC) is $131.67 per tablet, regardless of strength. This results in a cost of $3,950.10 per month or $47,401.20 per year based on recommended dosing.

Recommendations

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

Rezdiffra™ (Resmetirom) Approval Criteria:

1. An FDA approved indication of noncirrhotic nonalcoholic steatohepatitis (NASH); and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following:
    a. FibroScan with vibration controlled transient elastography (VCTE) ≥8.5kPa and controlled attenuation parameter (CAP) ≥280dB/min; or
    b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
    c. Liver biopsy showing stage F2 or F3 fibrosis with NASH; and
4. Member must not have known liver cirrhosis (e.g., stage F4); and
5. Must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and
6. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
    a. Type 2 diabetes; and
    b. Dyslipidemia; and
    c. Hypertension; and
7. Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra™; and
8. If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra™, prescriber must agree to reduce the dose as required in the package labeling; and
9. If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and
10. Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
11. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber documents the member is tolerating and responding well to the medication; and
12. A quantity limit of 30 tablets per 30 days will apply.

[1] National Institute of Diabetes and Digestive and Kidney Diseases. Nonalcoholic Fatty Liver Disease (NAFLD) & Nonalcoholic Steatohepatitis (NASH): Definition & Facts of NAFLD and NASH. Available online at: https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/definition-facts. Last revised 04/2021. Last accessed 05/23/2024.

[2] Chalasani N, Younossi Z, Lavine JE, et al. The Diagnosis and Management of Non-Alcoholic Fatty Liver Disease: Practice Guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association. *Hepatology* 2012; 55(6):2005-23. doi: 10.1002/hep.25762.

[3] Chalasani N, Younossi Z, Lavine JE, et al. The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology* 2018; 67(1):328-357. doi: 10.1002/hep.29367.

[4] Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (AASLD). *Endocr Pract* 2022; 28(5):528-562. doi: 10.1016/j.eprac.2022.03.010.

[5] Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the Clinical Assessment and Management of Nonalcoholic Fatty Liver Disease. *Hepatology* 2023; 77(5):1797-1835. doi: 10.1097/HEP.0000000000000323.

[6] Rinella ME, Lazarus JV, Ratziu V, et al. A Multi-Society Delphi Consensus Statement on New Fatty Liver Disease Nomenclature. *Hepatology* 2023; 78(6):1966-1986. doi: 10.1097/HEP.0000000000000520.

[7] Madrigal Pharmaceuticals, Inc. Madrigal Pharmaceuticals Announces FDA Approval of Rezdiffra™ (Resmetirom) for the Treatment of Patients with Noncirrhotic Nonalcoholic Steatohepatitis (NASH) with Moderate to Advanced Liver Fibrosis. Available online at: https://ir.madrigalpharma.com/news-releases/news-release-details/madrigal-pharmaceuticals-announces-fda-approval-rezdiffratm. Issued 03/14/2024. Last accessed 05/06/2024.

[8] Rezdiffra™ (Resmetirom) Prescribing Information. Madrigal Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217785s000lbl.pdf. Last revised 03/2024. Last accessed 05/03/2024.

Appendix L

Calendar Year 2023 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Risvan® [Risperidone Intramuscular (IM) Injection]

Oklahoma Health Care Authority
June 2024

Current Prior Authorization Criteria

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole IM inj (Abilify Asimtufii®)^	iloperidone (Fanapt®)	asenapine transdermal system (Secuado®)+
aripiprazole IM inj (Abilify Maintena®)^	lurasidone (Latuda®)	brexpiprazole (Rexulti®)
aripiprazole lauroxil IM inj (Aristada®)^	paliperidone (Invega®)	cariprazine (Vraylar®)
aripiprazole lauroxil IM inj (Aristada Initio®)^		clozapine (Fazaclo®)+
clozapine (Clozaril®)◊		clozapine oral susp (Versacloz®)+
olanzapine (Zyprexa®)		lumateperone (Caplyta®)
paliperidone palmitate IM inj (Invega Hafyera™)^		olanzapine/fluoxetine (Symbyax®)+
paliperidone palmitate IM inj (Invega Sustenna®)^		olanzapine/samidorphan (Lybalvi®)β
paliperidone palmitate IM inj (Invega Trinza®)^		quetiapine 150mg tablets+
quetiapine (Seroquel®)		risperidone IM inj (Risperdal Consta®)^∞
quetiapine ER (Seroquel XR®)		risperidone IM inj (Rykindo®)^∞
risperidone (Risperdal®)		
risperidone sub-Q inj (Perseris®)^		
risperidone sub-Q inj (Uzedy™)^		
ziprasidone (Geodon®)		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates,

and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
◊Clozapine does not count towards a Tier-1 trial.
^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
βUnique criteria applies to Lybalvi® (olanzapine/samidorphan).
∞Unique criteria applies to Tier-3 long-acting injectable (LAI) products.

Tier-1 products are available without prior authorization for members 5 years of age and older. Prior authorization requests for members younger than 5 years of age are reviewed by an Oklahoma Health Care Authority (OHCA)-contracted child psychiatrist.

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of 2 oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) or requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and
6. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the

oral sublingual tablet formulation. Tier structure rules continue to apply; and
7. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD):

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

Abilify MyCite® (Aripiprazole Tablet with Sensor) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must not have dementia-related psychosis; and
3. A patient-specific, clinically significant reason why the member cannot use all oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply. Please note, the ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established; and
4. Previous use of aripiprazole tablets and a reason why the Tier-1 aripiprazole tablets are no longer appropriate for the member must be provided; and
5. Prescriber agrees to closely monitor patient adherence; and
6. Patients should be capable and willing to use the MyCite® App and follow the Instructions for Use and ensure the MyCite® App is compatible with their specific smartphone; and
7. Initial approval will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance greater than 80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to oral aripiprazole tablets or to any of the oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply.

Long-Acting Injectable (LAI) Products Tier-3 Approval Criteria:

1. Use of LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower tiered LAI products available for the medication being requested, which are available without a prior authorization.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must have a positive clinical response to olanzapine and gained ≥10% from baseline body weight after starting olanzapine (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and any increase in body weight is <10% of baseline body weight (current weight must be provided) while on therapy must be provided.

Rexulti® (Brexpiprazole) Approval Criteria [Agitation Associated with Dementia Due to Alzheimer's Disease Diagnosis]:

1. An FDA approved indication of the treatment of agitation associated with dementia due to Alzheimer's disease; and
2. Diagnosis must be confirmed by the following:
    a. Mini-Mental State Exam (MMSE) score between 5 and 22; and
    b. Documentation of the member’s dementia due to Alzheimer's disease diagnosis [i.e., chart notes consistent with findings of a diagnosis of dementia due to Alzheimer's disease as per the National Institute on Aging and the Alzheimer’s Association (NIA-AA)]; and
    c. 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
    d. Neuropsychiatric Inventory (NPI)/NPI-Nursing Home (NH) agitation/aggression score ≥4; and
    e. Exhibiting sufficient agitation behaviors warranting the use of pharmacotherapy; and
3. Prescriber must document a baseline evaluation using the Cohen-Mansfield Agitation Inventory (CMAI) total score; and
4. Prescriber must verify member will be closely monitored due to the risk of dementia-related psychosis; and
5. Initial approvals will be for 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the CMAI total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Utilization of Atypical Antipsychotic Medications: Calendar Year 2023

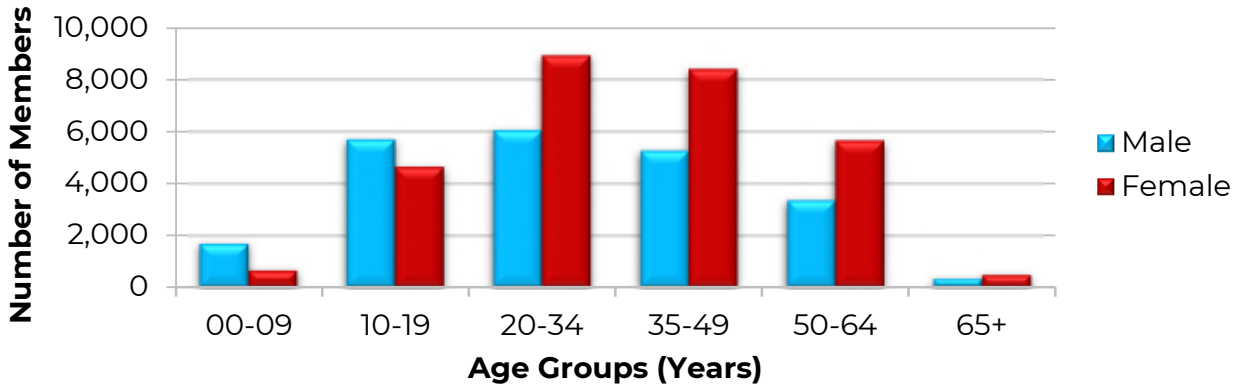
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	45,841	279,859	$110,465,452.06	$394.72	$11.36	11,335,806	9,726,160
2023	50,966	297,679	$116,761,389.13	$392.24	$10.94	12,228,465	10,677,322
% Change	**11.2%**	**6.4%**	**5.7%**	**-0.6%**	**-3.7%**	**7.9%**	**9.8%**
Change	**5,125**	**17,820**	**$6,295,937.07**	**-$2.48**	**-$0.42**	**892,659**	**951,162**

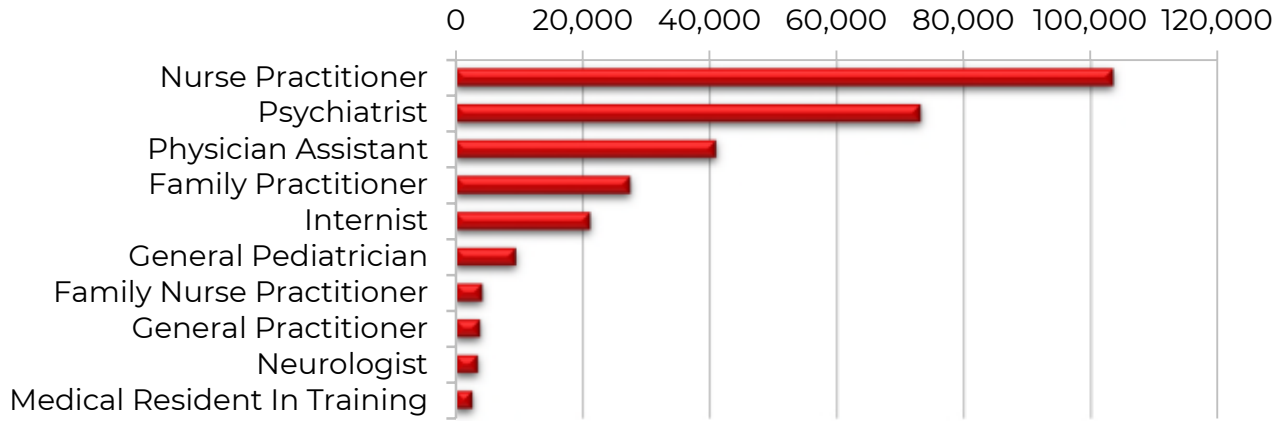
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

- Aggregate drug rebates collected during calendar year 2023 for atypical antipsychotic medications totaled $78,128,033.68[Δ]. Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Atypical Antipsychotic Medications



Top Prescriber Specialties of Atypical Antipsychotic Medications by Number of Claims

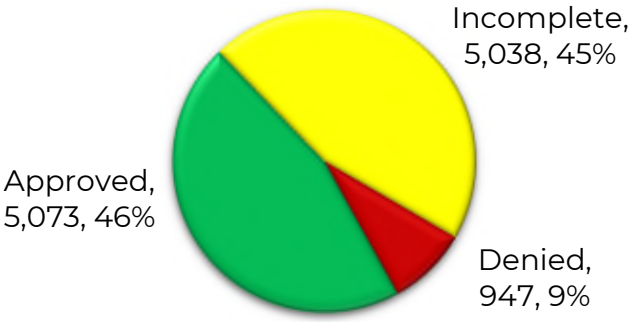


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Prior Authorization of Atypical Antipsychotic Medications

There were 11,058 prior authorization requests submitted for atypical antipsychotic medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



There were 67 prior authorization requests submitted for a total of 47 unique members for atypical antipsychotic medications during calendar year 2023 that were referred for a psychiatric consultation. Most requests were for children 3 or 4 years of age. The following chart shows the status of the submitted petitions that were referred for a psychiatric consultation for calendar year 2023.

Status of Psychiatric Consultations

Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available for the SoonerCare fee-for-service (FFS) population and can be scheduled by calling 1-405-522-7597.
- **Care Management (Including Behavioral Health):** Additional services are available for SoonerCare members, including Behavioral Health

Care Management, through the member's SoonerCare (FFS) or SoonerSelect (managed care) health plan.

- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care management for chronic and complex medical conditions at: https://health.okstate.edu/echo/index.html.
- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/index.html.

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

Anticipated Patent Expiration(s):

- Saphris® [asenapine sublingual (SL) tablet]: October 2026
- Perseris® [risperidone subcutaneous (sub-Q) injection]: February 2028
- Versacloz® (clozapine oral suspension): May 2028
- Vraylar® (cariprazine capsule): September 2029
- Invega Sustenna® [paliperidone intramuscular (IM) injection]: January 2031
- Latuda® (lurasidone tablet): November 2031
- Fanapt® (iloperidone tablet): December 2031
- Lybalvi® (olanzapine/samidorphan tablet): February 2032
- Rykindo® (risperidone ER IM injection): April 2032
- Rexulti® (brexpiprazole tablet): October 2032
- Abilify Asimtufii® (aripiprazole IM injection): April 2033
- Uzedy™ (risperidone ER sub-Q injection): April 2033
- Secuado® (asenapine transdermal system): September 2033
- Abilify MyCite® (aripiprazole tablet with sensor): October 2033
- Abilify Maintena® (aripiprazole IM injection): April 2034
- Invega Trinza® (paliperidone IM injection): April 2036
- Aristada® (aripiprazole lauroxil IM injection): April 2039
- Caplyta® (lumateperone capsule): August 2039
- Invega Hafyera™ (paliperidone palmitate IM injection): November 2041

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

- **March 2024:** The FDA approved Risvan® (risperidone IM injection) for the treatment of schizophrenia in adults. Risvan® 75mg and 100mg showed statistically significant improvement in patients' Positive and Negative Syndrome Scale (PANSS) total score from baseline to the end of the study at day 85 compared to placebo. Risvan® is given as 75mg or 100mg once monthly via IM injection after tolerability is established with oral risperidone.

- **April 2024:** The FDA approved Fanapt® (iloperidone) for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. The approval was based on a Phase 3 trial that showed patients treated with Fanapt® had statistically significant improvements in mania at week 4 when compared to placebo. Fanapt® was originally FDA approved in 2009 for the acute treatment of schizophrenia in adults.

Pipeline:

- **KarXT (Xanomeline/Trospium):** KarXT is an investigational M1/M4-preferring muscarinic agonist that is currently being studied for the treatment of schizophrenia and for the treatment of psychosis related to Alzheimer's disease. KarXT is thought to improve positive, negative, and cognitive symptoms of schizophrenia and unlike existing treatments, it does not directly block dopamine receptors. A New Drug Application (NDA) has been submitted to the FDA for the schizophrenia indication, and a Prescription Drug User Fee Act (PDUFA) date has been assigned for September 26, 2024.

Recommendations

The College of Pharmacy recommends the following changes to the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following tier chart and criteria):

1. Prior authorization of Risvan® (risperidone IM injection), placement into Tier-3, and the current Long-Acting Injectable (LAI) Tier-3 criteria will apply; and
2. Updating the Tier-2, Tier-3, Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD), and LAI Products Tier-3 approval criteria to be consistent with clinical practice.

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole IM inj (Abilify Asimtufii®)^	iloperidone (Fanapt®)	asenapine transdermal system (Secuado®)+
aripiprazole IM inj (Abilify Maintena®)^	lurasidone (Latuda®)	brexpiprazole (Rexulti®)
aripiprazole lauroxil IM inj (Aristada®)^	paliperidone (Invega®)	cariprazine (Vraylar®)
aripiprazole lauroxil IM inj (Aristada Initio®)^		clozapine (Fazaclo®)+
clozapine (Clozaril®)◊		clozapine oral susp (Versacloz®)+

olanzapine (Zyprexa®)		lumateperone (Caplyta®)
paliperidone palmitate IM inj (Invega Hafyera™)^		olanzapine/fluoxetine (Symbyax®)+
paliperidone palmitate IM inj (Invega Sustenna®)^		olanzapine/samidorphan (Lybalvi®)β
paliperidone palmitate IM inj (Invega Trinza®)^		quetiapine 150mg tablets+
quetiapine (Seroquel®)		risperidone IM inj (Risperdal Consta®)^∞
quetiapine ER (Seroquel XR®)		**risperidone IM inj (Risvan®)^∞**
risperidone (Risperdal®)		risperidone IM inj (Rykindo®)^∞
risperidone sub-Q inj (Perseris®)^		
risperidone sub-Q inj (Uzedy™)^		
ziprasidone (Geodon®)		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
◊Clozapine does not count towards a Tier-1 trial.
^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
βUnique criteria applies to Lybalvi® (olanzapine/samidorphan).
∞Unique criteria applies to Tier-3 long-acting injectable (LAI) products.

Tier-1 products are available without prior authorization for members 5 years of age and older. Prior authorization requests for members younger than 5 years of age are reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted child psychiatrist.

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial; and
2. Members currently stable on a Tier-2 medication may be approved for continuation of therapy.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of 2 oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Members currently stable on a Tier-3 medication may be approved for continuation of therapy; and
5. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) or requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and
7. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
8. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD):

1. Authorization of Symbyax® (olanzapine/fluoxetine), Rexulti® (brexpiprazole), or Vraylar® (cariprazine) for a diagnosis of MDD requires current use of an antidepressant and previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and aripiprazole tablets that did not yield adequate response; and
2. Members currently stable on the requested medication may be approved for continuation of therapy; and
3. Tier structure rules still apply.

Long-Acting Injectable (LAI) Products Tier-3 Approval Criteria:

1. Use of LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower tiered LAI products available for the medication being requested, which are available without a prior authorization; and
2. Members currently stable on the requested medication may be approved for continuation of therapy.

Utilization Details of Atypical Antipsychotic Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
ARIPIPRAZOLE ORAL PRODUCTS						
ARIPIPRAZOLE TAB 5MG	23,310	8,401	$332,985.80	$14.29	2.77	0.29%
ARIPIPRAZOLE TAB 10MG	18,705	6,526	$277,602.25	$14.84	2.87	0.24%
ARIPIPRAZOLE TAB 15MG	9,712	3,012	$143,769.43	$14.80	3.22	0.12%
ARIPIPRAZOLE TAB 2MG	9,710	3,691	$146,564.10	$15.09	2.63	0.13%
ARIPIPRAZOLE TAB 20MG	5,884	1,568	$101,877.15	$17.31	3.75	0.09%
ARIPIPRAZOLE TAB 30MG	3,100	749	$56,971.13	$18.38	4.14	0.05%
ARIPIPRAZOLE SOL 1MG/ML	476	96	$70,462.12	$148.03	4.96	0.06%
ABILIFY TAB 15MG	13	1	$7,411.13	$570.09	13	0.01%
ARIPIPRAZOLE ODT 10MG	10	5	$3,987.81	$398.78	2	0.00%
ABILIFY TAB 30MG	9	2	$17,407.24	$1,934.14	4.5	0.01%
ABILIFY TAB 10MG	5	2	$6,304.60	$1,260.92	2.5	0.01%
ABILIFY TAB 5MG	1	1	$1,691.84	$1,691.84	1	0.00%
SUBTOTAL	**70,935**	**24,054**	**$1,167,034.60**	**$16.45**	**2.95**	**1.00%**
QUETIAPINE ORAL PRODUCTS						
QUETIAPINE TAB 100MG	16,849	5,484	$199,512.08	$11.84	3.07	0.17%
QUETIAPINE TAB 50MG	14,513	5,102	$175,605.31	$12.10	2.84	0.15%
QUETIAPINE TAB 25MG	10,166	3,797	$120,906.07	$11.89	2.68	0.10%
QUETIAPINE TAB 200MG	9,304	2,677	$126,031.67	$13.55	3.48	0.11%
QUETIAPINE TAB 300MG	7,581	1,910	$122,514.45	$16.16	3.97	0.10%
QUETIAPINE TAB 400MG	6,467	1,428	$121,107.16	$18.73	4.53	0.10%
QUETIAPINE TAB 50MG ER	1,065	406	$17,263.44	$16.21	2.62	0.01%
QUETIAPINE TAB 300MG ER	1,013	248	$22,573.67	$22.28	4.08	0.02%
QUETIAPINE TAB 150MG ER	980	345	$17,357.41	$17.71	2.84	0.01%
QUETIAPINE TAB 400MG ER	940	178	$25,405.33	$27.03	5.28	0.02%
QUETIAPINE TAB 200MG ER	637	185	$11,969.99	$18.79	3.44	0.01%
SEROQUEL TAB 400MG	12	1	$13,563.48	$1,130.29	12	0.01%
SUBTOTAL	**69,527**	**21,761**	**$973,810.06**	**$14.01**	**3.2**	**0.83%**
RISPERIDONE ORAL PRODUCTS						
RISPERIDONE TAB 1MG	13,233	3,611	$156,595.40	$11.83	3.66	0.13%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RISPERIDONE TAB 0.5MG	10,076	2,656	$120,469.79	$11.96	3.79	0.10%
RISPERIDONE TAB 2MG	9,044	2,435	$109,295.59	$12.08	3.71	0.09%
RISPERIDONE TAB 3MG	3,735	856	$46,620.17	$12.48	4.36	0.04%
RISPERIDONE TAB 0.25MG	3,527	1,001	$41,440.94	$11.75	3.52	0.04%
RISPERIDONE TAB 4MG	1,891	408	$25,032.50	$13.24	4.63	0.02%
RISPERIDONE SOL 1MG/ML	1,315	262	$38,079.40	$28.96	5.02	0.03%
RISPERIDONE ODT 0.5MG	319	88	$14,441.78	$45.27	3.63	0.01%
RISPERIDONE ODT 1MG	202	70	$10,574.82	$52.35	2.89	0.01%
RISPERIDONE ODT 0.25	163	59	$16,314.03	$100.09	2.76	0.01%
RISPERIDONE ODT 2MG	96	33	$4,340.39	$45.21	2.91	0.00%
RISPERIDONE ODT 3MG	62	15	$3,601.49	$58.09	4.13	0.00%
RISPERIDONE ODT 4MG	23	8	$1,623.80	$70.60	2.88	0.00%
RISPERDAL SOL 1MG/ML	3	1	$7,425.93	$2,475.31	3	0.01%
RISPERDAL TAB 0.5MG	3	1	$641.03	$213.68	3	0.00%
SUBTOTAL	**43,692**	**11,504**	**$596,497.06**	**$13.65**	**3.8**	**0.51%**
OLANZAPINE ORAL PRODUCTS						
OLANZAPINE TAB 10MG	11,264	3,601	$156,138.04	$13.86	3.13	0.13%
OLANZAPINE TAB 20MG	8,127	1,829	$127,733.58	$15.72	4.44	0.11%
OLANZAPINE TAB 5MG	7,925	2,986	$106,793.01	$13.48	2.65	0.09%
OLANZAPINE TAB 15MG	3,964	1,113	$57,352.63	$14.47	3.56	0.05%
OLANZAPINE TAB 2.5MG	2,227	889	$28,903.51	$12.98	2.51	0.02%
OLANZAPINE TAB 7.5MG	1,231	360	$16,907.36	$13.73	3.42	0.01%
OLANZAPINE ODT 10MG	883	370	$24,207.91	$27.42	2.39	0.02%
OLANZAPINE ODT 5MG	872	398	$19,614.74	$22.49	2.19	0.02%
OLANZAPINE ODT 20MG	400	122	$15,414.81	$38.54	3.28	0.01%
OLANZAPINE ODT 15MG	246	70	$9,576.73	$38.93	3.51	0.01%
ZYPREXA TAB 10MG	1	1	$2,052.15	$2,052.15	1	0.00%
SUBTOTAL	**37,140**	**11,739**	**$564,694.47**	**$15.20**	**3.16**	**0.48%**
PALIPERIDONE INJECTABLE PRODUCTS						
INVEGA SUST INJ 234MG/1.5ML	9,185	1,889	$29,276,567.55	$3,187.43	4.86	25.07%
INVEGA SUST INJ 156MG/ML	3,762	1,262	$8,041,943.81	$2,137.68	2.98	6.89%
INVEGA TRINZ INJ 819MG/2.63ML	1,221	444	$11,647,209.57	$9,539.07	2.75	9.98%
INVEGA SUST INJ 117MG/0.75ML	746	203	$1,186,728.98	$1,590.79	3.67	1.02%
INVEGA TRINZ INJ 546MG/1.75ML	476	188	$3,001,126.82	$6,304.89	2.53	2.57%
INVEGA SUST INJ 78MG/0.5ML	147	37	$146,799.39	$998.64	3.97	0.13%
INVEGA TRINZ INJ 410MG/1.32ML	130	51	$607,093.12	$4,669.95	2.55	0.52%
INVEGA HAFYE INJ 1,560MG/5ML	117	83	$2,328,218.01	$19,899.30	1.41	1.99%
INVEGA HAFYE INJ 1,092MG/3.5ML	72	48	$954,121.10	$13,251.68	1.5	0.82%
INVEGA TRINZ INJ 273MG/0.88ML	32	14	$86,723.68	$2,710.12	2.29	0.07%
INVEGA SUST INJ 39MG/0.25ML	28	11	$12,755.42	$455.55	2.55	0.01%
SUBTOTAL	**15,916**	**4,230**	**$57,289,287.45**	**$3,599.48**	**3.76**	**49.07%**
CLOZAPINE ORAL PRODUCTS						
CLOZAPINE TAB 100MG	5,207	489	$249,455.88	$47.91	10.65	0.21%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLOZAPINE TAB 50MG	2,674	274	$91,370.28	$34.17	9.76	0.08%
CLOZAPINE TAB 200MG	1,903	185	$117,680.96	$61.84	10.29	0.10%
CLOZAPINE TAB 25MG	1,267	170	$31,671.67	$25.00	7.45	0.03%
CLOZARIL TAB 100MG	23	2	$32,948.28	$1,432.53	11.5	0.03%
SUBTOTAL	**11,074**	**1,120**	**$523,127.07**	**$47.24**	**9.89**	**0.45%**
ZIPRASIDONE ORAL PRODUCTS						
ZIPRASIDONE CAP 40MG	2,443	711	$60,876.46	$24.92	3.44	0.05%
ZIPRASIDONE CAP 20MG	2,124	807	$50,566.21	$23.81	2.63	0.04%
ZIPRASIDONE CAP 80MG	1,783	357	$54,940.24	$30.81	4.99	0.05%
ZIPRASIDONE CAP 60MG	1,425	354	$41,373.88	$29.03	4.03	0.04%
SUBTOTAL	**7,775**	**2,229**	**$207,756.79**	**$26.72**	**3.49**	**0.18%**
ARIPIPRAZOLE INJECTABLE PRODUCTS						
ABILIFY MAIN INJ 400MG	4,924	934	$12,671,896.78	$2,573.50	5.27	10.85%
ABILIFY MAIN INJ 300MG	829	206	$1,569,780.99	$1,893.58	4.02	1.34%
ABILIFY MAIN INJ 400MG	454	129	$1,129,801.86	$2,488.55	3.52	0.97%
ABILIFY ASIM INJ 960MG	68	48	$370,521.46	$5,448.85	1.42	0.32%
ABILIFY MAIN INJ 300MG	54	27	$98,142.48	$1,817.45	2	0.08%
ABILIFY ASIM INJ 720MG	24	21	$98,131.00	$4,088.79	1.14	0.08%
SUBTOTAL	**6,353**	**1,365**	**$15,938,274.57**	**$2,508.78**	**4.65**	**13.65%**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS						
ARISTADA INJ 882MG/3.2ML	1,539	287	$4,377,694.72	$2,844.51	5.36	3.75%
ARISTADA INJ 1,064MG/3.9ML	577	195	$1,962,648.49	$3,401.47	2.96	1.68%
ARISTADA INJ 662MG/2.4ML	363	85	$774,524.55	$2,133.68	4.27	0.66%
ARISTADA INJ 441MG/1.6ML	193	43	$269,586.44	$1,396.82	4.49	0.23%
ARISTADA INJ INITIO 675MG/2.4ML	163	149	$347,166.06	$2,129.85	1.09	0.30%
SUBTOTAL	**2,835**	**759**	**$7,731,620.26**	**$2,727.20**	**3.74**	**6.62%**
RISPERIDONE INJECTABLE PRODUCTS						
PERSERIS INJ 120MG	684	178	$1,836,701.07	$2,685.24	3.84	1.57%
PERSERIS INJ 90MG	279	100	$545,314.77	$1,954.53	2.79	0.47%
UZEDY INJ 100MG	43	21	$104,169.03	$2,422.54	2.05	0.09%
UZEDY INJ 125MG	15	9	$40,980.79	$2,732.05	1.67	0.04%
UZEDY INJ 250MG	6	5	$37,004.46	$6,167.41	1.2	0.03%
UZEDY INJ 200MG	4	3	$19,757.64	$4,939.41	1.33	0.02%
UZEDY INJ 75MG	3	3	$5,574.23	$1,858.08	1	0.00%
UZEDY INJ 150MG	2	2	$7,414.82	$3,707.41	1	0.01%
UZEDY INJ 50MG	2	2	$2,486.82	$1,243.41	1	0.00%
SUBTOTAL	**1,038**	**323**	**$2,599,403.63**	**$2,504.24**	**3.21**	**2.23%**
OLANZAPINE INJECTABLE PRODUCTS						
ZYPREXA RELP INJ 405MG	6	1	$6,867.90	$1,144.65	6	0.01%
OLANZAPINE INJ 10MG	5	5	$367.07	$73.41	1	0.00%
ZYPREXA RELP INJ 210MG	1	1	$601.09	$601.09	1	0.00%
SUBTOTAL	**12**	**7**	**$7,836.06**	**$653.01**	**1.71**	**0.01%**
ZIPRASIDONE INJECTABLE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ZIPRASIDONE INJ 20MG	3	3	$410.23	$136.74	1	0.00%
SUBTOTAL	**3**	**3**	**$410.23**	**$136.74**	**1**	**0.00%**
TIER-1 SUBTOTAL	**266,300**	**79,094**	**$87,599,752.25**	**$328.95**	**3.37**	**75.02%**
TIER-2 UTILIZATION						
LURASIDONE PRODUCTS						
LURASIDONE TAB 40MG	3,323	1,219	$90,847.52	$27.34	2.73	0.08%
LURASIDONE TAB 20MG	2,619	1,129	$61,998.43	$23.67	2.32	0.05%
LURASIDONE TAB 80MG	1,876	532	$63,289.25	$33.74	3.53	0.05%
LURASIDONE TAB 60MG	1,786	630	$51,695.52	$28.94	2.83	0.04%
LATUDA TAB 40MG	1,234	650	$1,940,377.92	$1,572.43	1.9	1.66%
LATUDA TAB 20MG	1,072	605	$1,721,165.47	$1,605.56	1.77	1.47%
LATUDA TAB 80MG	829	369	$1,401,941.67	$1,691.12	2.25	1.20%
LATUDA TAB 60MG	815	387	$1,342,557.14	$1,647.31	2.11	1.15%
LURASIDONE TAB 120MG	815	211	$35,132.88	$43.11	3.86	0.03%
LATUDA TAB 120MG	291	151	$707,011.63	$2,429.59	1.93	0.61%
SUBTOTAL	**14,660**	**5,883**	**$7,416,017.43**	**$505.87**	**2.49**	**6.35%**
PALIPERIDONE ORAL PRODUCTS						
PALIPERIDONE TAB ER 6MG	879	216	$90,479.06	$102.93	4.07	0.08%
PALIPERIDONE TAB ER 3MG	522	162	$42,299.93	$81.03	3.22	0.04%
PALIPERIDONE TAB ER 9MG	444	104	$49,325.88	$111.09	4.27	0.04%
PALIPERIDONE TAB ER 1.5MG	110	34	$7,814.80	$71.04	3.24	0.01%
INVEGA TAB 3MG	4	1	$4,267.26	$1,066.82	4	0.00%
INVEGA TAB 6MG	1	1	$365.16	$365.16	1	0.00%
SUBTOTAL	**1,960**	**518**	**$194,552.09**	**$99.26**	**3.78**	**0.17%**
ASENAPINE PRODUCTS						
ASENAPINE SUB 10MG	525	124	$83,791.89	$159.60	4.23	0.07%
ASENAPINE SUB 5MG	391	131	$58,555.66	$149.76	2.98	0.05%
ASENAPINE SUB 2.5MG	128	59	$20,419.79	$159.53	2.17	0.02%
SAPHRIS SUB 10MG	43	9	$44,178.75	$1,027.41	4.78	0.04%
SAPHRIS SUB 5MG	18	10	$19,364.94	$1,075.83	1.8	0.02%
SUBTOTAL	**1,105**	**333**	**$226,311.03**	**$204.81**	**3.32**	**0.19%**
ILOPERIDONE PRODUCTS						
FANAPT TAB 8MG	99	23	$173,395.80	$1,751.47	4.3	0.15%
FANAPT TAB 12MG	99	12	$281,774.51	$2,846.21	8.25	0.24%
FANAPT TAB 6MG	85	14	$153,600.46	$1,807.06	6.07	0.13%
FANAPT TAB 4MG	54	10	$71,331.83	$1,320.96	5.4	0.06%
FANAPT TAB 10MG	45	6	$119,576.43	$2,657.25	7.5	0.10%
FANAPT TAB 2MG	38	7	$50,591.15	$1,331.35	5.43	0.04%
FANAPT 1/2/4/6MG PACK	10	9	$2,440.50	$244.05	1.11	0.00%
FANAPT TAB 1MG	4	3	$3,474.52	$868.63	1.33	0.00%
SUBTOTAL	**434**	**84**	**$856,185.20**	**$1,972.78**	**5.17**	**0.73%**
TIER-2 SUBTOTAL	**18,159**	**6,818**	**$8,693,065.75**	**$478.72**	**2.66**	**7.45%**
TIER-3 UTILIZATION						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CARIPRAZINE PRODUCTS						
VRAYLAR CAP 3MG	3,079	918	$4,846,324.90	$1,573.99	3.35	4.15%
VRAYLAR CAP 1.5MG	2,988	1,128	$4,663,475.05	$1,560.73	2.65	3.99%
VRAYLAR CAP 4.5MG	1,357	357	$2,136,293.63	$1,574.28	3.8	1.83%
VRAYLAR CAP 6MG	1,088	233	$1,723,764.13	$1,584.34	4.67	1.48%
VRAYLAR CAP 1.5-3MG	6	6	$1,981.16	$330.19	1	0.00%
SUBTOTAL	**8,518**	**2,642**	**$13,371,838.87**	**$1,569.83**	**3.22**	**11.45%**
BREXPIPRAZOLE PRODUCTS						
REXULTI TAB 1MG	728	253	$1,189,274.16	$1,633.62	2.88	1.02%
REXULTI TAB 2MG	605	204	$1,059,662.26	$1,751.51	2.97	0.91%
REXULTI TAB 3MG	444	112	$755,330.68	$1,701.20	3.96	0.65%
REXULTI TAB 4MG	288	60	$446,577.38	$1,550.62	4.8	0.38%
REXULTI TAB 0.5MG	225	92	$367,770.56	$1,634.54	2.45	0.31%
REXULTI TAB 0.25MG	22	7	$31,198.55	$1,418.12	3.14	0.03%
SUBTOTAL	**2,312**	**728**	**$3,849,813.59**	**$1,665.14**	**3.18**	**3.30%**
LUMATEPERONE PRODUCTS						
CAPLYTA CAP 42MG	1,313	298	$1,950,426.74	$1,485.47	4.41	1.67%
CAPLYTA CAP 21MG	99	44	$147,745.37	$1,492.38	2.25	0.13%
CAPLYTA CAP 10.5MG	30	14	$45,574.96	$1,519.17	2.14	0.04%
SUBTOTAL	**1,442**	**356**	**$2,143,747.07**	**$1,486.65**	**4.05**	**1.84%**
OLANZAPINE/SAMIDORPHAN COMBINATION PRODUCTS						
LYBALVI TAB 20-10MG	154	29	$209,907.31	$1,363.03	5.31	0.18%
LYBALVI TAB 10-10MG	120	43	$170,424.98	$1,420.21	2.79	0.15%
LYBALVI TAB 5-10MG	103	34	$147,463.55	$1,431.68	3.03	0.13%
LYBALVI TAB 15-10MG	97	29	$129,028.86	$1,330.19	3.34	0.11%
SUBTOTAL	**474**	**135**	**$656,824.70**	**$1,385.71**	**3.51**	**0.56%**
RISPERIDONE INJECTABLE PRODUCTS						
RISPERDAL CONSTA INJ 50MG	144	14	$237,415.00	$1,648.72	10.29	0.20%
RISPERDAL CONSTA INJ 25MG	51	10	$44,879.96	$880.00	5.1	0.04%
RISPERDAL CONSTA INJ 37.5MG	23	4	$34,900.24	$1,517.40	5.75	0.03%
RISPERDAL CONSTA INJ 12.5MG	3	2	$1,146.21	$382.07	1.5	0.00%
SUBTOTAL	**221**	**30**	**$318,341.41**	**$1,440.46**	**7.37**	**0.27%**
CLOZAPINE ORALLY DISINTEGRATING PRODUCTS						
CLOZAPINE ODT 100MG	118	10	$39,771.53	$337.05	11.8	0.03%
CLOZAPINE ODT 150MG	49	9	$41,775.56	$852.56	5.44	0.04%
CLOZAPINE ODT 25MG	12	1	$1,688.76	$140.73	12	0.00%
CLOZAPINE ODT 200MG	10	3	$24,845.11	$2,484.51	3.33	0.02%
SUBTOTAL	**189**	**23**	**$108,080.96**	**$571.86**	**8.22**	**0.09%**
OLANZAPINE/FLUXOETINE COMBINATION PRODUCTS						
OLANZ/FLUOX CAP 12-50MG	21	2	$8,461.96	$402.95	10.5	0.01%
OLANZ/FLUOX CAP 6-25MG	18	2	$2,510.37	$139.47	9	0.00%
OLANZ/FLUOX CAP 6-50MG	11	1	$2,037.42	$185.22	11	0.00%
OLANZ/FLUOX CAP 12-25MG	8	1	$2,703.52	$337.94	8	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**58**	**6**	**$15,713.27**	**$270.92**	**9.67**	**0.01%**
QUETIAPINE ORAL PRODUCTS						
QUETIAPINE TAB 150MG	3	3	$170.23	$56.74	1	0.00%
SUBTOTAL	**3**	**3**	**$170.23**	**$56.74**	**1**	**0.00%**
ASENAPINE TRANSDERMAL SYSTEM PRODUCTS						
SECUADO PATCH 3.8MG	3	2	$4,041.03	$1,347.01	1.5	0.00%
SUBTOTAL	**3**	**2**	**$4,041.03**	**$1,347.01**	**1.5**	**0.00%**
TIER-3 SUBTOTAL	**13,220**	**3,925**	**$20,468,571.13**	**$1,548.30**	**3.37**	**17.53%**
TOTAL	**297,679**	**50,966***	**$116,761,389.13**	**$392.24**	**5.84**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASIM = Asimtufii; CAP = capsule; ER/XR = extended release; HAFYE = Hafyera; INJ = injection; MAIN = Maintena; ODT = orally disintegrating tablet; OLANZ/FLUOX = olanzapine/fluoxetine; PS = prefilled syringe; RELP = Relprevv; SOL = solution; SUST = Sustenna; SUB = sublingual; TAB = tablet; TRINZ = Trinza

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 03/2024. Last accessed 05/24/2024.
[2] Risvan® (Risperidone) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_risvan_2024-0404.pdf. Issued 04/02/2024. Last accessed 04/24/2024.
[3] Burton K. FDA Approves Iloperidone for Bipolar Disorder. *Medscape*. Available online at: https://www.medscape.com/viewarticle/fda-approves-iloperidone-bipolar-disorder-2024a10006bq. Issued 04/03/2024. Last accessed 05/24/2024.
[4] Bristol Myers Squibb. Bristol Myers Squibb Presents New Interim Long-Term Efficacy Data from the EMERGENT-4 Trial Evaluating KarXT in Schizophrenia at the 2024 Annual Congress of the Schizophrenia International Research Society. Available online at: https://news.bms.com/news/corporate-financial/2024/Bristol-Myers-Squibb-Presents-New-Interim-Long-Term-Efficacy-Data-from-the-EMERGENT-4-Trial-Evaluating-KarXT-in-Schizophrenia-at-the-2024-Annual-Congress-of-the-Schizophrenia-International-Research-Society/default.aspx. Issued 04/06/2024. Last accessed 05/24/2024.
[5] Bristol Myers Squibb. Bristol Myers Squibb Strengthens Neuroscience Portfolio with Acquisition of Karuna Therapeutics. Available online at: https://news.bms.com/news/corporate-financial/2023/Bristol-Myers-Squibb-Strengthens-Neuroscience-Portfolio-with-Acquisition-of-Karuna-Therapeutics/default.aspx. Issued 12/22/2023. Last accessed 05/24/2024.

Appendix M

Calendar Year 2023 Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-day Notice to Prior Authorize Qalsody® (Tofersen) and Rilutek® (Riluzole Oral Tablet)

Oklahoma Health Care Authority
June 2024

Current Prior Authorization Criteria

Exservan™ (Riluzole Oral Film) and Tiglutik® (Riluzole Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. A patient-specific, clinically significant reason why the member cannot use riluzole tablets, even when tablets are crushed, must be provided; and
3. The following quantity limits apply:
    a. A quantity limit of 2 films per day or 60 films per 30 days will apply for Exservan™; or
    b. A quantity limit of 20mL per day or 600mL per 30 days will apply for Tiglutik®.

Radicava® (Edaravone) and Radicava ORS® (Edaravone Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must have been evaluated by a physician specializing in the treatment of ALS within the last 3 months; and
3. Disease duration of 2 years or less (for initial approval); or
    a. A prior authorization request with patient-specific information may be submitted for consideration of edaravone for members with disease duration >2 years, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and
4. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression.

Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must be 18 years of age or older; and
3. Disease duration of 18 months or less (for initial approval); or

a. A prior authorization request with patient-specific information may be submitted for consideration of Relyvrio™ for members with disease duration >18 months, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and

4. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and
5. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression; and
6. A quantity limit of 56 packets per 28 days will apply.

Utilization of ALS Medications: Calendar Year 2023

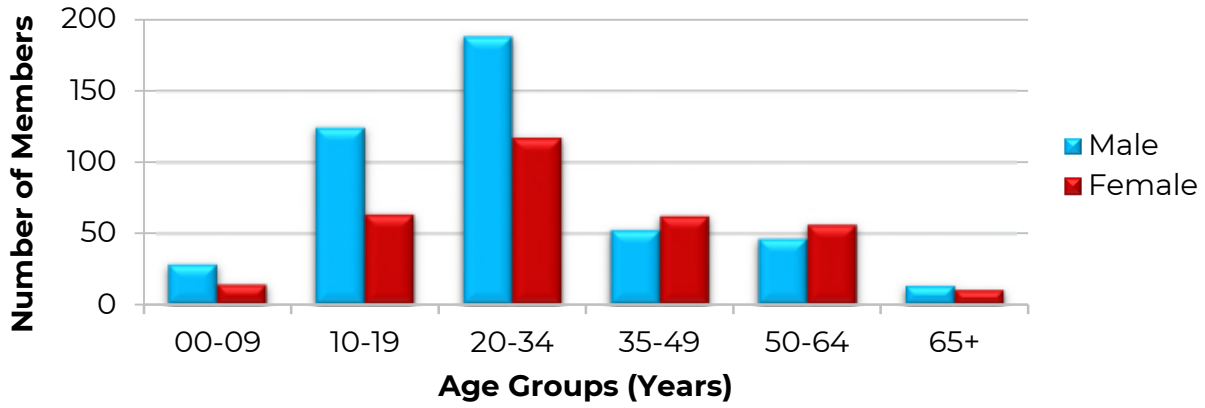
Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	600	3,518	$286,890.46	$81.55	$2.85	259,350	100,776
2023	773	5,484	$544,405.64	$99.27	$3.43	384,328	158,499
% Change	**28.80%**	**55.90%**	**89.80%**	**21.70%**	**20.40%**	**48.20%**	**57.30%**
Change	**173**	**1,966**	**$257,515.18**	**$17.72**	**$0.58**	**124,978**	**57,723**

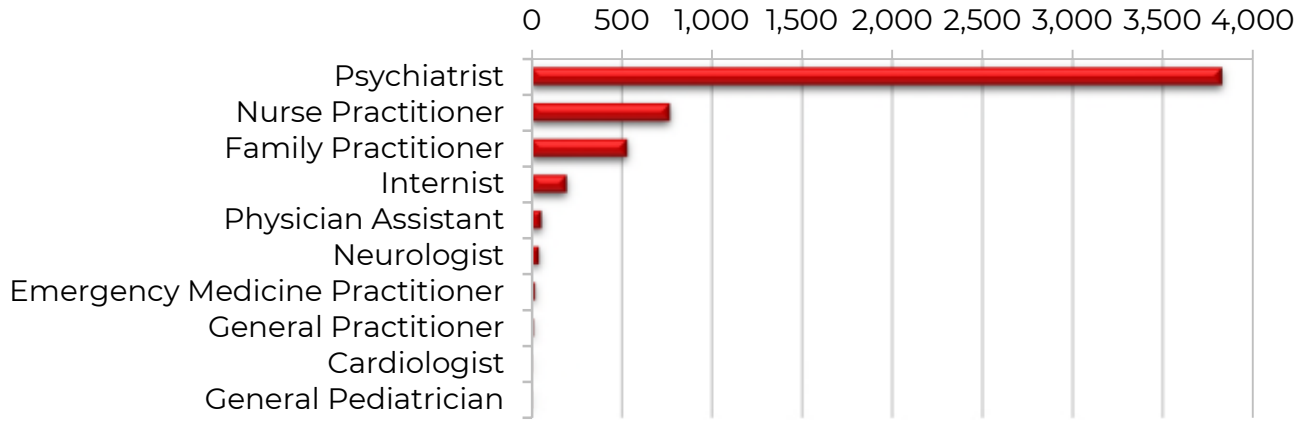
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Utilization data includes generic riluzole 50mg tablets used for all diagnoses and does not differentiate between use for ALS and other diagnoses. Riluzole 50mg tablets have not previously required prior authorization.

- There were no paid medical claims for Radicava® (edaravone) during calendar year 2022 or 2023.

Demographics of Members Utilizing ALS Medications



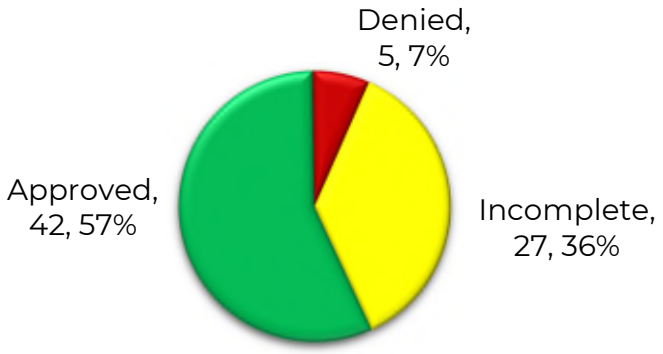
Top Prescriber Specialties of ALS Medications by Number of Claims



Prior Authorization of ALS Medications

There were 74 prior authorization requests submitted for 38 unique members for ALS medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent and/or Exclusivity Expiration(s):

- Tiglutik® (riluzole oral suspension): March 2029
- Qalsody® (tofersen): April 2035
- Radicava ORS® (edaravone oral suspension): November 2039
- Relyvrio™ (sodium phenylbutyrate/taurursodiol powder for oral suspension): July 2040

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

- **December 1995:** The FDA approved Rilutek® (riluzole oral tablet) for the treatment of ALS. Generic riluzole tablets are currently available from multiple manufacturers.

- **April 2023:** The FDA approved Qalsody® (tofersen) for the treatment of ALS in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. Qalsody® is the first FDA approved treatment for SOD1 ALS, a rare genetic form of ALS. The SOD1 mutation is estimated to be responsible for approximately 2% of all ALS cases.

News:

- **January 2024:** Tiglutik® (riluzole oral suspension) is currently on shortage due to a product recall in the United States based on out-of-specification viscosity testing results. To help alleviate the shortage of Tiglutik®, the FDA announced that they will allow temporary importation of the non-FDA approved product Teglutik (riluzole oral suspension) from Greece and Spain. The safety profiles of the imported products are comparable to Tiglutik®, but health care providers are encouraged to report adverse events or medication errors in patients taking Teglutik to AnovoRx or the FDA's MedWatch Adverse Event Reporting Program.
- **April 2024:** Amylyx Pharmaceuticals, the manufacturer of Relyvrio™ (sodium phenylbutyrate/taurursodiol), announced plans to voluntarily remove Relyvrio™ from the market based on results from the Phase 3 PHOENIX study which failed to meet the prespecified primary or secondary endpoints. As of April 2024, Relyvrio™ is no longer available for new patients, but Amylyx plans to allow patients who are already receiving treatment with Relyvrio™ to obtain the medication through a free drug program. Relyvrio™ was previously approved by the FDA for the treatment of adults with ALS in September 2022.

Qalsody® (Tofersen) Product Summary[8]

Therapeutic Class: Antisense oligonucleotide

Indication(s): Treatment of ALS in adults who have a mutation in the SOD1 gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients treated with Qalsody®. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

How Supplied: 100mg/15mL solution in a single-dose vial for intrathecal administration

Dosing and Administration: Each dose is 100mg given as an intrathecal bolus injection over 1 to 3 minutes, administered as 3 initial loading doses every 14 days, followed by a maintenance dose every 28 days thereafter.

Cost: The Wholesale Acquisition Cost (WAC) of Qalsody® is $977.13 per milliliter, resulting in a cost of $14,656.95 per dose and $205,197.30 for the first year of treatment, including the loading doses.

Rilutek® (Riluzole Oral Tablet) Product Summary[9]

Therapeutic Class: Glutamate antagonist

Indication(s): Treatment of ALS

How Supplied: 50mg oral tablet

Dosing and Administration: 50mg twice daily, taken at least 1 hour before or 2 hours after a meal

Cost: The National Average Drug Acquisition Cost (NADAC) of generic riluzole 50mg tablets is $0.24 per tablet, resulting in a cost of $14.40 per month or $172.80 per year based on recommended dosing.

Recommendations

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

Qalsody® (Tofersen) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must have a confirmed pathogenic mutation in the superoxide dismutase 1 (SOD1) gene (results of genetic testing must be submitted); and
3. Member must have weakness attributable to ALS; and
4. Member must be 18 years of age or older; and
5. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and
6. Must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
    a. Qalsody® must be shipped to the facility where the member is scheduled to receive treatment; and
7. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression.

Next, the College of Pharmacy recommends the prior authorization of Rilutek® (riluzole oral tablet) to ensure appropriate use with the following criteria (shown in red):

Rilutek® (Riluzole Oral Tablet) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and
3. A quantity limit of 60 tablets per 30 days will apply.

Lastly, the College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for Relyvrio™ (sodium phenylbutyrate/taurursodiol) based on the planned withdrawal of the medication from the market (changes noted in red):

~~**Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Approval Criteria:**~~

~~1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and~~
~~2. Member must be 18 years of age or older; and~~
~~3. Disease duration of 18 months or less (for initial approval); or~~
   ~~a. A prior authorization request with patient-specific information may be submitted for consideration of Relyvrio™ for members with disease duration >18 months, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and~~
~~4. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and~~
~~5. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression; and~~
~~6. A quantity limit of 56 packets per 28 days will apply.~~

Utilization Details of ALS Medications: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RILUZOLE PRODUCTS						
RILUZOLE TAB 50MG	5,458	771	$216,251.92	$39.62	7.08	39.72%
SUBTOTAL	**5,458**	**771**	**$216,251.92**	**$39.62**	**7.08**	**39.72%**
EDARAVONE PRODUCTS						
RADICAVA INJ 30MG	10	1	$123,361.50	$12,336.15	10	22.66%
RADICAVA ORS SUS 105MG/5ML	5	2	$64,779.79	$12,955.96	2.5	11.90%
RADICAVA ORS SUS START 105MG/5ML	3	3	$53,981.50	$17,993.83	1	9.92%
SUBTOTAL	**18**	**6**	**$242,122.79**	**$13,451.27**	**3**	**44.47%**
SODIUM PHENYLBUTYRATE/TAURURSODIOL PRODUCTS						
RELYVRIO PAK 3-1GM	8	3	$86,030.93	$10,753.87	2.67	15.80%
SUBTOTAL	**8**	**3**	**$86,030.93**	**$10,753.87**	**2.67**	**15.80%**
TOTAL	**5,484**	**773***	**$544,405.64**	**$99.27**	**7.09**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; PAK = packet; START = starter kit; SUS = suspension; TAB = tablet
Utilization data includes generic riluzole 50mg tablets used for all diagnoses and does not differentiate between use for ALS and other diagnoses. Riluzole 50mg tablets have not previously required prior authorization.

[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 05/2024. Last Accessed 05/06/2024.
[2] U.S. FDA. Rilutek® (Riluzole) Approval Letter and Review. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020599Orig1s000rev.pdf. Issued 12/12/1995. Last accessed 05/29/2024.
[3] Biogen, Inc. FDA Grants Accelerated Approval for Qalsody® (Tofersen) for SOD1-ALS, a Major Scientific Advancement as the First Treatment to Target a Genetic Cause of ALS. Available online at: https://investors.biogen.com/news-releases/news-release-details/fda-grants-accelerated-approval-qalsodytm-tofersen-sod1-als. Issued 04/25/2023. Last accessed 05/06/2024.
[4] U.S. FDA. Temporary Importation of Teglutik (Riluzole Oral Suspension, 5mg/mL) with Non-English Labeling to Address Drug Shortage in the United States. Available online at: https://www.fda.gov/media/175475/download. Issued 01/2024. Last accessed 05/06/2024.
[5] U.S. FDA. Temporary Importation of Teglutik (Riluzole Oral Suspension, 5mg/mL) with Non-English Labeling to Address Drug Shortage in the United States. Available online at: https://www.fda.gov/media/177206/download. Issued 02/2024. Last accessed 05/06/2024.
[6] Amylyx Pharmaceuticals, Inc. Amylyx Pharmaceuticals Announces Topline Results from Global Phase 3 PHOENIX Trial of AMX0035 in ALS. Available online at: https://www.amylyx.com/news/amylyx-pharmaceuticals-announces-topline-results-from-global-phase-3-phoenix-trial-of-amx0035-in-als. Issued 03/08/2024. Last accessed 05/06/2024.
[7] Amylyx Pharmaceuticals, Inc. Amylyx Pharmaceuticals Announces Formal Intention to Remove Relyvrio®/Albrioza™ from the Market; Provides Updates on Access to Therapy, Pipeline, Corporate Restructuring, and Strategy. Available online at: https://www.amylyx.com/news/amylyx-pharmaceuticals-announces-formal-intention-to-remove-relyvrior/albriozatm-from-the-market-provides-updates-on-access-to-therapy-pipeline-corporate-restructuring-and-strategy. Issued 04/04/2024. Last accessed 05/06/2024.
[8] Qalsody® (Tofersen) Prescribing Information. Biogen MA, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215887Orig1s000Correctedlbl.pdf. Last revised 04/2023. Last accessed 05/06/2024.
[9] Rilutek® (Riluzole) Prescribing Information. Covis Pharma. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/020599s019lbl.pdf. Last revised 03/2020. Last accessed 05/29/2024.

Appendix N

Calendar Year 2023 Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Liqrev® (Sildenafil Oral Suspension), Opsynvi® (Macitentan/Tadalafil), and Winrevair™ (Sotatercept-csrk)

Oklahoma Health Care Authority
June 2024

Current Prior Authorization Criteria

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; or
4. A clinical exception for use as initial combination therapy with Letairis® (ambrisentan) applies; and
5. A quantity limit of 60 tablets per 30 days will apply.

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of PAH must have previous failed trials of at least 1 medication in each of the following categories:
        i. Adcirca® (tadalafil) or Revatio® (sildenafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and
4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonia (PH-IIP); and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® Risk Evaluation and Mitigation Strategy (REMS) program; and
6. A quantity limit of 90 tablets per 30 days will apply.

Opsumit® (Macitentan) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program; and
5. A quantity limit of 30 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A quantity limit of 180 tablets per 30 days will apply.

Revatio® (Sildenafil Tablets) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. An age restriction will apply. The oral suspension formulation may be approvable for members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member is not able to use the oral tablet formulation; and
4. A quantity limit of 224mL (2 bottles) per 30 days will apply.

Tadliq® (Tadalafil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and

3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension must be provided; and
4. An age restriction will apply. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member cannot use generic tadalafil 20mg oral tablets, even when the tablets are crushed; and
5. A quantity limit of 300mL per 30 days (2 bottles) will apply.

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

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

Uptravi® (Selexipag) Approval Criteria:

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

Utilization of Pulmonary Hypertension Medications: Calendar Year 2023

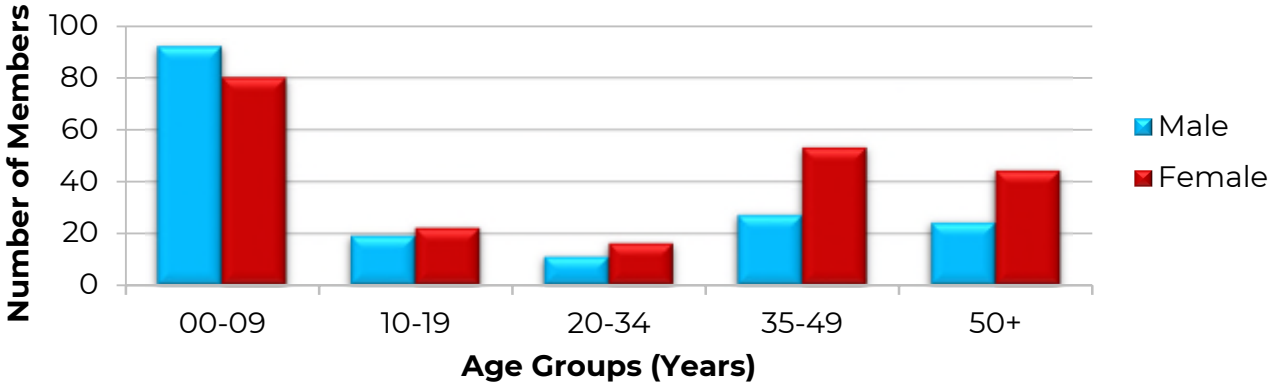
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	285	2,246	$11,853,145.98	$5,277.45	$168.74	164,101	70,246
2023	388	3,238	$15,988,516.76	$4,937.78	$157.46	242,576	101,543
% Change	**36.1%**	**44.2%**	**34.9%**	**-6.4%**	**-6.7%**	**47.8%**	**44.6%**
Change	**103**	**992**	**$4,135,370.78**	**-$339.67**	**-$11.28**	**78,475**	**31,297**

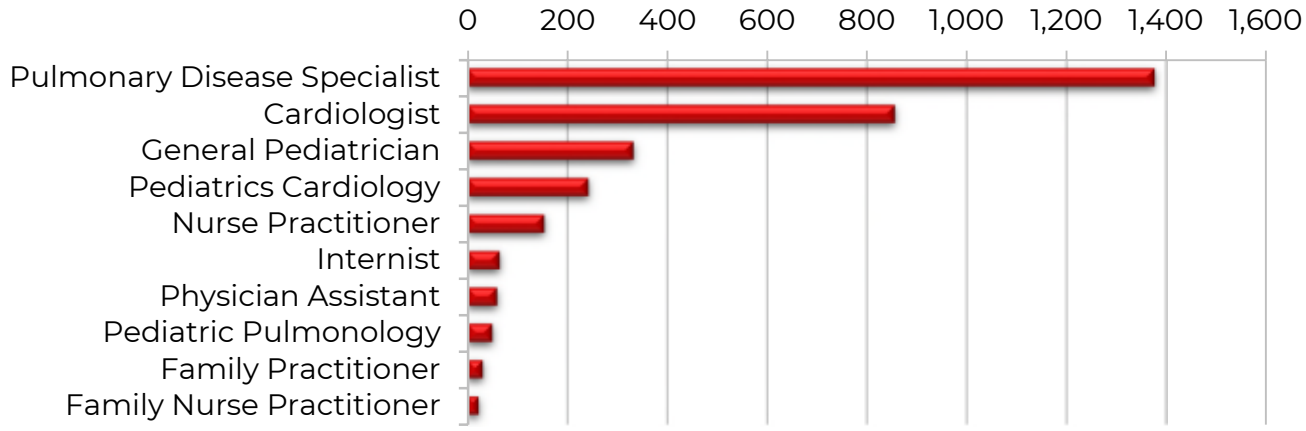
Costs do not reflect rebated prices or net costs.
Total number of unduplicated utilizing members.

are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Pulmonary Hypertension Medications



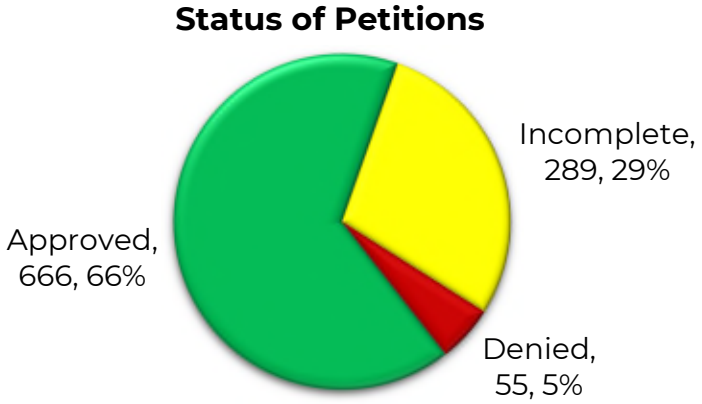
Top Prescriber Specialties of Pulmonary Hypertension Medications by Number of Claims



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

Prior Authorization of Pulmonary Hypertension Medications

There were 1,010 prior authorization requests submitted for pulmonary hypertension medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



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

Anticipated Patent Expiration(s):

- Veletri® (epoprostenol injection): March 2027
- Tracleer® (bosentan tablet for oral suspension): December 2027
- Tyvaso® (treprostinil inhalation solution): December 2028
- Remodulin® (treprostinil injection): March 2029
- Opsumit® (macitentan tablet): April 2029
- Opsynvi® (macitentan/tadalafil tablet): April 2029
- Orenitram® (treprostinil tablet): August 2031
- Letairis® (ambrisentan tablet): October 2031
- Adempas® (riociguat tablet): February 2034
- Tyvaso DPI® (treprostinil powder for inhalation): April 2035
- Uptravi® (selexipag tablet): December 2036
- Liqrev® (sildenafil oral suspension): December 2038
- Tadliq® (tadalafil oral suspension): December 2038

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

- **April 2023:** The FDA approved Liqrev® (sildenafil oral suspension) for the treatment of pulmonary arterial hypertension (PAH) in adults. Liqrev® is a ready-made version of a sildenafil suspension that was formulated for patients with dysphagia and was launched in June 2023. Revatio® (sildenafil oral suspension) was approved in 2012 and is a sildenafil suspension for reconstitution.
- **March 2024:** The FDA approved Opsynvi® (macitentan/tadalafil) for the chronic treatment of adults with World Health Organization (WHO) functional class (FC) II-III PAH. Opsynvi® is a combination tablet containing an endothelin receptor antagonist (ERA) and a

phosphodiesterase 5 (PDE5) inhibitor. The approval of Opsynvi® is based on a Phase 3 trial where Opsynvi® was compared to tadalafil or macitentan and showed a greater reduction in pulmonary vascular resistance after 16 weeks when compared to either medication used as monotherapy.

- **March 2024:** The FDA approved Winrevair™ (sotatercept-csrk) for adults with PAH to increase exercise capacity, improve WHO FC, and reduce the risk of clinical worsening events. Winrevair™ is an activin signaling inhibitor therapy and is the first FDA approved medication with this mechanism of action.

Winrevair™ (Sotatercept-csrk) Product Summary[6]

Therapeutic Class: Activin signaling inhibitor

Indication(s): Treatment of adults with PAH to increase exercise capacity, improve WHO FC, and reduce the risk of clinical worsening events

How Supplied:

- 45mg or 60mg lyophilized cake or powder in a single-dose vial (SDV)
- Available in 1-vial and 2-vial kits:
  - Each kit contains SDV(s), vial adapters, alcohol pads, dosing syringe for injection, safety needle, and a prefilled syringe of sterile water for injection.

Dosing and Administration:

- Recommended starting dose is 0.3mg/kg by subcutaneous (sub-Q) injection
- Recommended target dose is 0.7mg/kg sub-Q every 3 weeks
- Hemoglobin (Hgb) and platelet count should be obtained prior to initiating Winrevair™, before the first 5 doses, and periodically thereafter.
- Winrevair™ should not be initiated in patients with a platelet count <50,000/mm^3.
- Refer to the full *Prescribing Information* for the proper reconstitution and administration of Winrevair™.

Cost: The Wholesale Acquisition Cost (WAC) of Winrevair™ is $14,000 per 1-vial kit regardless of strength. A member weighing 80kg would have an annual cost of $238,000 at the recommended target dose of 0.7mg/kg every 3 weeks.

Cost Comparison: Sildenafil Products

Product	Cost Per Unit	Cost Per Month*	Cost Per Year*
Liqrev® (sildenafil) 10mg/mL suspension	**$15.53**	**$2,795.40**	**$33,544.80**
sildenafil 10mg/mL suspension (generic Revatio®)	$0.74	$133.20	$1,598.40
sildenafil 20mg tablet (generic)	$0.06	$5.40	$64.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per month and per year based on the initial FDA recommended dosing of 20mg 3 times daily

Cost Comparison: Endothelin Receptor Antagonist (ERA) and PDE-5 Inhibitor Products

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
Opsynvi® (macitentan/tadalafil) 10/40mg	**$421.18**	**$12,635.40***	**$151,624.80***
Opsumit® (macitentan) 10mg	$421.18	$12,635.40$^{\infty}$	$151,624.80$^{\infty}$
ambrisentan 10mg (generic)	$37.12	$1,113.60$^{\infty}$	$13,363.20$^{\infty}$
bosentan 125mg (generic)	$11.40	684.00^{\alpha}$	$8,208.00$^{\alpha}$
tadalafil 20mg tablet (generic)	$0.31	18.60^{¥}$	223.20^{¥}$
sildenafil 20mg tablet (generic)	$0.06	5.40^{\beta}$	64.80^{\beta}$

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month and per year based on the FDA recommended maintenance dose of 10/40mg once daily
$^{\infty}$Cost per month and per year based on the FDA recommended dosing of 10mg once daily
$^{\alpha}$Cost per month and per year based on the FDA recommended maintenance dosing of 125mg twice daily
$^{¥}$Cost per month and per year based on the initial FDA recommended dosing of 40mg once daily
$^{\beta}$Cost per month and per year based on the initial FDA recommended dosing of 20mg 3 times daily

Recommendations

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

Liqrev® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A patient-specific, clinically significant reason why the member cannot use generic sildenafil 20mg oral tablets, even when tablets are crushed, must be provided; and

5. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension (generic Revatio®) must be provided.

The College of Pharmacy also recommends the prior authorization of Opsynvi® (macitentan/tadalafil) with criteria similar to Opsumit® (macitentan) (changes shown in red):

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

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Requests for Opsynvi® will also require a patient-specific, clinically significant reason why the member cannot use Opsumit® in combination with generic sildenafil or tadalafil; and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program or the Macitentan-Containing Products REMS program; and
6. A quantity limit of 30 tablets per 30 days will apply.

Next, the College of Pharmacy recommends the prior authorization of Winrevair™ (sotatercept-csrk) with the following criteria (shown in red):

Winrevair™ (Sotatercept-csrk) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Previous failed trials of at least 1 of each of the following categories (alone or in combination) or have a contraindication to use of all alternatives:
   a. Revatio® (sildenafil), Adcirca® (tadalafil), or Adempas® (riociguat); and
   b. Letairis® (ambrisentan), Tracleer® (bosentan), or Opsumit® (macitentan); and
   c. Orenitram® (treprostinil) or Uptravi® (selexipag); and
4. Medical supervision by a pulmonary specialist and/or cardiologist; and
5. Prescriber must confirm the member or caregiver has been trained by a health care professional on the preparation, subcutaneous (sub-Q) administration, and proper storage of Winrevair™; and

6. Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and
7. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 4 months after the last dose; and
8. 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
9. A quantity limit of 1 kit every 3 weeks will apply.
    a. Members requiring (2) 45mg or (2) 60mg vials based on their body weight will not be approved for multiple 1-vial kits but should use the 2-vial kits to achieve the dose required.

Finally, the College of Pharmacy recommends the following changes to the Adcirca® (tadalafil), Adempas® (riociguat), Orenitram® (treprostinil), Tadliq® (tadalafil oral suspension), Tyvaso DPI® (treprostinil powder for inhalation), and Uptravi® (selexipag) criteria to be consistent with clinical practice:

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; or
4. A clinical exception for use as initial combination therapy with Letairis® (ambrisentan) applies; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 60 tablets per 30 days will apply.

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of pulmonary arterial hypertension must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
        i. Adcirca® (tadalafil) or Revatio® (sildenafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and

4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonia (PH-IIP); and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® Risk Evaluation and Mitigation Strategy (REMS) program; and
6. Members who are stabilized inpatient and who have a PAH or CTEPH diagnosis will be approved for continuation of therapy; and
7. A quantity limit of 90 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
    a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
5. A quantity limit of 180 tablets per 30 days will apply.

Tadliq® (Tadalafil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension must be provided; and
4. An age restriction will apply. The oral suspension formulation may be approvable for ages 6 years and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member cannot use generic tadalafil 20mg oral tablets, even when the tablets are crushed; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 300mL per 30 days (2 bottles) will apply.

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

1. An FDA approved diagnosis of 1 of the following:
    a. Pulmonary arterial hypertension (PAH); or
    b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and
        i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and
2. Medical supervision by a pulmonary specialist or cardiologist; and

3. For a diagnosis of PAH:
    a. Member must have previous failed trials of at least 1 of each of the following categories or have a contraindication to use of all alternatives:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. A patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and
4. For a diagnosis of PH-ILD, a patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.

Uptravi® (Selexipag) Approval Criteria:

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

Utilization Details of Pulmonary Hypertension Medications: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS						
TADLIQ SUS 20MG/5ML	632	138	$871,333.15	$1,378.69	4.58	5.45%
SILDENAFIL TAB 20MG	603	119	$9,925.48	$16.46	5.07	0.06%
TADALAFIL TAB 20MG	575	107	$14,124.62	$24.56	5.37	0.09%
SILDENAFIL SUS 10MG/ML	41	10	$7,435.02	$181.34	4.1	0.05%
REVATIO SUS 10MG/ML	6	1	$61,106.82	$10,184.47	6	0.38%
ALYQ TAB 20MG	4	2	$75.49	$18.87	2	0.00%
SUBTOTAL	**1,861**	**377**	**$964,000.58**	**$518.00**	**4.94**	**6.03%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						
OPSUMIT TAB 10MG	305	44	$3,519,705.88	$11,540.02	6.93	22.01%
AMBRISENTAN TAB 10MG	271	59	$320,837.52	$1,183.90	4.59	2.01%
LETAIRIS TAB 10MG	130	41	$1,621,788.98	$12,475.30	3.17	10.14%
TRACLEER TAB 32MG	85	18	$678,041.87	$7,976.96	4.72	4.24%
AMBRISENTAN TAB 5MG	49	14	$62,161.23	$1,268.60	3.5	0.39%
BOSENTAN TAB 62.5MG	41	5	$40,052.52	$976.89	8.2	0.25%
LETAIRIS TAB 5MG	19	7	$258,948.91	$13,628.89	2.71	1.62%
BOSENTAN TAB 125MG	8	1	$15,104.60	$1,888.08	8	0.09%
SUBTOTAL	**908**	**189**	**$6,516,641.51**	**$7,176.92**	**4.8**	**40.76%**
PROSTACYCLIN VASODILATORS						
TYVASO REFILL SOL 0.6MG/ML	48	8	$924,585.96	$19,262.21	6	5.78%
ORENITRAM TAB 5MG	40	5	$1,573,222.83	$39,330.57	8	9.84%
REMODULIN INJ 2.5MG/ML	38	7	$347,673.18	$9,149.29	5.43	2.17%
ORENITRAM TAB 1MG	38	6	$449,295.08	$11,823.55	6.33	2.81%
TYVASO DPI 64MCG	35	9	$754,558.83	$21,558.82	3.89	4.72%
UPTRAVI TAB 1400MCG	35	4	$769,538.63	$21,986.82	8.75	4.81%
UPTRAVI TAB 600MCG	25	3	$536,797.31	$21,471.89	8.33	3.36%
REMODULIN INJ 5MG/ML	21	4	$140,187.53	$6,675.60	5.25	0.88%
REMODULIN INJ 10MG/ML	18	3	$266,958.98	$14,831.05	6	1.67%
ORENITRAM TAB 2.5MG	14	3	$226,537.27	$16,181.23	4.67	1.42%
ORENITRAM TAB 0.25MG	13	3	$38,168.60	$2,936.05	4.33	0.24%
UPTRAVI TAB 1000MCG	11	1	$243,110.75	$22,100.98	11	1.52%
UPTRAVI TAB 1600MCG	10	4	$196,067.54	$19,606.75	2.5	1.23%
UPTRAVI TAB 400MCG	8	3	$176,525.21	$22,065.65	2.67	1.10%
TYVASO DPI 48MCG	8	4	$149,479.67	$18,684.96	2	0.93%
UPTRAVI TAB 800MCG	8	2	$176,082.52	$22,010.32	4	1.10%
TYVASO DPI 16-32-48	7	7	$151,536.95	$21,648.14	1	0.95%
UPTRAVI TAB 200MCG	7	4	$208,097.12	$29,728.16	1.75	1.30%
UPTRAVI PACK TAB 200/800MCG	5	3	$166,467.90	$33,293.58	1.67	1.04%
ORENITRAM TAB 0.125MG	4	3	$12,159.88	$3,039.97	1.33	0.08%
TYVASO DPI 32MCG	3	2	$65,821.67	$21,940.56	1.5	0.41%
TYVASO START SOL 0.6MG/ML	2	2	$44,480.48	$22,240.24	1	0.28%
SUBTOTAL	**398**	**90**	**$7,617,353.89**	**$19,139.08**	**4.42**	**47.64%**
SOLUBLE GUANYLATE CYCLASE (sGC) STIMULATORS						
ADEMPAS TAB 2.5MG	56	7	$711,469.14	$12,704.81	8	4.45%
ADEMPAS TAB 1.5MG	12	2	$139,868.71	$11,655.73	6	0.87%
ADEMPAS TAB 1MG	2	2	$26,120.62	$13,060.31	1	0.16%
ADEMPAS TAB 2MG	1	1	$13,062.31	$13,062.31	1	0.08%
SUBTOTAL	**71**	**12**	**$890,520.78**	**$12,542.55**	**5.92**	**5.57%**
TOTAL	**3,238**	**388***	**$15,988,516.76**	**$4,937.78**	**8.35**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DPI = dry powder inhaler; INJ = injection; SOL = solution; SUS = suspension; TAB = tablet

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 03/2024. Last accessed 05/24/2024.
[2] Liqrev® (Sildenafil) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_liqrev_2023-0503.pdf. Issued 04/28/2023. Last accessed 05/24/2024.
[3] CMP Pharma. CMP Pharma, Inc Announces that Liqrev®, the First and Only Ready-Made FDA-Approved Liquid Suspension of Sildenafil is Now Available. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/cmp-pharma-inc-announces-that-liqrev-the-first-and-only-ready-made-fda-approved-liquid-suspension-of-sildenafil-is-now-available-301856229.html. Issued 06/21/2023. Last accessed 05/24/2024.
[4] Johnson & Johnson. U.S. FDA Approves Opsynvi® (Macitentan and Tadalafil) as the First and Only Once-Daily Single-Tablet Combination Therapy for Patients with Pulmonary Arterial Hypertension (PAH). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/us-fda-approves-opsynvi-macitentan-and-tadalafil-as-the-first-and-only-once-daily-single-tablet-combination-therapy-for-patients-with-pulmonary-arterial-hypertension-pah-302097530.html. Issued 03/22/2024. Last accessed 05/24/2024.
[5] Merck. FDA Approves Merck's Winrevair™ (Sotatercept-csrk), a First-in-Class Treatment for Adults with Pulmonary Arterial Hypertension (PAH, WHO* Group 1). Available online at: https://www.merck.com/news/fda-approves-mercks-winrevair-sotatercept-csrk-a-first-in-class-treatment-for-adults-with-pulmonary-arterial-hypertension-pah-who-group-1/. Issued 03/26/2024. Last accessed 05/24/2024.
[6] Winrevair™ (Sotatercept-csrk) Prescribing Information. Merck. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761363s000lbl.pdf. Last revised 03/2024. Last accessed 05/24/2024.

Appendix O

Calendar Year 2023 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Baclofen 15mg Tablet, Chlorzoxazone 250mg Tablet, Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser), Combogesic® IV [Acetaminophen/Ibuprofen Intravenous (IV)], Elyxyb™ (Celecoxib Oral Solution), Ingrezza® Sprinkle (Valbenazine), Lodoco® (Colchicine), Millipred™ (Prednisolone 5mg Tablet), Motpoly XR™ [Lacosamide Extended-Release (ER) Capsule], Neo-Synalar® (Neomycin/Fluocinolone Cream), Ozobax® DS [Baclofen Double Strength (DS) 10mg/5mL Oral Solution], PoKonza™ (Potassium Chloride 10mEq Packet for Oral Solution), Suflave™ [Polyethylene Glycol (PEG)-3350/Sodium Sulfate/Potassium Chloride/ Magnesium Sulfate/Sodium Chloride], and Valsartan Oral Solution

Oklahoma Health Care Authority
June 2024

Introduction

Multiple formulations of medications are made for ease of administration, to increase bioavailability, or as new technologies are created to provide a more efficient treatment response. Some of the new formulations incur greater costs for production, resulting in greater costs for the payer and consumer. A clinical review of each product and its comparative cost to other formulations is provided in the following report for reference.

Current Prior Authorization Criteria

Absorica LD® (Isotretinoin Capsule) Approval Criteria:

1. An FDA approved diagnosis of severe recalcitrant nodular acne in non-pregnant members 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater; and
2. Absorica LD® is not covered for members older than 20 years of age; and

3. Prescriber must verify member is enrolled in the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program; and
4. Prescriber must verify lipid profile and liver function tests will be monitored prior to initiation of Absorica LD® and at regular intervals during treatment in accordance with the package labeling; and
5. A patient-specific, clinically significant reason why the member cannot use other isotretinoin capsules available without prior authorization must be provided; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of medication according to package labeling.

Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Approval Criteria:

1. An FDA approved diagnosis of chronic angina; and
2. A patient-specific, clinically significant reason why the member cannot use ranolazine ER tablets must be provided.

Ermeza™ (Levothyroxine Oral Solution), Thyquidity™ (Levothyroxine Oral Solution), Tirosint® (Levothyroxine Capsule), and Tirosint®-SOL (Levothyroxine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
    b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the oral solutions, a reason why the member cannot use the levothyroxine tablet formulation, even when the tablets are crushed, must be provided; and
3. Tirosint® (levothyroxine capsule) is brand preferred. Use of generic levothyroxine capsules will require a patient specific, clinically significant reason why the member cannot use the brand formulation; and
4. Prescriber must verify member has been compliant with levothyroxine tablets at a greatly increased dose for at least 8 weeks; and
5. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite a greatly increased dose and compliance with levothyroxine tablets.

Gimoti® (Metoclopramide Nasal Spray) Approval Criteria:

1. An FDA approved indication of acute or recurrent diabetic gastroparesis in adult members; and
2. A patient-specific, clinically significant reason why the member cannot use metoclopramide oral tablets and metoclopramide oral solution must be provided; and
3. For members 65 years of age or older, approvals will not be granted for initiation of metoclopramide therapy; and
4. For members 65 years of age or older requesting to switch from an alternative metoclopramide product to Gimoti®:
    a. Member must be taking a stable dose of metoclopramide 10mg 4 times daily for at least 10 days; and
    b. Duration of current metoclopramide treatment must be provided; and
5. A maximum approval duration of 8 weeks total from all sources will apply; and
6. A quantity limit of 9.8mL per 28 days will apply.

GoNitro® (Nitroglycerin Sublingual Powder) Approval Criteria:

1. An FDA approved indication of acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease; and
2. A patient-specific, clinically significant reason why the member cannot use nitroglycerin sublingual tablets or nitroglycerin lingual spray must be provided.

Gralise® [Gabapentin Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved indication of postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
    a. Tricyclic antidepressants; or
    b. Anticonvulsants; or
    c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Horizant® [Gabapentin Enacarbil Extended-Release (ER) Tablet] Approval Criteria:

1. For the FDA approved indication of restless leg syndrome:
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts at recommended dosing with at least 2 of the following medications that did not yield adequate relief:
        i. Carbidopa/levodopa; or

ii. Pramipexole; or
iii. Ropinirole; and

c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

2. For the FDA approved indication of postherpetic neuralgia (PHN):
   a. Member must be 18 years of age or older; and
   b. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
      i. Tricyclic antidepressants; or
      ii. Anticonvulsants; or
      iii. Topical or oral analgesics; and
   c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Jylamvo® (Methotrexate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or
   b. Mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or
   c. Relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or
   d. Rheumatoid arthritis; or
   e. Severe psoriasis; and
2. Member must be 18 years of age or older; and
3. A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

Khapzory™ (Levoleucovorin Injection) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or
   b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or
   c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and
2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection must be provided.

Klor-Con® (Potassium Chloride 20mEq Packet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the potassium chloride tablet formulation must be provided.

Kristalose® (Lactulose Packet for Oral Solution) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the liquid lactulose formulation must be provided.

Lyrica® CR [Pregabalin Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Neuropathic pain associated with diabetic peripheral neuropathy (DPN); or
    b. Neuropathic pain associated with postherpetic neuralgia (PHN); and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of pregabalin must be provided; and
3. Requests exceeding once daily dosing will not be approved.

Metozolv® ODT [Metoclopramide Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the metoclopramide oral tablet formulation must be provided.

Nextstellis® (Drospirenone/Estetrol Tablet) and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided.

Otrexup®, Rasuvo®, and RediTrex® (Methotrexate Injection Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Severe, active rheumatoid arthritis (RA) in adult members; or
    b. Active polyarticular juvenile idiopathic arthritis (pJIA) in pediatric members; or
    c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
2. A patient-specific, clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided; and
3. Authorization of Otrexup® will also require a patient-specific, clinically significant reason why the member cannot use Rasuvo® or RediTrex®.

Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an over-the-counter (OTC) spermicide and all other forms of contraception (e.g., condoms, oral contraceptives) must be provided. Various OTC spermicides containing nonoxynol 9 are covered by SoonerCare without prior authorization.

Purixan® (Mercaptopurine Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of acute lymphoblastic leukemia (ALL); and
2. An age restriction for members older than 10 years of age applies. Purixan® does not require prior authorization for members 10 years of age and younger; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Pyridostigmine 30mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use pyridostigmine 60mg tablets, which are available without prior authorization, must be provided.

Reltone® (Ursodiol Capsule) Approval Criteria:

1. An FDA approved indication for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter or the prevention of gallstone formation in obese members experiencing rapid weight loss; and
2. For the indication of dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter:
    a. Prescriber must confirm member is not a candidate for elective cholecystectomy due to 1 or more of the following:
        i. Increased surgical risk due to systemic disease; or
        ii. Advanced age; or
        iii. Idiosyncratic reaction to general anesthesia; or
        iv. Member refuses surgery; and
    b. Prescriber must confirm the member does not have compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula; and
3. For the indication of prevention of gallstone formation in obese members experiencing rapid weight loss:
    a. Member's baseline body mass index (BMI) and weight must be provided; and
    b. Member's current weight must be provided supporting rapid weight loss compared to baseline; and

4. For both FDA approved indications, a patient-specific, clinically significant reason why the member cannot use other generic formulations of ursodiol must be provided; and
5. Initial approvals for the indication of dissolution of gallstones will be for the duration of 6 months, after which time the prescriber must confirm (via ultrasound imaging) partial or complete dissolution of gallstone(s). Subsequent approvals will be for the duration of 12 months; and
6. Approvals for prevention of gallstone formation in obese members experiencing rapid weight loss will be for 6 months, after which time the member's current weight must be provided to justify continued rapid weight loss and need for preventative treatment; and
7. Treatment duration will be limited to a maximum of 24 months for all diagnoses.

Soltamox® (Tamoxifen Citrate 10mg/5mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of metastatic breast cancer in women and men; or
    b. Adjuvant treatment of node-positive breast cancer in postmenopausal women and for the adjuvant treatment of axillary node-negative breast cancer in women following total mastectomy or segmental mastectomy, axillary dissection, and breast irradiation; or
    c. To reduce the risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS), following breast surgery and radiation; or
    d. To reduce the incidence of breast cancer in women at high risk for breast cancer; and
2. A patient-specific, clinically significant reason why the member cannot use tamoxifen oral tablets must be provided.

Taytulla® (Norethindrone Acetate/Ethinyl Estradiol Capsule and Ferrous Fumarate Capsule) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use all other generic formulations of norethindrone acetate/ethinyl estradiol tablets with ferrous fumarate tablets must be provided.

Vuity® (Pilocarpine Hydrochloride 1.25% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication of the treatment of presbyopia in adults; and
2. Must be prescribed by an ophthalmologist or optometrist; and
3. Prescriber must verify the member does not have iritis; and
4. Prescriber must verify the member has been counseled on the risk of retinal detachment with use of Vuity® and when to seek immediate medical care; and

5. Prescriber must verify the member has been advised to use caution with night driving and hazardous occupations in poor illumination as vision may not be clear in these conditions while using Vuity®; and
6. A patient-specific, clinically significant reason why the member cannot use corrective lenses must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use generic pilocarpine ophthalmic solution (Isopto® Carpine) must be provided.

Xatmep® (Methotrexate 2.5mg/mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of pediatric members with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen; or
   b. Management of pediatric members with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy; and
2. A patient-specific, clinically significant reason why the oral tablets or generic injectable formulation cannot be used must be provided.

Utilization of Various Special Formulations: Calendar Year 2023

Comparison of Calendar Years

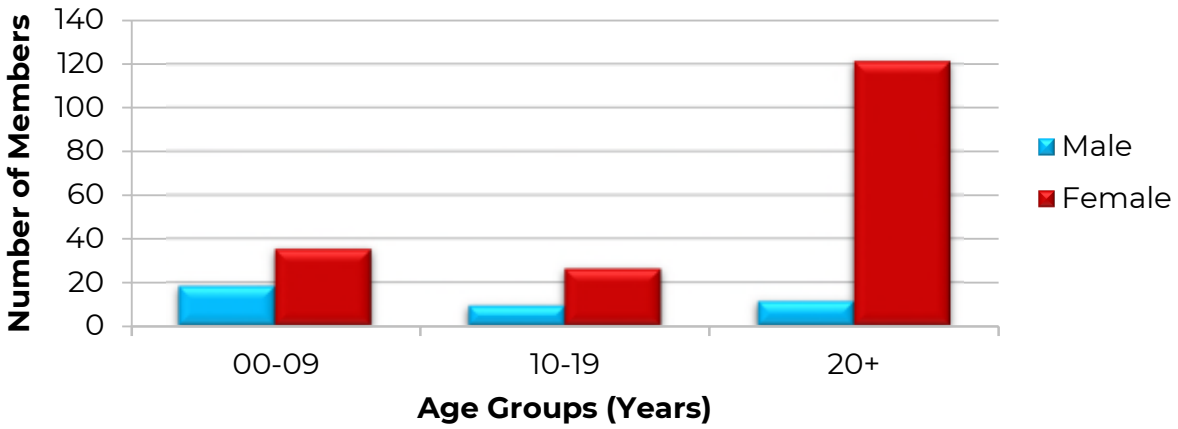
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	150	754	$281,146.38	$327.87	$9.95	35,130	28,270
2023	220	886	$336,840.21	$380.18	$9.74	37,098	34,578
% Change	**46.70%**	**17.50%**	**19.80%**	**2.00%**	**-2.10%**	**5.60%**	**22.30%**
Change	**70**	**132**	**$55,693.83**	**$7.31**	**-$0.21**	**1,968**	**6,308**

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

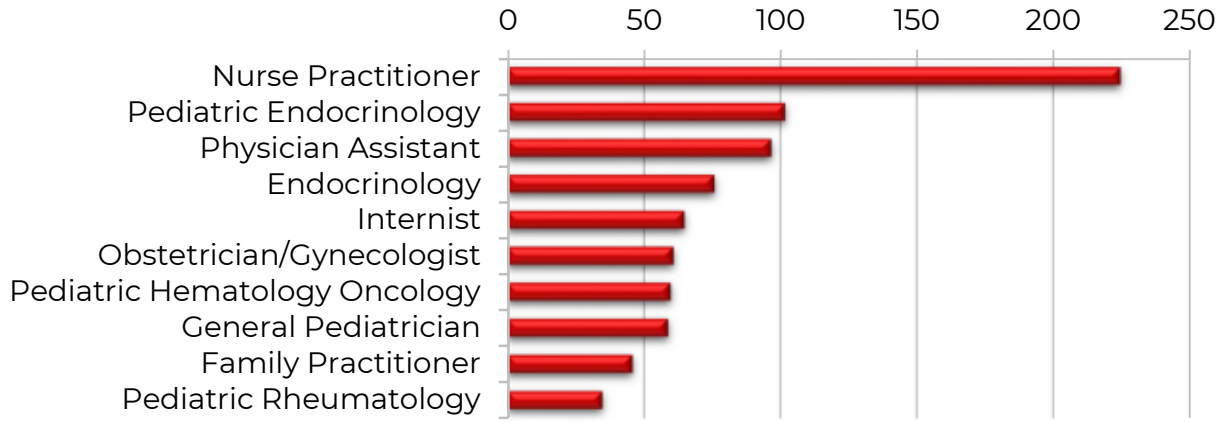
- Due to the evolving nature of this category, calendar year comparisons may not reflect the same product utilization from year to year.
- There were no paid medical claims for various special formulations during calendar year 2023.
- Aggregate drug rebates collected during calendar year 2023 for the various special formulations totaled $153,212.76.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Various Special Formulations



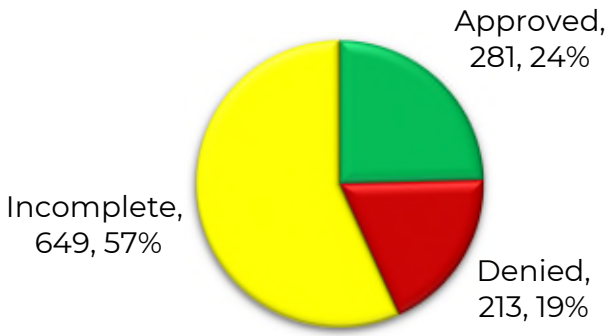
Top Prescriber Specialties of Various Special Formulations by Number of Claims



Prior Authorization of Various Special Formulations

There were 1,143 prior authorization requests submitted for various special formulations during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



Baclofen 15mg Tablet and Ozobax® DS (Baclofen DS 10mg/5mL Oral Solution) Product Summary[1,2,3,4,5]

Therapeutic Class: Gamma-aminobutyric acid agonist

Indication(s): Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity

- **Limitation(s) of Use:** Ozobax® DS and baclofen 15mg tablets are not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. Baclofen tablets have an additional limitation stating that the efficacy of baclofen tablets in stroke, cerebral palsy, and Parkinson's disease has not been established and, therefore, it is not recommended for these conditions.

How Supplied:

- Ozobax® DS contains 10mg/5mL of baclofen. It is supplied as a clear, colorless solution in 237mL and 473mL bottles that can be stored at room temperature.
- Baclofen oral tablets are available in 4 strengths: 5mg, 10mg, 15mg, and 20mg.

Dosing and Administration:

- Ozobax® DS and baclofen tablets should be initiated with a low dosage, preferably in divided doses, administered orally. The dosage may be increased gradually based on clinical response and tolerability.
- The maximum dosage is 80mg daily (20mg 4 times a day).
- When discontinuing, the dose should be reduced slowly.

Other Formulation(s) Available:

- Fleqsuvy® (Baclofen 25mg/mL Oral Suspension), Lyvispah® (Baclofen Oral Granules), and Ozobax® (Baclofen 5mg/5mL Oral Solution):
  - Fleqsuvy®, Lyvispah®, and Ozobax® have the same indication and *Limitation(s) of Use* as Ozobax® DS and baclofen tablets.
  - The recommended dosing for Fleqsuvy®, Lyvispah®, and Ozobax® is also the same as Ozobax® DS and baclofen tablets.
  - Fleqsuvy®, Ozobax®, and Ozobax® DS are available in generic formulations.
  - Ozobax® 5mg/5mL oral solution is supplied as clear, colorless solution with a grape aroma in a 473mL bottle that must be stored in the refrigerator.
  - Fleqsuvy® 25mg/5mL oral suspension is a concentrated orange to yellow-colored, grape flavored suspension supplied in 120mL and 300mL bottles that can be stored at room temperature.
  - Lyvispah® is supplied as white to off-white, strawberry flavored oral granules in a child resistant packet in 5mg, 10mg, and 20mg

strengths that can be stored at room temperature. The oral granules can be mixed with soft food for administration within 2 hours or administered via enteral feeding tube.

Formulation Cost Comparison:

Product	Cost Per Unit†	Cost Per 30 Days*
baclofen 10mg/5mL oral solution (generic Ozobax® DS)	**$2.79**	**$2,511.00**
baclofen 15mg tablet (generic)	**$1.95**	**$234.00**
baclofen 5mg/5mL oral solution (generic Ozobax®)	$1.40	$2,520.00
baclofen 25mg/5mL oral suspension (generic Fleqsuvy®)	$5.44α	$1,958.40
Lyvispah® (baclofen oral granules) 20mg packet	$3.60	$324.00
baclofen 10mg tablet (generic)	$0.04	$7.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†Unit = mL, packet, or tablet
αCost per mL varies per NDC.
*Cost per 30 days is based on an FDA approved dose of 60mg daily for each product.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of Ozobax® DS 10mg/5mL or baclofen 15mg tablets during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
BACLOFEN TAB 10MG	18,415	5,824	$247,071.43	$0.48	3.16	$13.42
BACLOFEN SOL 5MG/5ML	41	8	$13,906.00	$11.72	5.13	$339.17
BACLOFEN SUS 25MG/5ML	6	2	$5,041.49	$28.01	3	$840.25
LYVISPAH GRA 5MG	4	1	$1,932.63	$18.23	4	$483.16
FLEQSUVY SUS 25MG/5ML	3	1	$837.40	$9.30	3	$279.13
TOTAL	**18,469**	**5,833***	**$268,788.95**	**$0.52**	**3.17**	**$14.55**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
GRA = granules; SOL = solution; SUS = suspension; TAB = tablet

Chlorzoxazone 250mg Tablet Product Summary[6,7]

Therapeutic Class: Skeletal muscle relaxant

Indication(s): As an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions

How Supplied: 250mg oral tablet

Dosing and Administration:

- The recommended dose for chlorzoxazone 250mg is 1 tablet 3 or 4 times daily.

- Initial dosage for painful musculoskeletal conditions should be 500mg 3 or 4 times daily.
- If adequate response is not obtained with this dose, it may be increased to 750mg 3 or 4 times daily. As improvement occurs, dosage can usually be reduced.

Other Formulation(s) Available:

- Chlorzoxazone 375mg, 500mg, and 750mg tablets

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
chlorzoxazone 250mg tablet (generic)	**$18.91**	**$6,807.60**
chlorzoxazone 375mg tablet (generic)	$2.04	$489.60
chlorzoxazone 750mg tablet (generic)	$2.47	$296.40
chlorzoxazone 500mg tablet (generic)	$0.22	$39.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the maximum FDA approved dose of 750mg orally 4 times daily.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of chlorzoxazone 250mg tablet during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
CHLORZOXAZONE TAB 500MG	881	328	$22,248.99	$1.00	2.69	$25.25
CHLORZOXAZONE TAB 750MG	8	3	$2,693.78	$11.22	2.67	$336.72
TOTAL	**889**	**328***	**$24,942.77**	**$1.11**	**2.71**	**$28.06**

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

Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser) Product Summary[8,9,10,11]

Therapeutic Class: Antibacterial

Indication(s): Treatment of acne vulgaris

How Supplied: 1 carton of 60 swabs of Clindacin® ETZ (clindamycin 1% phosphate) and 1 bottle of AcuWash® moisturizing daily cleanser

Dosing and Administration:

- AcuWash®:
  - Wet skin and pump cleanser into hands
  - Massage gently into skin working into a full lather
  - Rinse thoroughly and pat dry with a soft towel
  - AcuWash® should be used twice daily before Clindacin® ETZ

- Clindacin® ETZ:
  - Clean and dry skin areas to be treated
  - Apply a thin film to the affected area twice daily
  - Use sparingly, avoiding eyes and mouth
  - Discard swab after single use

Other Formulation(s) Available:

- Clindamycin 1% Gel, Clindamycin 1% Lotion, Clindamycin 1% Solution, and Clindamycin 1% Swabs:
  - All products have the same indication and dosing as Clindacin® ETZ.
  - Clindamycin 1% gel is supplied as a clear, colorless topical gel in a 30gram or 60gram tube.
  - Clindamycin 1% lotion is supplied as a topical lotion in a 60mL bottle.
  - Clindamycin 1% solution is supplied as a topical solution in a 30mL or 60mL bottle.
  - Clindamycin 1% swabs are supplied as a topical solution on 60 individually wrapped swabs.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Clindacin® ETZ kit (clindamycin 1% swab & cleanser)	**$668.81**	**$668.81**
clindamycin phosphate 1% gel (generic)	$0.32	$19.20
clindamycin phosphate 1% swab (generic)	$0.30	$18.00
clindamycin phosphate 1% lotion (generic)	$0.29	$17.40
clindamycin phosphate 1% solution (generic)	$0.21	$12.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = gram, kit, mL, or swab
*Cost per 30 days is based on the FDA approved twice daily application with the use of 1 kit or 60 grams, mL, or swabs.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of Clindacin® ETZ Kit during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
CLINDAMYCIN GEL 1%	4,856	2,729	$137,991.18	$1.07	1.78	$28.42
CLINDAMYCIN SOL 1%	2,426	1,353	$53,494.26	$0.85	1.79	$22.05
CLINDAMYCIN LOT 1%	2,168	1,205	$74,108.00	$1.30	1.8	$34.18
CLINDAMYCIN SWAB 1%	1,033	393	$29,041.26	$0.92	2.63	$28.11
CLINDACIN-P PAD 1%	5	4	$158.85	$1.06	1.25	$31.77
TOTAL	**10,488**	**5,510***	**$294,793.42**	**$1.05**	**1.9**	**$28.11**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
LOT = lotion, SOL = solution

Combogesic® IV (Acetaminophen/Ibuprofen) Product Summary[12,13,14,15]

Therapeutic Class: Analgesic

Indication(s): In adults where an intravenous (IV) route of administration is considered clinically necessary for the relief of mild to moderate pain or the management of moderate to severe pain as an adjunct to opioid analgesics

- **Limitation(s) of Use:** Combogesic® IV is indicated for short-term use of 5 days or less.

How Supplied: Single-dose vial containing 1,000mg acetaminophen and 300mg ibuprofen in 100mL of solution

Dosing and Administration:

- Adults Weighing ≥50kg: 1 vial administered as a 15-minute IV infusion every 6 hours, as necessary
- Adults Weighing <50kg: 15mg/kg and 4.5mg/kg ibuprofen administered as a 15-minute IV infusion every 6 hours, as necessary
- See full package labeling for IV administration instructions.
- The lowest effective dose for the shortest duration should be used to be consistent with individual patient treatment goals.
- A maximum total daily dose of Combogesic® IV of 4,000mg acetaminophen and 1,200mg ibuprofen should not be exceeded.

Other Formulation(s) Available:

- Acetaminophen Injection, Caldolor® (Ibuprofen Injection), and Ibuprofen Oral Tablets:
  - Acetaminophen injection and Caldolor® injection have the same indications as Combogesic® IV and both are also indicated to reduce fever.
  - The maximum total daily dose for Caldolor® injection for the treatment of pain in adults is 3,200mg per day.
  - The maximum total daily dose for acetaminophen injection for the treatment of pain in adults is 4,000mg per day.
  - Both acetaminophen injection and Caldolor® injection can be used in pediatric patients (see package labeling for details on dosing).
  - Ibuprofen tablets are indicated for the relief of mild to moderate pain, relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis, and for the treatment of primary dysmenorrhea.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 5 days*
Combogesic® IV (acetaminophen/ibuprofen injection)	**$23.00**	**$460.00**
acetaminophen 1,000mg/100mL injection (generic)	$28.00	$560.00
Caldolor® (ibuprofen injection) 800mg/8mL	$23.70	$473.92
ibuprofen 400mg oral tablet (generic)	$0.05	$1.50

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 = vial or tablet
*Cost per 5 days is based on the FDA approved maximum dosing for pain.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of acetaminophen injection, Caldolor®, or Combogesic® IV during calendar year 2023 through pharmacy claims.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
IBUPROFEN TAB 800MG	87,342	58,738	$1,036,668.38	$0.71	1.49	$11.87
IBUPROFEN TAB 600MG	19,704	17,116	$214,836.75	$0.99	1.15	$10.90
IBUPROFEN TAB 400MG	2,649	2,127	$30,692.57	$0.87	1.25	$11.59
TOTAL	**109,695**	**75,645***	**$1,282,197.70**	**$0.75**	**1.45**	**$11.69**

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

Elyxyb™ (Celecoxib Oral Solution) Product Summary[16,17,18,19,20,21,22]

Therapeutic Class: Nonsteroidal anti-inflammatory drug (NSAID)

Indication(s): Acute treatment of migraine with or without aura in adults
- **Limitation(s) of Use:** Elyxyb™ is not indicated for the preventative treatment of migraine.

How Supplied: 120mg/4.8mL (25mg/mL) clear colorless oral solution

Dosing and Administration:
- The recommended dose is 120mg taken orally, with or without food.
- The maximum daily dose is 120mg. The safety and effectiveness of a second dose in a 24-hour period has not been established.
- Use Elyxyb™ for the fewest number of days per month, as needed.

Other Formulation(s) Available:
- Celecoxib Capsules:
  - Celecoxib capsules contain the same active ingredient as Elyxyb™; however, celecoxib capsules are not FDA approved or guideline supported for acute migraine treatment.

- There was 1 small randomized, open-label trial, that compared celecoxib 400mg to naproxen 550mg in 60 patients. The results showed that when compared to naproxen, celecoxib was equally effective in relieving pain in acute migraine and caused significantly less gastric pain.

Other NSAIDs Available for Acute Migraine Treatment:

- Cambia® (Diclofenac Potassium Powder):
  - Cambia® is indicated for acute treatment of migraine attacks with or without aura in adults.
  - It is supplied as a flavored powder for oral solution.
  - The recommended dose is 1 packet (50mg) administered for acute migraine. The packet should be mixed with 1 to 2 ounces of water for immediate use.
  - The safety and effectiveness of a second dose have not been established and the lowest effective dose for the shortest duration should be used.
- Ibuprofen Tablets, and Naproxen Tablets:
  - Both are recommended by the American Headache Society (AHS) for acute treatment of migraine.
  - The AHS recommends limiting the use of acute migraine treatment to 2 headaches per week to reduce the risk of medication overuse headache.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 8 Days*
Elyxyb™ 120mg/4.8mL (celecoxib oral solution)	**$28.90**	**$1,109.76**[α]
diclofenac potassium 50mg powder (generic Cambia®)	$27.07	$216.56[α]
celecoxib 200mg capsule (generic)	$0.09	$1.44[β]
ibuprofen 400mg tablet (generic)	$0.04	$0.96[+]
naproxen 500mg tablet (generic)	$0.05	$0.80[+]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule, mL, packet, or tablet
*Cost is calculated per 8 days based on the AHS recommendation to limit acute migraine treatment to 2 headaches per week.
[α]Cost per 8 days is based on the maximum FDA approved dosing for acute migraine treatment.
[β]Cost per 8 days is based on the maximum dose supported by the randomized controlled trial for acute migraine treatment.
[+]Cost per 8 days is based on the maximum FDA approved dosing for pain.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of Elyxyb™ during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
IBUPROFEN TAB 800MG	87,343	58,739	$1,036,687.79	$0.71	1.49	$11.87
NAPROXEN TAB 500MG	30,523	20,945	$344,939.32	$0.55	1.46	$11.30
IBUPROFEN TAB 600MG	19,704	17,116	$214,836.75	$0.99	1.15	$10.90
CELECOXIB CAP 200MG	14,373	5,389	$215,228.81	$0.41	2.67	$14.97
CELECOXIB CAP 100MG	6,161	2,550	$91,925.14	$0.47	2.42	$14.92
IBUPROFEN TAB 400MG	2,649	2,127	$30,692.57	$0.87	1.25	$11.59
NAPROXEN TAB 375MG	2,408	1,745	$30,269.22	$0.62	1.38	$12.57
NAPROXEN TAB 250MG	1,679	1,117	$21,473.77	$0.57	1.5	$12.79
NAPROXEN TAB 500MG DR	647	471	$78,819.16	$5.68	1.37	$121.82
EC-NAPROXEN TAB 500MG	415	264	$47,235.32	$5.31	1.57	$113.82
CELECOXIB CAP 50MG	258	107	$3,838.32	$0.50	2.41	$14.88
NAPROXEN TAB 375MG DR	104	73	$2,034.86	$0.92	1.42	$19.57
DICLOFENAC POW 50MG	4	2	$1,688.71	$14.81	2	$422.18
EC-NAPROXEN TAB 375MG	2	2	$32.35	$0.87	1	$16.18
TOTAL	**166,270**	**101,745***	**$2,119,702.09**	**$0.67**	**1.63**	**$12.75**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed release; EC = enteric coated; POW = powder; TAB = tablet

Ingrezza® Sprinkle (Valbenazine) Product Summary[23]

Therapeutic Class: Vesicular monoamine transporter 2 (VMAT2) inhibitor

Indication(s): Treatment of adults with tardive dyskinesia and chorea associated with Huntington's disease

How Supplied: 40mg, 60mg, or 80mg capsule

Dosing and Administration:

- Tardive Dyskinesia: The initial dose is 40mg once daily. After 1 week, the dose may be increased to the recommended 80mg once daily dose.
- Chorea Associated with Huntington's Disease: The initial dose is 40mg once daily. The dose may be increased in 20mg increments every 2 weeks to the recommended 80mg once daily dose.
- A lower dose of 40mg or 60mg once daily may be considered depending on response and tolerability.
- Ingrezza® Sprinkle may be opened and sprinkled over soft food such as applesauce, yogurt, or pudding before taking; however, it should not be added to milk or water. Ingrezza® Sprinkle capsule may also be swallowed whole with water. It should not be crushed or chewed.

Other Formulation(s) Available:

- Ingrezza® (Valbenazine) Capsule:
  - Ingrezza® capsule has the same indications, *Boxed Warning*, and dosing as Ingrezza® Sprinkle.

- The capsule is also available in the same strengths as Ingrezza® Sprinkle; however, the capsule must be swallowed whole.

Formulation Cost Comparison:

Product	Cost Per Capsule	Cost Per 30 Days*
Ingrezza® Sprinkle (valbenazine) 80mg capsule	**$275.17**	**$8,255.10**
Ingrezza® (valbenazine) 80mg capsule	$264.60	$7,938.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the maximum FDA approved dose 80mg once daily.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of Ingrezza® Sprinkle during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
INGREZZA CAP 80MG	445	79	$3,469,562.57	$260.85	5.63	$7,796.77
INGREZZA CAP 40MG	291	75	$2,088,815.61	$244.02	3.88	$7,178.06
INGREZZA CAP 60MG	77	19	$612,518.57	$268.06	4.05	$7,954.79
INGREZZA CAP 40MG-80MG	10	10	$80,326.10	$286.88	1	$8,032.61
TOTAL	**823**	**149***	**$6,251,222.85**	**$255.92**	**5.52**	**$7,595.65**

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

Lodoco® (Colchicine) Product Summary[24,25,26,27,28,29,30]

Therapeutic Class: Anti-inflammatory drug

Indication(s): To reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular (CV) death in adult patients with established atherosclerotic disease or with multiple risk factors for CV disease (CVD)

How Supplied: 0.5mg tablet

Dosing and Administration:
- The recommended dose of Lodoco® (colchicine) is 0.5mg orally once daily.

Other Formulation(s) Available:
- Colchicine 0.6mg Capsule/Tablet and Gloperba® 0.6mg/5mL (Colchicine) Oral Solution:
  - Colchicine 0.6mg capsule/tablet is only FDA approved for prophylaxis of gout flares, treatment of gout flares, and Familial Mediterranean Fever (FMF).
  - Gloperba® is only FDA approved for prophylaxis of gout flare.

- There are several off-label uses for colchicine with clinical support, such as for acute and recurrent pericarditis and Behcet's syndrome.

Guideline Update:

- The 2023 American Heart Association (AHA)/American College of Cardiology Foundation (ACC) Guideline for the Management of Patients with Chronic Coronary Disease recommends the use of colchicine 0.5mg daily for secondary prevention of recurrent atherosclerotic cardiovascular disease (ASCVD) events. They note that given colchicine's narrow therapeutic index and risk for drug interactions, the use should be limited to patients at very high risk despite maximum tolerated guideline directed therapy until further data becomes available.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Lodoco® (colchicine) 0.5mg tablet	**$16.50**	**$495.00**
Gloperba® (colchicine) 0.6mg/5mL oral solution	$3.97	$595.50
colchicine 0.6mg capsule (generic)	$3.23	$96.90
colchicine 0.6mg tablet (generic)	$0.24	$7.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule, mL, or tablet
*Cost per 30 days is based on a 0.5mg or 0.6mg once daily dose.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of Lodoco® or Gloperba® during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
COLCHICINE TAB 0.6MG	1,174	591	$15,333.51	$1.95	1.99	$13.06
COLCHICINE CAP 0.6MG	122	73	$3,172.89	$4.84	1.67	$26.01
MITIGARE CAP 0.6MG	1	1	$29.59	$14.79	1	$29.59
TOTAL	**1,297**	**649***	**$18,535.99**	**$2.18**	**2**	**$14.29**

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

Millipred™ (Prednisolone 5mg Tablet) Product Summary[31,32]

Therapeutic Class: Glucocorticoid

Indication(s): Endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic diseases, neoplastic diseases, edematous states, gastrointestinal diseases, nervous system, and miscellaneous diagnoses

How Supplied: 5mg oral tablet

Dosing and Administration:

- The initial recommended dose for prednisolone varies from 5mg to 60mg per day depending on the specific disease being treated.
- See full package labeling for dosing.

Other Formulation(s) Available:

- Prednisone 5mg tablet

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
prednisolone 5mg tablet (generic Millipred™)	**$14.00**	**$420.00**
prednisone 5mg tablet (generic)	$0.04	$1.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on once daily dosing of each product.

Calendar Year 2023 Utilization:

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PREDNISONE TAB 5MG	5,718	3,188	$61,415.20	$0.38	1.79	$10.74
PREDNISOLONE TAB 5MG	1	1	$1,123.61	$12.48	1	$1,123.61
TOTAL	**5,719**	**3,188***	**$62,538.81**	**$0.39**	**1.79**	**$10.94**

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

Motpoly XR™ (Lacosamide ER Capsule) Product Summary[33,34]

Therapeutic Class: Anticonvulsant

Indication(s): Treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50kg

How Supplied: 100mg, 150mg, and 200mg ER capsules

Dosing and Administration:

- See full package labeling for recommended initial and titration doses.
- Recommended maintenance dosing:
  - Adults (17 Years of Age and Older):
    - Monotherapy: 300mg to 400mg once daily
    - Adjunctive Therapy: 200mg to 400mg once daily
  - Pediatric Patients (Weighing at Least 50kg):
    - Monotherapy: 300mg to 400mg once daily
    - Adjunctive Therapy: 200mg to 400mg once daily

Other Formulation(s) Available:

- Lacosamide 50mg, 100mg, 150mg, 200mg Immediate-Release (IR) Tablets:
  - Lacosamide IR tablets have the same indication as Motpoly XR™; however, lacosamide is indicated in patients 4 years of age or older and the package labeling includes dosing for pediatric patients weighing 11kg or more. See full package labeling for recommended dosing.
  - The total daily dose for lacosamide tablets is the same as Motpoly XR™; however, the IR tablets are dosed twice daily.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*
Motpoly XR™ (lacosamide ER) 200mg capsule	**$20.83**	**$1,249.80**
lacosamide 200mg tablet (generic)	$0.32	$19.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the maximum FDA approved maintenance dose for an adult (17 years of age and older).
ER = extended-release

Calendar Year 2023 Utilization: There was no SoonerCare utilization of Motpoly XR™ during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
LACOSAMIDE TAB 200MG	2,850	421	$97,757.75	$1.10	6.77	$34.30
LACOSAMIDE TAB 100MG	2,275	528	$60,155.94	$0.86	4.31	$26.44
LACOSAMIDE TAB 150MG	1,328	254	$37,538.76	$0.91	5.23	$28.27
LACOSAMIDE TAB 50MG	1,139	301	$22,224.46	$0.64	3.78	$19.51
VIMPAT TAB 200MG	358	61	$420,560.52	$36.84	5.87	$1,174.75
VIMPAT TAB 100MG	217	50	$225,517.02	$33.38	4.34	$1,039.25
VIMPAT TAB 150MG	109	27	$105,582.15	$31.85	4.04	$968.64
VIMPAT TAB 50MG	63	22	$60,727.96	$29.80	2.86	$963.94
TOTAL	**8,339**	**1,190***	**$1,030,064.56**	**$3.98**	**7.01**	**$123.52**

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

Neo-Synalar® (Neomycin 0.5%/Fluocinolone 0.025% Cream) Product Summary[35,36,37,38,39,40,41]

Therapeutic Class: Topical antibiotic/topical corticosteroid

Indication(s): Treatment of corticosteroid-responsive dermatoses with secondary infection

- **Limitation(s) of Use:** It has not been demonstrated that this steroid-antibiotic combination provides greater benefit than the steroid component alone after 7 days of treatment.

How Supplied: 60 gram tube for topical use

Dosing and Administration:
- Neo-Synalar® should be applied to the affected area as a thin film 2 to 4 times daily depending on the severity of the condition.

Other Formulation(s) Available:
- Fluocinolone 0.025% Cream and Neosporin® Ointment (Bacitracin/ Neomycin/Polymyxin B):
  - Fluocinolone 0.025% cream and Neosporin® ointment have similar indications as Neo-Synalar®; however, Neosporin® is an over-the-counter product; therefore, it is not currently covered by SoonerCare.

Other Topical Antibiotics Available:
- Gentamicin 0.1% cream, gentamicin 0.1% ointment, mupirocin 2% cream, and mupirocin 2% ointment

Formulation Cost Comparison:

Product	Cost Per Gram	Cost Per 60 Grams
Neo-Synalar® (neomycin 0.5%/fluocinolone 0.025% cream)	**$15.54**	**$932.40**
mupirocin 2% cream (generic)	$1.79	$107.40
fluocinolone 0.025% cream (generic)	$1.15	$69.00
gentamicin 0.1% cream (generic)	$1.18	$70.80
gentamicin 0.1% ointment (generic)	$1.02	$61.20
mupirocin 2% ointment (generic)	$0.20	$12.00

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).

Calendar Year 2023 Utilization: There was no SoonerCare utilization of fluocinolone 0.025% cream or Neo-Synalar® during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
MUPIROCIN OINT 2%	51,345	43,902	$749,737.84	$1.32	1.17	$15.48
GENTAMICIN OINT 0.1%	367	199	$26,734.09	$5.43	1.84	$72.84
GENTAMICIN CRE 0.1%	204	131	$8,441.41	$2.08	1.56	$41.38
MUPIROCIN CRE 2%	21	16	$1,255.12	$4.42	1.31	$59.77
TOTAL	**51,937**	**44,169***	**$831,168.46**	**$1.36**	**1.18**	**$16.00**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; OINT = ointment

PoKonza™ (Potassium Chloride 10mEq Packet for Oral Solution) Product Summary[42,43,44,45,46,47]

Therapeutic Class: Electrolyte

Indication(s): Treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient

How Supplied: Each pouch contains 0.75g of potassium chloride providing potassium 10mEq and chloride 10mEq

Dosing and Administration:

- Treatment of Hypokalemia:
  - Adults: Initial doses range from 40-100mEq/day in 2-5 divided doses; doses should be limited to 40mEq per dose and total daily doses should not exceed 200mEq.
  - Pediatric Patients (Birth to 16 Years of Age): 2-4mEq/kg/day in divided doses; doses should not exceed 1mEq/kg as a single dose or 40mEq whichever is lower and total daily doses should not exceed 100mEq.
- Maintenance or Prophylaxis of Hypokalemia:
  - Adults: 20mEq per day
  - Pediatric Patients (Birth to 16 Years of Age): 1mEq/kg/day; doses should not exceed 3mEq/kg/day.
- The contents of 1 packet of PoKonza™ should be diluted in at least 4oz of cold water and taken with meals or immediately after eating.

Other Formulation(s) Available:

- Potassium Chloride ER Tablet, Potassium Chloride ER Dispersible Tablet, Potassium Chloride ER Sprinkle Capsule, Potassium Chloride Oral Solution, and Potassium Chloride Packet for Oral Solution:
  - All formulations have the same indications and recommended dose; however, the administration is different.
  - Potassium chloride ER tablet is a film coated tablet and must be swallowed whole. It is available in 8mEq, 10mEq, and 20mEq strengths.
  - For those who have difficulties swallowing, potassium chloride ER dispersible tablet, potassium chloride ER sprinkle capsules, potassium chloride oral solution, and potassium chloride packet for oral solution are available.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
PoKonza™ (potassium chloride 10mEq packet)	**$28.66**	**$1,719.60**
potassium chloride 20mEq packet (generic)	$1.30	$39.00
potassium chloride 20mEq/15mL oral solution (generic)	$0.08	$36.00
potassium chloride 10mEq ER sprinkle capsule (generic)	$0.12	$7.20
potassium chloride 10mEq ER tablet (generic)	$0.10	$6.00
potassium chloride 10mEq dispersible tablet (generic)	$0.10	$6.00

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, mL, packet, or tablet; ER = extended-release
*Cost per 30 days is based on the FDA approved maintenance dose of 20mEq per day for adults.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of PoKonza™ during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
POT CHLORIDE TAB 10MEQ ER	6,912	2,782	$99,384.68	$0.32	2.48	$14.38
POT CHLORIDE TAB 20MEQ ER	3,374	1,610	$75,547.23	$0.51	2.1	$22.39
POT CHLORIDE CAP 10MEQ ER	3,135	1,150	$53,422.49	$0.42	2.73	$17.04
POT CHLORIDE SOL 20MEQ/15ML	638	173	$30,423.15	$1.70	3.69	$47.69
POT CHLORIDE TAB 8MEQ ER	506	177	$8,888.93	$0.40	2.86	$17.57
POT CHLORIDE CAP 8MEQ ER	213	63	$3,968.43	$0.41	3.38	$18.63
POT CHLORIDE SOL 40MEQ/15ML	165	46	$15,793.38	$3.43	3.59	$95.72
KLOR-CON PAK 20MEQ	32	8	$2,411.08	$2.71	4	$75.35
POT CHOLORIDE POW 20MEQ	5	2	$286.73	$2.56	2.5	$57.35
TOTAL	**14,980**	**5,714***	**$290,126.10**	**$0.46**	**2.62**	**$19.37**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; MEQ = milliequivalent; PAK = packet; POT = potassium; POW = powder; SOL = solution; TAB = tablet

Suflave™ (PEG-3350/Sodium Sulfate/Potassium Chloride/Magnesium Sulfate/Sodium Chloride) Product Summary[48,49,50,51]

Therapeutic Class: Osmotic laxative

Indication(s): For cleansing of the colon in preparation for colonoscopy in adults

How Supplied: Suflave™ is supplied as a white powder for reconstitution and is available in a carton that contains 2 bottles with lemon-lime flavor enhancing packets.

Dosing and Administration:

- Administration of 2 doses is required for complete preparation for colonoscopy. One dose of Suflave™ is equal to 1 bottle plus 1 flavor enhancing packet.
- Split-Dose (2-Day) Regimen:
  - Dose 1:
    - Starting in the early evening prior to the colonoscopy, 1 bottle should be consumed with 1 flavor enhancing packet.
    - Each bottle should be reconstituted with water up to the fill line and 1 flavor enhancing packet should be added.
    - Drink 8 ounces of solution every 15 minutes until the bottle is empty then drink an additional 16 ounces of water during the evening.
  - Dose 2:
    - The morning of the colonoscopy the second dose should be consumed at least 5 to 8 hours prior to the colonoscopy and no sooner than 4 hours from starting dose 1.
    - Repeat dosing instructions under dose 1.
    - All liquids should be stopped at least 2 hours prior to colonoscopy.

Other Formulation(s) Available:

- GoLYTELY® (PEG-3350/Sodium Sulfate/Sodium Bicarbonate/Sodium Chloride/Potassium Chloride Powder), Nulytely® (PEG-3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride), and Moviprep® (PEG-3350/Sodium Sulfate/Sodium Chloride/Potassium Chloride/ Sodium Ascorbate/Ascorbic Acid Powder):
  - GoLYTELY®, NuLYTELY®, and MoviPrep® have the same indication as Suflave™ with an additional indication for GoLYTELY® of preparation for barium enema X-ray examination in adults.
  - GoLYTELY®, NuLYTELY®, and MoviPrep® offer different flavoring options such as pineapple, lemon-lime, and lemon.
  - Additionally, MoviPrep® is a low-volume colonoscopy prep that requires a similar amount of fluid to Suflave™.

Formulation Cost Comparison:

Product	Cost Per Treatment*
Suflave™ (PEG-3350/sodium sulfate/potassium chloride/ magnesium sulfate/sodium chloride powder)	**$119.77**
PEG-3350/sodium sulfate/sodium chloride/potassium chloride/ sodium ascorbate/ascorbic acid powder (generic MoviPrep®)	$77.87
PEG-3350/sodium chloride/sodium bicarbonate/potassium chloride powder (generic NuLYTELY®)	$27.88

Product	Cost Per Treatment*
PEG-3350/sodium sulfate/sodium bicarbonate/sodium chloride/ potassium chloride powder (generic GoLYTELY®)	$15.76

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per treatment based on the FDA recommended dose for colonoscopy preparation.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of Suflave™ during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
GAVILYTE-G SOL	5,219	4,933	$112,520.35	$15.21	1.06	$21.56
PEG-3350 SOL ELECTROL 236GM	1,325	1,259	$29,384.73	$13.41	1.05	$22.18
GAVILYTE-C SOL	1,029	995	$18,693.09	$13.57	1.03	$18.17
PEG-3350/KCL/SODIUM SOL	947	913	$34,118.25	$13.68	1.04	$36.03
PEG/NASUL/NACL/POT SOL	628	603	$55,749.36	$39.15	1.04	$88.77
GOLYTELY SOL	134	127	$3,262.56	$10.95	1.06	$24.35
MOVIPREP SOL	57	50	$7,516.85	$53.31	1.14	$131.87
PEG 3350 SOL ELECTROL 240GM	9	9	$156.23	$17.36	1	$17.36
GAVILYTE-N SOL FLAV PK	4	4	$114.76	$1.85	1	$28.69
TOTAL	**9,352**	**8,666***	**$261,516.18**	**$16.98**	**1.08**	**$27.96**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ELECTROL = electrolytes; FLAV = flavor; KCL = potassium chloride; NACL = sodium chloride; NASUL = sodium sulfate; PEG = polyethylene glycol; PK = pack; POT = potassium; SOL = solution

Valsartan Oral Solution Product Summary[52,53]

Therapeutic Class: Angiotensin II receptor blocker (ARB)

Indication(s):

- Hypertension in adults and children 6 years of age and older, to lower blood pressure
- Heart failure [New York Heart Association (NYHA) class II-IV] in adults
- Stable left ventricular failure or left ventricular dysfunction following myocardial infarction in adults

How Supplied: 4mg/mL oral solution in a 120mL bottle

Dosing and Administration:

- Hypertension in Adults: 40-160mg twice daily
- Hypertension in Children (6-16 Years of Age): 0.65-1.35mg/kg twice daily (up to 40mg total daily dose)
- Heart Failure in Adults: 40mg-160mg twice daily
- Post-Myocardial Infarction in Adults: 20mg to 160mg twice daily

Other Formulation(s) Available:

- Valsartan Tablets:
  - Valsartan tablets have the same indications as the valsartan solution; however, the tablets are indicated to treat hypertension in pediatric patients 1 year of age or older.
  - Valsartan solution is not therapeutically equivalent to the tablet formulation. The peak concentration of the oral solution is higher than with the tablets. The dosing provided in each package labeling should be followed.
  - The tablets are available in 40mg, 80mg, 160mg, and 320mg tablets. They are film coated so they cannot be crushed and must be swallowed whole.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
valsartan 4mg/mL oral solution (generic)	**$8.17**	**$2,451.00**
valsartan 40mg tablet (generic)	$0.12	$3.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days is based on the recommended maximum starting dose for pediatric hypertension of 40mg once daily.

Calendar Year 2023 Utilization: There was no SoonerCare utilization of valsartan oral solution during calendar year 2023.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
VALSARTAN 160MG TAB	1,293	504	$28,228.13	$0.38	2.57	$21.83
VALSARTAN 80MG TAB	1,202	471	$22,598.14	$0.34	2.55	$18.80
VALSARTAN 320MG TAB	738	273	$18,333.94	$0.38	2.7	$24.84
VALSARTAN 40MG TAB	674	241	$11,918.36	$0.34	2.8	$17.68
TOTAL	**3,907**	**1,345***	**$81,078.57**	**$0.36**	**2.9**	**$20.75**

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

Recommendations

The College of Pharmacy recommends the prior authorization of baclofen 15mg tablet, chlorzoxazone 250mg tablet, and Ozobax® DS 10mg/5mL (baclofen DS oral solution) with placement into the Special Prior Authorization (PA) Tier of the Muscle Relaxant Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Baclofen 5mg Tablet and Baclofen 15mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a baclofen 10mg tablet to achieve a 5mg or 15mg dose must be provided.

Fleqsuvy® (Baclofen 25mg/5mL Oral Suspension), Lyvispah® (Baclofen Oral Granules), ~~and~~ Ozobax® (Baclofen 5mg/5mL Oral Solution), and Ozobax® DS [Baclofen Double Strength (DS) 10mg/5mL Oral Solution] Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Requests for Fleqsuvy®, ~~and~~ Ozobax®, or Ozobax® DS will require a patient-specific, clinically significant reason why the member cannot use Lyvispah®; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Chlorzoxazone 250mg Tablet Approval Criteria:

1. A patient-specific, clinically specific reason why the member cannot split a 500mg chlorzoxazone tablet to achieve the 250mg dose must be provided.

Additionally, the College of Pharmacy recommends the prior authorization of Clindacin® ETZ Kit (clindamycin 1% swabs and cleanser) with the following criteria (shown in red):

Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason the member cannot use the preferred topical clindamycin products including lotion, solution, swabs, or the preferred generic clindamycin gel (generic Cleocin T®) must be provided; and
3. Clindacin® ETZ kit will not be covered for members older than 20 years of age.

The College of Pharmacy also recommends the prior authorization of Combogesic® IV (ibuprofen/acetaminophen injection) and Elyxyb™ (celecoxib oral solution) with placement into the Special PA Tier of the NSAIDs PBPA category with the following additional criteria (shown in red):

Combogesic® IV (Ibuprofen/Acetaminophen Injection) Approval Criteria:

1. An FDA approved indication in members where an intravenous (IV) route of administration is considered clinically necessary for 1 of the following:

a. Relief of mild-to-moderate pain; or
b. Management of moderate-to-severe pain as an adjunct to opioid analgesics; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member requires IV administration and cannot use Tier-1 oral and/or topical alternatives must be provided; and
4. A quantity limit of 2,000mL (20 vials) per 5 days will apply; and
5. A maximum approval duration of 5 days will apply, as Combogesic® IV is only indicated for short-term use of 5 days or less.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and
4. Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose; and
5. Additionally, use of Elyxyb™ (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
6. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products; and
7. Additionally, use of Tivorbex® will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.

Additionally, the College of Pharmacy recommends the prior authorization of Ingrezza® Sprinkle (valbenazine) with criteria similar to Ingrezza® (valbenazine) with the following additional criteria based on net cost and to be consistent with clinical practice (changes shown in red):

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

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and

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

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

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and
    b. History of treatment with dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and

2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist, or a mid-level practitioner with a supervising physician that is a neurologist or psychiatrist; and
4. Use of Ingrezza® Sprinkle will require a patient-specific, clinically significant reason why the member cannot use Ingrezza®; and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
6. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
7. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
8. Member must not be taking monoamine oxidase inhibitors (MAOIs) in the last 14 days; and
9. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
10. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
11. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
12. Female members must not be pregnant or breastfeeding; and
13. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
14. Prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
15. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
16. A quantity limit of 1 capsule per day will apply; and
17. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

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

Lodoco® (Colchicine) Approval Criteria:

1. An FDA approved indication to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death; and
2. Member must be 18 years of age or older; and

3. Member must have a diagnosis history of clinical atherosclerotic cardiovascular disease (ASCVD); and
    a. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD must be provided;
4. Member must already be receiving guideline-directed therapy for atherosclerotic disease, as documented in the member's pharmacy claims history, unless contraindicated; and
5. Lodoco® must be prescribed by a cardiologist or other specialist with expertise in the treatment and management of ASCVD; and
6. Member must not have kidney failure, severe liver disease, or pre-existing blood dyscrasias; and
7. The member must not be taking any P-gp inhibitors (e.g., cyclosporine, ranolazine) or strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole) concurrently with Lodoco®; and
8. A quantity limit of 30 tablets per 30 days will apply.

Additionally, the College of Pharmacy recommends removing the prior authorization of Colcrys® (colchicine tablet) based on net cost (changes shown in red):

~~Colcrys® (Colchicine Tablet),~~ Gloperba® (Colchicine Oral Solution)~~,~~ and Mitigare® (Colchicine Capsule) Approval Criteria:

1. A quantity of 6 ~~tablets/~~capsules for a 3-day supply is available without prior authorization for treatment of acute gouty attacks; and
2. Failure of allopurinol after 6 months of treatment defined by persistent gouty attacks with serum urate levels greater than 6.0mg/dL; and
3. A patient-specific, clinically significant reason why colchicine tablets (generic Colcrys®) or colchicine/probenecid would not be a viable option for the member must be provided; and
4. For authorization of Gloperba, a patient-specific, clinically significant reason why the member cannot use colchicine tablets or capsules must be provided; and
5. A quantity limit of 60 ~~tablets/~~capsules per 30 days or 300mL per 30 days will apply for gout; and
6. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

The College of Pharmacy also recommends the prior authorization of Millipred™ (prednisolone) tablet and Motpoly XR™ (lacosamide ER) with the following criteria (shown in red):

Millipred™ (Prednisolone 5mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use prednisone 5mg tablets must be provided.

Motpoly XR™ [Lacosamide Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must weigh ≥50kg; and
3. A patient specific, clinically significant reason why the member cannot use the immediate-release tablets must be provided; and
4. The following quantity limits will apply:
    a. Motpoly XR™ 100mg: 30 capsules per 30 days; or
    b. Motpoly XR™ 150mg and 200mg: 60 capsules per 30 days.

The College of Pharmacy also recommends the prior authorization of Neo-Synalar® with placement into Tier-2 of the Topical Antibiotic Products PBPA category with the following additional criteria (shown in red):

Neo-Synalar® (Neomycin 0.5%/Fluocinolone 0.025% Cream) Approval Criteria:

1. An FDA approved diagnosis of corticosteroid-responsive dermatoses with secondary infection; and
2. A patient specific, clinically significant reason why the member cannot use a Tier-1 topical antibiotic in combination with a Tier-1 medium to very-high potency topical corticosteroid must be provided; and
3. Approvals will be for 1 tube for the duration of 7 days.

The College of Pharmacy also recommends the prior authorization of PoKonza™ (potassium chloride 10mEq packet) with criteria similar to Klor-Con® (potassium chloride 20mEq packet) and updating the criteria as follows (changes shown in red):

Klor-Con® (Potassium Chloride 20mEq Packet) and Pokonza™ (Potassium Chloride 10mEq Packet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all the following must be provided:
    a. Potassium chloride tablet; and
    b. Potassium chloride extended-release (ER) dispersible tablet; and
    c. Potassium chloride ER sprinkle capsule; and
    d. Potassium chloride oral solution.

The College of Pharmacy also recommends the prior authorization of Suflave® (PEG-3350/sodium sulfate/potassium chloride/magnesium sulfate/sodium chloride) with criteria similar to the other bowel preparation medications (changes shown in red):

Clenpiq®, ColPrep™ Kit, OsmoPrep®, Plenvu®, Prepopik®, Suflave®, SUPREP®, and Sutab® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use other bowel preparation medications available without prior authorization must be provided; and
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, Moviprep® is available without prior authorization. Other medications currently available without a prior authorization include: Colyte®, Gavilyte®, Golytely®, and Trilyte®.

The College of Pharmacy also recommends the prior authorization of valsartan 4mg/mL oral solution with placement into Tier-3 of the ARBs and ARB Combination Products PBPA category with the following additional criteria (shown in red):

Valsartan 4mg/mL Oral Solution Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Hypertension in adults and pediatric members 6 years of age and older; or
   b. Heart failure; or
   c. Post-myocardial infarction; and
2. A patient specific, clinically significant, reason why the member cannot use valsartan tablets must be provided; and
3. A quantity limit of 360mL per 36 days will apply.

Finally, the College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for RediTrex® due to product discontinuation and recommends updating the following criteria based on net cost (shown in red):

Otrexup®~~, and Rasuvo®, and RediTrex®~~ (Methotrexate Injection Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Severe, active rheumatoid arthritis (RA) in adult members; or
   b. Active polyarticular juvenile idiopathic arthritis (pJIA) in pediatric members; or
   c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
2. A patient-specific, clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.~~; and~~

~~3. Authorization of Otrexup® will also require a patient-specific, clinically significant reason why the member cannot use Rasuvo® or RediTrex®.~~

Utilization Details of Various Special Formulations: Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEVOTHYROXINE PRODUCTS					
TIROSINT-SOL SOL 62.5MCG/ML	32	6	$4,720.32	$147.51	5.33
TIROSINT CAP 200MCG	31	8	$7,893.67	$254.63	3.88
TIROSINT CAP 137MCG	30	8	$6,240.92	$208.03	3.75
TIROSINT CAP 125MCG	29	11	$6,218.78	$214.44	2.64
TIROSINT CAP 100MCG	28	8	$7,240.64	$258.59	3.5
TIROSINT CAP 25MCG	26	4	$7,096.70	$272.95	6.5
TIROSINT CAP 112MCG	25	8	$6,392.61	$255.70	3.13
TIROSINT CAP 75MCG	22	6	$5,378.06	$244.46	3.67
TIROSINT-SOL SOL 75MCG/ML	18	4	$2,678.38	$148.80	4.5
TIROSINT-SOL SOL 200MCG/ML	17	6	$2,503.05	$147.24	2.83
TIROSINT-SOL SOL 88MCG/ML	17	3	$2,498.97	$147.00	5.67
TIROSINT-SOL SOL 50MCG/ML	15	5	$1,674.71	$111.65	3
TIROSINT CAP 50MCG	14	3	$3,532.26	$252.30	4.67
TIROSINT CAP 150MCG	13	6	$3,120.93	$240.07	2.17
TIROSINT-SOL SOL 25MCG/ML	13	8	$1,825.99	$140.46	1.63
TIROSINT-SOL SOL 100MCG/ML	8	3	$1,165.88	$145.74	2.67
TIROSINT-SOL SOL 125MCG/ML	8	4	$1,173.18	$146.65	2
TIROSINT CAP 88MCG	8	4	$1,287.06	$160.88	2
TIROSINT-SOL SOL 13MCG/ML	7	3	$1,189.87	$169.98	2.33
LEVOTHYROXINE CAP 112MCG	7	3	$1,952.25	$278.89	2.33
TIROSINT-SOL SOL 112MCG/ML	7	2	$1,035.47	$147.92	3.5
TIROSINT-SOL SOL 37.5MCG/ML	7	2	$1,041.27	$148.75	3.5
ERMEZA SOL 150MCG/5ML	6	2	$678.63	$113.11	3
LEVOTHYROXINE CAP 75MCG	6	2	$2,297.68	$382.95	3
TIROSINT-SOL SOL 150MCG/ML	5	2	$1,901.95	$380.39	2.5
LEVOTHYROXINE CAP 13MCG	4	1	$540.78	$135.20	4
TIROSINT-SOL SOL 44MCG/ML	4	2	$595.84	$148.96	2
TIROSINT CAP 175MCG	3	2	$695.02	$231.67	1.5
LEVOTHYROXINE CAP 125MCG	3	1	$414.81	$138.27	3
TIROSINT-SOL SOL 137MCG/ML	1	1	$140.61	$140.61	1
TIROSINT-SOL SOL 175MCG/ML	1	1	$140.61	$140.61	1
SUBTOTAL	**415**	**129**	**$85,266.90**	**$205.46**	**3.22**
METHOTREXATE PRODUCTS					
RASUVO INJ 25MG	48	14	$22,432.52	$467.34	3.43
XATMEP SOL 2.5MG/ML	39	9	$20,607.18	$528.39	4.33
RASUVO INJ 7.5MG	30	5	$16,254.30	$541.81	6
RASUVO INJ 15MG	25	7	$12,459.58	$498.38	3.57
RASUVO INJ 20MG	16	5	$8,601.60	$537.60	3.2
OTREXUP INJ 17.5MG	3	1	$2,241.03	$747.01	3
RASUVO INJ 22.5MG	3	1	$1,666.23	$555.41	3

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OTREXUP INJ 15MG	2	1	$1,494.02	$747.01	2
OTREXUP INJ 25MG	1	1	$90.80	$90.80	1
SUBTOTAL	**167**	**44**	**$85,847.26**	**$514.06**	**3.8**
DROSPIRENONE PRODUCTS					
SLYND TAB 4MG	82	33	$30,306.24	$369.59	2.48
SUBTOTAL	**82**	**33**	**$30,306.24**	**$369.59**	**2.48**
MERCAPTOPURINE PRODUCTS					
PURIXAN SUS 20MG/ML	73	19	$95,789.90	$1,312.19	3.84
SUBTOTAL	**73**	**19**	**$95,789.90**	**$1,312.19**	**3.84**
POTASSIUM PRODUCTS					
KLOR-CON PAK 20MEQ	32	8	$2,411.08	$75.35	4
POT CHLORIDE POW 20MEQ	5	2	$286.73	57.35	2.5
SUBTOTAL	**37**	**10**	**$2,697.81**	**$72.91**	**3.7**
DROSPIRENONE/ESTETROL PRODUCTS					
NEXTSTELLIS TAB 3/14.2MG	30	5	$6,177.48	$205.92	6
SUBTOTAL	**30**	**5**	**$6,177.48**	**$205.92**	**6**
GABAPENTIN PRODUCTS					
HORIZANT TAB 600MG ER	14	5	$12,633.16	$902.37	2.8
GRALISE TAB 600MG	11	1	$3,390.32	$308.21	11
SUBTOTAL	**25**	**6**	**$16,023.48**	**$640.94**	**4.17**
NORETHINDRONE ACE/ETHINYL ESTRADIOL/FE PRODUCTS					
GEMMILY CAP 1MG/20MCG	13	1	$616.09	$47.39	13
TAYTULLA CAP 1MG/20MCG	12	1	$2,763.96	$230.33	12
SUBTOTAL	**25**	**2**	**$3,380.05**	**$135.20**	**12.5**
PREGABALIN PRODUCTS					
PREGABALIN ER TAB 165MG	20	3	$3,390.62	$169.53	6.67
PREGABALIN ER TAB 330MG	2	1	$590.26	$295.13	2
SUBTOTAL	**22**	**4**	**$3,980.88**	**$180.95**	**5.5**
LACTULOSE PRODUCTS					
KRISTALOSE PAK 20GM	5	2	$3,305.45	$661.09	2.5
SUBTOTAL	**5**	**2**	**$3,305.45**	**$661.09**	**2.5**
LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE PRODUCTS					
PHEXXI GEL 1.8/1/0.4%	3	1	$1,006.74	$335.58	3
SUBTOTAL	**3**	**1**	**$1,006.74**	**$335.58**	**3**
PREDNISOLONE PRODUCTS					
PREDNISOLONE TAB 5MG	1	1	$1,123.61	$1,123.61	1
SUBTOTAL	**1**	**1**	**$1,123.61**	**$1,123.61**	**1**
METOCLOPRAMIDE PRODUCTS					
GIMOTI SPR 15MG	1	1	$1,935.41	$1,935.41	1
SUBTOTAL	**1**	**1**	**$1,935.41**	**$1,935.41**	**1**
TOTAL	**886**	**220***	**$336,840.21**	**$380.18**	**4.03**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACE = acetate; CAP = capsule; ER = extended release; FE = iron; INJ = injection; PAK = packet; POT = potassium; POW = powder; SOL = solution; SUS = suspension; TAB = tablet

- There were no SoonerCare paid pharmacy claims for calendar year 2023 for the following various special formulation products: Absorica LD® (isotretinoin capsule), Aspruzyo Sprinkle™ (ranolazine ER granules), GoNitro™ (nitroglycerin sublingual powder), Jylamvo® (methotrexate oral solution), Khapzory™ (levoleucovorin injection), Metozolv® ODT [metoclopramide orally disintegrating tablet (ODT)], pyridostigmine 30mg tablet, RediTrex® (methotrexate injection solution), Reltone® (ursodiol capsule), Soltamox® (tamoxifen citrate 10mg/5mL oral solution), and Vuity™ (pilocarpine hydrochloride ophthalmic solution 1.25%).

---

[1] Ozobax® DS (Baclofen 10mg/5ml Oral Solution) Prescribing Information. Metacel Pharmaceuticals, LLC. Available online at: https://ozobaxds.com/wp-content/uploads/2023/10/Ozobax-DS-baclofen-Oral-Solution-10-mg-5-mL-Prescribing-Information-v00-rev0923.pdf. Last revised 09/2023. Last accessed 04/18/2024.
[2] Baclofen Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=68aa591e-ea98-4438-9a4a-4f7e9ea2b285. Last revised 08/17/2024. Last accessed 04/29/2024.
[3] Fleqsuvy® (Baclofen 25mg/5mL Oral Solution) Prescribing Information. Azurity Pharmaceuticals, LLC. Available online at: https://azurity.com/wp-content/uploads/2022/02/FLEQSUVY-PI-02-04-2022.pdf. Last revised 02/2023. Last accessed 04/18/2024.
[4] Lyvispah® (Baclofen Oral Granules) Prescribing Information. Saol Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215422lbl.pdf. Last revised 11/2021. Last accessed 04/18/2024.
[5] Ozobax® (Baclofen 5mg/5ml Oral Solution) Prescribing Information. Metacel Pharmaceuticals, LLC. Available online at: https://ozobax.com/wp-content/uploads/2020/08/P-010165-V1.pdf. Last revised 05/2020. Last accessed 04/18/2024.
[6] Chlorzoxazone 250mg Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e0d10d67-9716-450b-b8a9-4e157008864e. Last revised 08/25/2023. Last accessed 04/19/2024.
[7] Chlorzoxazone Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=52d3aa2c-f88f-4de7-b5ae-df8a46e94879. Last revised 09/05/2023. Last accessed 04/19/2024.
[8] Clindacin® ETZ Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=89fed26e-1cad-4c0b-8695-d6f3562ba8d5. Last revised 11/14/2023. Last accessed 04/19/2024.
[9] Clindamycin Phosphate Gel Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=96434354-a646-4869-92a2-4052d3f7a4aa. Last revised 04/04/2024. Last accessed 04/19/2024.
[10] Clindamycin Phosphate Lotion Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ba6ae5da-affa-422b-9a53-28f3fc001523. Last revised 01/20/2022. Last accessed 04/19/2024.
[11] Clindamycin Phosphate Solution Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=461ab478-3cf6-4e9b-ba7d-0331b379cacf. Last revised 05/26/2022. Last accessed 04/19/2024.
[12] Combogesic® IV Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=be408a5a-48e4-43c0-9cb1-bbf830b54f5b&audience=consumer. Last revised 04/29/2024. Last accessed 05/15/2024.
[13] Ibuprofen Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=24731405-219c-79b4-ecf0-7d5fbfda94ba. Last revised 04/30/2022. Last accessed 04/22/2024.
[14] Caldolor® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1eaa7790-f1a1-4f51-b10a-cbbaf033f684. Last revised 05/17/2023. Last accessed 04/22/2024.

[15] Acetaminophen Injection Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3b4ab1cf-8642-44f5-b3a2-3f1f7c620ce9. Last revised 05/14/2020. Last accessed 04/22/2024.
[16] Elyxyb™ Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a0bfcba9-0af6-4b45-80e3-c4c94065b777&audience=consumer. Last revised 10/01/2021. Last accessed 04/25/2024.
[17] Celecoxib Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=806e5f8a-f986-4f88-ba3e-8265f86afa48&audience=consumer. Last revised 09/30/2021. Last accessed 04/25/2024.
[18] Loo C, Tan H, Teh H, et al. Randomized, Open Label, Controlled Trial of Celecoxib in the Treatment of Acute Migraine. *Singapore Med J* 2007; 48(9):834-839.
[19] Cambia® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d249ced1-4ca0-4f57-adcb-23440f58f659&audience=consumer. Last revised 04/30/2021. Last accessed 04/25/2024.
[20] Ailani J, Burch R, Robbins M, et al. The American Headache Society Consensus Statement: Update on Integrating New Migraine Treatments into Clinical Practice. *Headache* 2021; 61:1021–1039. doi: 10.1111/head.14153.
[21] Ibuprofen Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=24731405-219c-79b4-ecf0-7d5fbfda94ba. Last revised 04/30/2022. Last accessed 05/23/2024.
[22] Naproxen Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6c5bb008-e66f-4ef0-bf84-aca7eb5983e9. Last revised 05/31/2021. Last accessed 05/23/2024.
[23] Ingrezza® (Valbenazine) Prescribing Information. Neurocrine Biosciences, Inc. Available online at: https://www.neurocrine.com/assets/2024/04/INGREZZA-Full-Prescribing-Information_PI_Approved.pdf. Last revised 04/2024. Last accessed 05/08/2024.
[24] Lodoco® (Colchicine) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ff06d68f-d65f-d097-e053-6294a90a7e5f. Last revised 08/24/2023. Last accessed 04/26/2024.
[25] Colchicine Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7daef7e2-888d-4116-81a9-2c02b9ef97ef. Last revised 12/27/2021. Last accessed 04/26/2024.
[26] Colchicine Capsule Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ee1583ac-c308-4beb-b602-9ecac4977026&audience=consumer. Last revised 11/27/2023. Last accessed 04/26/2024.
[27] Gloperba® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6971137c-deef-4309-909e-552f1930999d&audience=consumer. Last revised 02/05/2019. Last accessed 04/26/2024.
[28] Chiabrando J, Bonaventura A, Vecchié A, et al. Management of Acute and Recurrent Pericarditis. *J Am Coll Cardiol* 2020; 75(1):76-92. doi: 10.1016/j.jacc.2019.11.021.
[29] Alibaz-Oner F, Direskeneli H. Advances in the Treatment of Behcet's Disease. *Curr Rheumatol Rep* 2021; 23(6):47. doi: 10.1007/s11926-021-01011-z.
[30] Virani S, Newby K, Arnold S, et al. 2023 AHA/ACC/ASPC/NLA/PCNA Guideline for the Management of Patients with Chronic Coronary Disease: A Report of the American Heart Association/American College of Cardiology Join Committee on Clinical Practice Guidelines. *Circulation* 2023; 148: e9-e119. doi: 10.1161/CIR.0000000000001168.
[31] Millipred Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b9a97cfa-53a3-4080-98da-7cca8ba1e0fb&audience=consumer. Last revised 12/13/2021. Last accessed 04/29/2024.
[32] Prednisone Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aa0b1582-6ef3-4697-9ea6-5391e6e57853&audience=consumer. Last revised 10/01/2015. Last accessed 04/29/2024.
[33] Motpoly XR™ (Lacosamide ER) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fb8235b4-4cd3-6f22-e053-6294a90a545c. Last revised 12/21/2023. Last accessed 04/29/2024.
[34] Lacosamide Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=46b98d5e-fdb6-483a-b022-8b1f0aa832c5&audience=consumer. Last revised 01/27/2023. Last accessed 04/29/2024.

[35] Neo-Synalar® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1141956e-8a4c-4f80-95d1-f15bdb57fdf6. Last revised 01/10/2023. Last accessed 04/30/2024.
[36] Synalar® 0.025% Cream Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5af2e4c1-082b-48a0-aae7-72d4a68cbb2d&audience=consumer. Last revised 12/08/2023. Last accessed 05/01/2024.
[37] Neosporin® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a3e6fe2e-1b74-4f22-9c7c-a00057439690&audience=consumer. Last revised 01/11/2023. Last accessed 05/01/2024.
[38] Gentamicin 0.1% Cream Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4cfbe37e-11d6-46fc-b287-0561387b17b7&audience=consumer. Last revised 09/24/2021. Last accessed 05/01/2024.
[39] Gentamicin 0.1% Ointment Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=16474069-510b-0754-9d78-9bc0354f6549&audience=consumer. Last revised 11/23/2023. Last accessed 05/01/2024.
[40] Mupirocin 2% Ointment Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ff7428fb-9ce9-4743-b58c-01a05424a57a&audience=consumer. Last revised 11/24/2023. Last accessed 05/01/2024.
[41] Mupirocin 2% Cream Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a69cd608-d2e6-4a7a-8cd7-f761bd333542&audience=consumer. Last revised 12/11/2023. Last accessed 05/01/2024.
[42] PoKonza® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7c5cc705-e5da-4487-86c9-9d545a95afb4. Last revised 03/22/2024. Last accessed 05/03/2024.
[43] Potassium Chloride ER Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0224e5b3-3c49-4e6e-aa78-1abcc6969246. Last revised 12/26/2019. Last accessed 05/07/2024.
[44] Potassium Chloride ER Dispersible Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c75665fb-0a99-4766-84a4-254987db6908. Last revised 02/06/2024. Last accessed 05/07/2024.
[45] Potassium Chloride ER Capsule Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ed5baaf6-270b-4dd3-b100-36030c0098fc. Last revised 08/01/2022. Last accessed 05/07/2024.
[46] Potassium Chloride Oral Solution Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=142c30ff-a839-4616-8167-ad4b07d8456f. Last revised 08/10/2022. Last accessed 05/07/2024.
[47] Potassium Chloride 20mEq Packet for Oral Solution Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=23d818e7-c076-40de-8dc1-0b51ba4be96a. Last revised 08/28/2020. Last accessed 05/08/2024.
[48] Suflave™ Prescribing Information. Braintree Laboratories, Inc. Available online at: https://suflave.com/media/SUFLAVE-FPI-Med-Leaflet_2023-06-23.pdf. Last revised 06/2023. Last accessed 05/09/2024.
[49] GoLYTELY® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=57d22b0b-1ae0-4203-babc-f3bac17bd1c9&audience=consumer. Last revised 05/28/2021. Last accessed 05/09/2024.
[50] NuLYTELY® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e7cf708c-937e-4aae-ab0a-0361c144a256&audience=consumer. Last revised 06/16/2022. Last accessed 05/09/2024.
[51] MoviPrep® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8ff46193-2a3b-4de0-9572-775dda8cd8b2&audience=consumer, Last revised 06/01/2023. Last accessed 05/09/2024.
[52] Valsartan Oral Solution Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=130e1659-9c2d-49ca-9db8-d28aa23fd133. Last revised04/07/2022. Last accessed 05/10/2024.
[53] Valsartan Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0878f27e-5368-c93f-e063-6394a90a1086. Last revised 10/24/2023. Last accessed 05/10/2024.

Appendix P

Calendar Year 2023 Annual Review of Daybue™ (Trofinetide)

Oklahoma Health Care Authority
June 2024

Current Prior Authorization Criteria

Daybue™ (Trofinetide) Approval Criteria:

1. Diagnosis of typical Rett syndrome confirmed by all of the following:
    a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
        i. A period of regression followed by recovery or stabilization; and
        ii. Partial or complete loss of acquired purposeful hand skills; and
        iii. Partial or complete loss of acquired spoken language; and
        iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
        v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
        vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
        vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and
    b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene (results of genetic testing must be submitted); and
2. Member must be 2 years of age or older; and
3. Daybue™ must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea and weight loss associated with Daybue™ and agree to monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue™, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have moderate or severe renal impairment; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to

ensure accurate weight-based dosing according to package labeling; and

8. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
9. A quantity limit of 3,600mL per 30 days will apply.

Utilization of Daybue™ (Trofinetide): Calendar Year 2023

Calendar Year 2023 Utilization

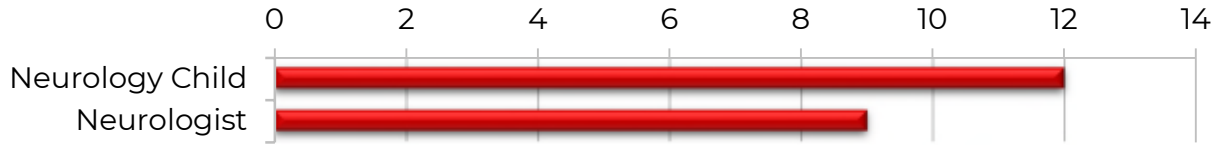
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2023	8	21	$797,763.47	$37,988.74	$1,363.70	46,800	585

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

Demographics of Members Utilizing Daybue™ (Trofinetide)

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

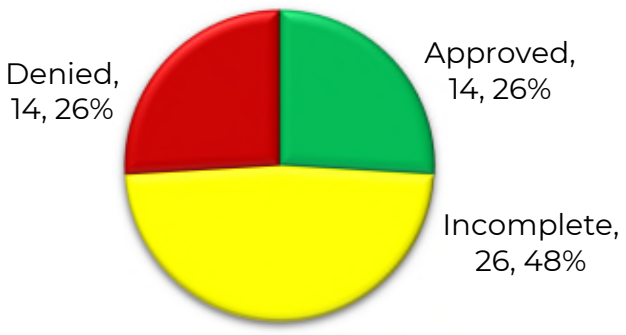
Top Prescriber Specialties of Daybue™ (Trofinetide) by Number of Claims



Prior Authorization of Daybue™ (Trofinetide)

There were 54 prior authorization requests submitted for 10 unique members for Daybue™ during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Daybue™ (trofinetide): August 2040

Recommendations

The College of Pharmacy does not recommend any changes to the current Daybue™ (trofinetide) prior authorization criteria at this time.

Utilization Details of Daybue™ (Trofinetide): Calendar Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DAYBUE SOL 200MG/ML	21	8	$797,763.47	$37,988.74	2.63	100%
TOTAL	**21**	**8***	**$797,763.47**	**$37,988.74**	**2.63**	**100%**

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

[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 05/2024. Last Accessed 05/14/2024.

Appendix Q

Calendar Year 2023 Annual Review of Joenja® (Leniolisib)

Oklahoma Health Care Authority
June 2024

Current Prior Authorization Criteria

Joenja® (Leniolisib) Approval Criteria:

1. An FDA approved diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS). Diagnosis must be confirmed by the following:
    a. Genetic testing identifying a documented pathogenic variant in either the *PIK3CD* or *PIK3R1* gene (results of genetic testing must be submitted); and
2. Member must be 12 years of age or older and weigh ≥45kg; and
3. Joenja® must be prescribed by, or in consultation with, an immunologist, geneticist, or a specialist with expertise in treatment of APDS; and
4. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation, and must agree to use effective contraception during treatment and for 1 week after the final dose of Joenja®; and
5. Member must not have moderate to severe hepatic impairment (Child-Pugh class B or C); and
6. Member must not be taking any of the following medications concomitantly with Joenja®:
    a. Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
    b. Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone); and
    c. CYP1A2 metabolized drugs with a narrow therapeutic range (e.g., tizanidine, theophylline); and
    d. OATP1B1/3 substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and
    e. BCRP transporter substrates (e.g., sulfasalazine, ubrogepant, tenofovir); and
7. Initial approvals will be for the duration of 3 months. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 tablets per 30 days will apply.

Utilization of Joneja® (Leniolisib): Calendar Year 2023

There was no SoonerCare utilization of Joneja® (leniolisib) during calendar year 2023.

Prior Authorization of Joneja® (Leniolisib)

There were no prior authorization requests submitted for Joenja® (leniolisib) during calendar year 2023.

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Joenja® (leniolisib): February 2032

Pipeline:

- **Joenja® (Leniolisib):** Joenja® tablets are currently being evaluated in a Phase 3 trial in patients 4 to 11 years of age with activated phosphoinositide 3-kinase delta syndrome (APDS), and enrollment for this trial is now complete. Additionally, a new granule formulation of leniolisib is also being evaluated in Phase 3 trials in patients 1 to 6 years of age with APDS.

Recommendations

The College of Pharmacy does not recommend any changes to the current Joenja® (leniolisib) prior authorization criteria at this time.

---

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 05/2024. Last accessed 05/01/2024.

[2] Pharming. Pharming Announces Completion of Enrollment in Pediatric Clinical Trial of Leniolisib. Available online at: https://www.pharming.com/sites/default/files/imce/Press%20releases/PED%201_Completion%20of%20Enrollment_EN_8APRIL2024.pdf. Issued 04/08/2024. Last accessed 05/01/2024.

[3] Pharming. Pharming Announces First Patient Dosed in Pediatric Clinical Trial for Children Aged 1 to 6 Years for Leniolisib. Available online at: https://www.pharming.com/sites/default/files/imce/Press%20releases/Pharming%20PED2%20Press%20Release_EN_21NOV23.pdf. Issued 11/21/2023. Last accessed 05/01/2024.

Appendix R

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

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

FDA NEWS RELEASE

For Immediate Release: May 28, 2024

FDA Approves First Interchangeable Biosimilar for Two Rare Diseases

The FDA approved Bkemv™ (eculizumab-aeeb) as the first interchangeable biosimilar to Soliris® (eculizumab) to treat certain rare diseases. Bkemv™ is approved for the following treatment indications, which are also currently approved for Soliris®:

- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis; and
- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

A disease is considered rare if it affects fewer than 200,000 people in the United States. The conditions PNH and aHUS are rare diseases characterized by the breakdown of red blood cells. PNH results in anemia, thrombosis, pancytopenia, and dark urine, while aHUS results in anemia, thrombocytopenia, and kidney failure.

Bkemv™ is a monoclonal antibody that binds to the complement C5 protein and inhibits activation of the complement system. This binding prevents the breakdown of red blood cells in the bloodstream (intravascular hemolysis) in patients with PNH and aHUS. Bkemv™, like Soliris®, has a *Boxed Warning* that states that eculizumab products increase the risk of serious and life-threatening meningococcal infections caused by *Neisseria meningitidis*. Patients should have completed meningococcal vaccination before starting Bkemv™ or Soliris®, be monitored for early signs and symptoms of meningococcal infections, and undergo further evaluation immediately if signs of infection develop.

As an interchangeable biosimilar, Bkemv™ is highly similar with no clinically meaningful differences to Soliris®. Bkemv™ has the same safety warnings and is expected to have the same adverse reactions as Soliris®. The most frequently reported adverse reactions in the PNH randomized trial for Soliris® (≥10% overall and greater than placebo) are headache, nasopharyngitis, back pain, and nausea. The most frequently reported adverse reactions in aHUS single arm prospective trials for Soliris® (≥20%) are headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, swelling of lower legs or hands, nausea, urinary tract infections, and fever.

Bkemv™ is available only through a restricted program called the Bkemv™ Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. Bkemv™ is the 53rd approved biosimilar in the United States. The FDA has approved 13 of these as interchangeable biosimilars. An interchangeable biosimilar is a biosimilar that has been shown to meet other requirements under the law and may be substituted for the reference product without consulting the prescriber. The substitution may occur at the pharmacy, subject to state pharmacy laws which vary by state, a practice commonly called “pharmacy-level substitution” - similar to generic drug substitution for brand name drugs. All biological products are approved only after meeting the FDA’s rigorous approval standards. This

means health care providers and patients can expect the same safety and effectiveness from both a biosimilar and an interchangeable biosimilar, just as they would for a reference product.

The approval of biosimilar and interchangeable biosimilar products furthers the FDA's longstanding commitment to support a competitive marketplace for biological products and increase patient access to more affordable treatment options. The FDA granted the approval of Bkemv™ to Amgen Inc.

FDA NEWS RELEASE

For Immediate Release: April 24, 2024

FDA Approves New Treatment for Uncomplicated Urinary Tract Infections (UTIs)

The FDA approved Pivya™ (pivmecillinam) tablets for the treatment of female adults with uncomplicated UTIs caused by susceptible isolates of *Escherichia coli*, *Proteus mirabilis,* and *Staphylococcus saprophyticus*. Uncomplicated UTIs are bacterial infections of the bladder in females with no structural abnormalities of their urinary tract. Approximately one-half of all women experience at least 1 UTI in their lifetime.

The efficacy of Pivya™ in treating females 18 years of age or older with uncomplicated UTIs was assessed in 3 controlled clinical trials comparing different Pivya™ dosing regimens to placebo, to another oral antibacterial drug, and to ibuprofen. The primary measure of efficacy for the 3 trials was the composite response rate, which included clinical cure and microbiological response. The composite response rate was assessed approximately 8 to 14 days after patients were enrolled into the studies. In the clinical trial comparing Pivya™ to placebo, 62% of the 137 subjects who received Pivya™ achieved the composite response compared to 10% of the 134 who received placebo. In the clinical trial comparing Pivya™ to another oral antibacterial drug, 72% of the 127 subjects who received Pivya™ achieved composite response compared to 76% of the 132 who received the comparator drug. In the clinical trial comparing Pivya™ to ibuprofen, 66% of the 105 subjects who received Pivya™ achieved composite response compared to 22% of the 119 who received ibuprofen.

The most common side effects of Pivya™ included nausea and diarrhea. Patients should not use Pivya™ if they have a known history of severe hypersensitivity to Pivya™ or other beta-lactam antibacterial drugs. Patients should also not use Pivya™ if they have primary or secondary carnitine deficiency resulting from inherited disorders of mitochondrial fatty acid oxidation and carnitine metabolism, or if they are suffering from porphyria. Pivya™ comes with certain warnings and precautions such as hypersensitivity reactions, severe cutaneous adverse reactions, carnitine depletion, *Clostridioides difficile*-associated diarrhea, and interference with a newborn screening test for isovaleric acidemia, a rare metabolic disorder.

Pivya™ was granted Priority Review and Qualified Infectious Disease Product designations for this indication. The FDA granted the approval of Pivya™ to UTILITY therapeutics Ltd.

Current Drug Shortages Index (as of May 29, 2024):

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

Albuterol Sulfate Solution	***Currently in Shortage***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Disopyramide Phosphate Capsule	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***

Epinephrine Injection, Syringes	***Currently in Shortage***
Erythromycin Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Mefloquine Hydrochloride Tablet	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methotrexate Sodium Tablet	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***

Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sodium Chloride 0.9% Irrigation	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sucralfate Tablet	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***