OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
July 10, 2024
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – July 10, 2024

DATE: July 3, 2024

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

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

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Enclosed are the following items related to the July 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/Chronic Medication Adherence (CMA) Program Update – Appendix B

Action Item – Vote to Prior Authorize Rezdiffra™ (Resmetirom) – Appendix C

Action Item – Vote to Prior Authorize Risvan® (Risperidone Extended-Release Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications – Appendix D

Action Item – Vote 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 and Update the Approval Criteria for the Various Special Formulations – Appendix E

Action Item – Vote to Prior Authorize Qalsody™ (Tofersen) and Rilutek® (Riluzole) and Update the Approval Criteria for the Amyotrophic Lateral Sclerosis (ALS) Medications – Appendix F

Action Item – Vote to Prior Authorize Liqrev® (Sildenafil Oral Suspension), Opsynvi® (Macitentan/Tadalafil), and Winrevair™ (Sotatercept-csrk) and Update the Approval Criteria for the Pulmonary Arterial Hypertension (PAH) Medications – Appendix G

Action Item – Vote to Prior Authorize Akeega™ (Niraparib/Abiraterone Acetate) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications – Appendix H

Action Item – Annual Review of Testosterone Products – Appendix I

Annual Review of Colorectal Cancer Medications and 30-Day Notice to Prior Authorize Avzivi® (Bevacizumab-tnjn) and Fruzaqla® (Fruquintinib) – Appendix J

30-Day Notice to Prior Authorize Wegovy® (Semaglutide) – Appendix K

Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Filsuvez® (Birch Triterpenes Topical Gel – Appendix L

Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Kisunla™ (Donanemab-azbt) – Appendix M

30-Day Notice to Prior Authorize Defencath® (Taurolidine/Heparin Catheter Lock System) – Appendix N

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 10, 2024 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

Viewing Access Only via Zoom:

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After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 958 2294 2095
Passcode: 65079339

Public Comment for Meeting:

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

Items to be presented by Dr. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. June 12, 2024 DUR Board Meeting Minutes
   B. June 12, 2024 DUR Board Recommendations Memorandum
   C. Correspondence

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

4. **Update on Medication Coverage Authorization Unit/Chronic Medication Adherence (CMA) Program Update – See Appendix B**
   A. Pharmacy Help Desk Activity for June 2024
   B. Medication Coverage Activity for Jume 2024
   C. CMA Program Update

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

5. **Action Item – Vote to Prior Authorize Rezdiffra™ (Resmetirom) – See Appendix C**
   A. Market News and Updates
   B. Rezdiffra™ (Resmetirom) Product Summary
   C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Risvan® (Risperidone Extended-Release Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications – See Appendix D**
   A. Market News and Updates
   B. Risvan® (Risperidone Extended-Release Injection) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote 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 and Update the Approval Criteria for the Various Special Formulations – See Appendix E**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Qalsody™ (Tofersen) and Rilutek® (Riluzole) and Update the Approval Criteria for the Amyotrophic Lateral Sclerosis (ALS) Medications – See Appendix F**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Liqrev® (Sildenafil Oral Suspension), Opsynvi® (Macitentan/Tadalafil), and Winrevair™ (Sotatercept-csrk) and Update the Approval Criteria for the Pulmonary Arterial Hypertension (PAH) Medications – See Appendix G**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Akeega™ (Niraparib/Abiraterone Acetate) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications – See Appendix H**
    A. Market News and Updates
    B. Akeega™ (Niraparib/Abiraterone Acetate) Product Summary
    C. College of Pharmacy Recommendations

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

11. **Action Item – Annual Review of Testosterone Products – See Appendix I**
    A. Current Prior Authorization Criteria
    B. Utilization of Testosterone Products
    C. Prior Authorization of Testosterone Products
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Testosterone Products

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

12. **Annual Review of Colorectal Cancer Medications and 30-Day Notice to Prior Authorize Avzivi® (Bevacizumab-tnjn) and Fruzaqla® (Fruquintinib) – See Appendix J**
    A. Current Prior Authorization Criteria
    B. Utilization of Colorectal Cancer Medications
    C. Prior Authorization of Colorectal Cancer Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Colorectal Cancer Medications

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

13. **30-Day Notice to Prior Authorize Wegovy® (Semaglutide) – See Appendix K**
    A. Introduction
    B. Market News and Updates
    C. Wegovy® (Semaglutide) Product Summary
    D. College of Pharmacy Recommendations

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

14. **Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Filsuvez® (Birch Triterpenes Topical Gel) – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of EB Medications
    C. Prior Authorization of EB Medications
    D. Market News and Updates

E. Filsuvez® (Birch Triterpenes Topical Gel) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of EB Medications

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

15. Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Kisunla™ (Donanemab-azbt) – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of Alzheimer's Disease Medications
C. Prior Authorization of Alzheimer's Disease Medications
D. Market News and Updates
E. Kisunla™ (Donanemab-azbt) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Alzheimer's Disease Medications

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

16. 30-Day Notice to Prior Authorize Defencath® (Taurolidine/Heparin Catheter Lock System) – See Appendix N

A. Introduction
B. Market News and Updates
C. Defencath® (Taurolidine/Heparin Catheter Lock System) Product Summary
D. College of Pharmacy Recommendations

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

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

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

18. Future Business* (Upcoming Product and Class Reviews)
No live DUR Board meeting scheduled for August 2024. August 2024 will be a packet-only meeting.

A. Corticosteroid Special Formulations
B. Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications
C. Topical Corticosteroids
D. Various Systemic Antibiotics

*Future product and class reviews subject to change.

19. 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 JUNE 12, 2024

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

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

Paula Root, M.D.; Senior Medical Director, Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
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:	
Gary Parenteau, Dexcom	Melissa Abbott, Eisai
Paul Ford, Johnson & Johnson	Peter Lee, OMES
John Omick, Travere	Dave Miley, Teva Pharmaceuticals
Tony Salicos, Phathom Pharmaceuticals	Brent Young, Karuna Therapeutics
Deidra Williams, Humana	Jim Gibbs, Intra-Cellular Therapies
Kalpesh Patel, Astellas	Ron Frost, Astellas
Kyle Armstrong, Astellas	Victor Sopina, Mitsubishi Tanabe Pharma
Danielle Walters, Bluebird bio	Erik Kuhta, Phathom Pharmaceuticals
Bridgett Wright, Sanofi	Tina Hartmann, Arcutis Biotherapeutics
Kenneth Berry, Alkermes	Jacob Jameson, Johnson & Johnson
Jay Milton, Bayer	David Williams, Luye Pharma
Brandon Ross, Merck	Audrey Rattan, Alkermes
Matt John, Otsuka	David Mendoza, Otsuka
Saurabh Patel, AbbVie	Mark Kaiser, Otsuka
John King, AbbVie	Pete Johnson, Oklahoma Children's Hospital
Rhonda Clark, Indivior	Janie Huff, Madrigal Pharmaceuticals
Brent Parker, Merck	Tara McKinley, Madrigal Pharmaceuticals
Lindsey Baker, Genentech	Todd Ness, AbbVie
Eardie Curry, Genentech	Kristen Winters, Centene
JJ Roth, Mirum	Rich Ortega, Lundbeck
Shellie Keast, ADURS	Rodney Brown, Genentech
Kim Greenberg, Acadia	Irene Chung, Aetna
Bryan Steffan, Boehringer	Camille Kerr, Regeneron
David Prather, Novo Nordisk	

PRESENT FOR PUBLIC COMMENT:	
Tara McKinley, Madrigal Pharmaceuticals	Kenneth Berry, Alkermes
Pete Johnson, Oklahoma Children's Hospital	Jacob Jameson, Johnson & Johnson
Brandon Ross, Merck	

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. 13 TARA MCKINLEY
2B: AGENDA ITEM NO. 14 KENNETH BERRY
2C: AGENDA ITEM NO. 16 PETE JOHNSON
2D: AGENDA ITEM NO. 16 JACOB JAMESON
2E: AGENDA ITEM NO. 16 BRANDON ROSS

ACTION: NONE REQUIRED

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

3A: APRIL 10, 2024 DUR MINUTES – VOTE

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/CONCOMITANT USE OF OPIOIDS AND GABAPENTINOIDS MAILING UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR APRIL 2024
4B: MEDICATION COVERAGE ACTIVITY FOR APRIL 2024
4C: PHARMACY HELPDESK ACTIVITY FOR MAY 2024
4D: MEDICATION COVERAGE ACTIVITY FOR MAY 2024
4C: CONCOMITANT USE OF OPIOIDS AND GABAPENTINOIDS MAILING UPDATE

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **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)**

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

Materials included in agenda packet; presented by Dr. O'Halloran
Mr. Foster moved to approve; seconded by Dr. West

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE IZERVAY™ (AVACINCAPTAD PEGOL) AND UPDATE THE APPROVAL CRITERIA FOR THE AGE-RELATED MACULAR DEGENERATION (AMD) MEDICATIONS**

6A: MARKET NEWS AND UPDATES
6B: IZERVAY™ (AVACINCAPTAD PEGOL) PRODUCT SUMMARY
6C: COST COMPARISON: COMPLEMENT INHIBITORS
6D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE REZZAYO™ (REZAFUNGIN)**

7A: MARKET NEWS AND UPDATES
7B: REZZAYO™ (REZAFUNGIN) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **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
8A: MARKET NEWS AND UPDATES
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Mr. Foster moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE AUGTYRO™ (REPOTRECTINIB) AND PEMRYDI RTU® (PEMETREXED) AND UPDATE THE APPROVAL CRITERIA FOR THE LUNG CANCER MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Mr. Foster moved to approve; seconded by Dr. Thomas
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF NASAL ALLERGY MEDICATIONS
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF NASAL ALLERGY MEDICATIONS
10C: PRIOR AUTHORIZATION OF NASAL ALLERGY MEDICATIONS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF NASAL ALLERGY MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

AGENDA ITEM NO. 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)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
11C: PRIOR AUTHORIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 12: ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT
12A: SUMMARY
12B: MEDICAID DRUG REBATE PROGRAM
12C: ALTERNATIVE PAYMENT MODELS
12D: DRUG APPROVAL TRENDS

12E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
12F: TOP 10 TRADITIONAL THERAPEUTIC CLASSES BY REIMBURSEMENT
12G: TOP 10 SPECIALTY THERAPEUTIC CLASSES BY REIMBURSEMENT
12H: TOP 10 MEDICATIONS BY REIMBURSEMENT
12I: COST PER CLAIM
12J: MARKET PROJECTIONS
12K: CONCLUSION
12L: TOP 50 REIMBURSED DRUGS BY CALENDAR YEAR
12M: TOP 50 MEDICATIONS BY TOTAL NUMBER OF CLAIMS: CALENDAR YEAR 2023
12N: TOP 10 TRADITIONAL AND SPECIALTY THERAPEUTIC CATEGORIES BY CALENDAR YEAR
12O: CALENDAR YEAR AGE GROUP COMPARISON
Materials included in agenda packet; presented by Dr. Morgan
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: 30-DAY NOTICE TO PRIOR AUTHORIZE REZDIFFRA™ (RESMETIROM)
13A: INTRODUCTION
13B: REZDIFFRA™ (RESMETIROM) PRODUCT SUMMARY
13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE RISVAN® [RISPERIDONE INTRAMUSCULAR (IM) INJECTION)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
14C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
14D: OKLAHOMA RESOURCES
14E: MARKET NEWS AND UPDATES
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 15: ANNUAL REVIEW OF AMYOTROPHIC LATERAL SCLEROSIS (ALS) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE QALSODY® (TOFERSEN) AND RILUTEK® (RILUZOLE ORAL TABLET)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ALS MEDICATIONS
15C: PRIOR AUTHORIZATION OF ALS MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: PRODUCT SUMMARIES
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ALS MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 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)

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF PULMONARY HYPERTENSION MEDICATIONS
16C: PRIOR AUTHORIZATION OF PULMONARY HYPERTENSION MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: WINREVAIR™ (SOTATERCEPT-CSRK) PRODUCT SUMMARY
16F: COST COMPARISONS
16G: COLLEGE OF PHARMACY RECOMMENDATIONS
16H: UTILIZATION DETAILS OF PULMONARY HYPERTENSION MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 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
17A: INTRODUCTION
17B: CURRENT PRIOR AUTHORIZATION CRITERIA
17C: UTILIZATION OF VARIOUS SPECIAL FORMULATIONS
17D: PRIOR AUTHORIZATION OF VARIOUS SPECIAL FORMULATIONS
17E: MARKET NEWS AND UPDATES
17F: PRODUCT SUMMARIES
17G: COLLEGE OF PHARMACY RECOMMENDATIONS
17H: UTILIZATION DETAILS OF VARIOUS SPECIAL FORMULATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 18: ANNUAL REVIEW OF DAYBUE™ (TROFINETIDE)
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF DAYBUE™ (TROFINETIDE)
18C: PRIOR AUTHORIZATION OF DAYBUE™ (TROFINETIDE)
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF DAYBUE™ (TROFINETIDE)
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: ANNUAL REVIEW OF JOENJA® (LENIOLISIB)
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF JOENJA® (LENIOLISIB)
19C: PRIOR AUTHORIZATION OF JOENJA® (LENIOLISIB)
19D: MARKET NEWS AND UPDATES
19E: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES**

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

21A: ALZHEIMER'S DISEASE MEDICATIONS

21B: COLORECTAL CANCER MEDICATIONS

21C: EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS

21D: TESTOSTERONE PRODUCTS

*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 6:10pm.

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

Memorandum

Date: June 14, 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 June 12, 2024

Recommendation 1: Concomitant Use of Opioids and Gabapentinoids Mailing Update

NO ACTION REQUIRED.

Recommendation 2: 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)

MOTION CARRIED by unanimous approval.

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 Prior Authorization (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			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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			
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/ sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	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 (Synjardy®)		ertugliflozin (Steglatro®)
	empagliflozin/ metformin ER (Synjardy® XR)		ertugliflozin/ metformin (Segluromet®)
	dapagliflozin/ metformin ER (Xigduo® XR)		**sotagliflozin (Inpefa®)***
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)
Sulfonylureas			
glimepiride (Amaryl®)			**glipizide 2.5mg IR tab***

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

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

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.

Recommendation 3: Vote to Prior Authorize Izervay™ (Avacincaptad Pegol) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications

MOTION CARRIED by unanimous approval.

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.

Recommendation 4: Vote to Prior Authorize Rezzayo™ (Rezafungin)

MOTION CARRIED by unanimous approval.

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.

Recommendation 5: 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

MOTION CARRIED by unanimous approval.

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.

Recommendation 6: Vote to Prior Authorize Augtyro™ (Repotrectinib) and Pemrydi RTU® (Pemetrexed) and Update the Approval Criteria for the Lung Cancer Medications

MOTION CARRIED by unanimous approval.

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 National Comprehensive Cancer Network (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 rearranged during transfection (RET)-mutant medullary thyroid cancer (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.

Recommendation 7: Annual Review of Nasal Allergy Medications

MOTION CARRIED by unanimous approval.

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.

Recommendation 8: Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Akeega® (Niraparib/Abiraterone) and Anktiva® (Nogapendekin Alfa Inbakicept-pmln)

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

Recommendation 9: Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED.

Recommendation 10: 30-Day Notice to Prior Authorize Rezdiffra™ (Resmetirom)

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

Recommendation 11: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Risvan® [Risperidone Intramuscular (IM) Injection]

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

Recommendation 12: Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-Day Notice to Prior Authorize Qalsody® (Tofersen) and Rilutek® (Riluzole Oral Tablets)

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

Recommendation 13: Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Liqrev® (Sildenafil Oral Suspension), Opsynvi® (Macitentan/Tadalafil), and Winrevair™ (Sotatercept-csrk)

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

Recommendation 14: 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

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

Recommendation 15: Annual Review of Daybue™ (Trofinetide)

NO ACTION REQUIRED.

Recommendation 16: Annual Review of Joenja® (Leniolisib)

NO ACTION REQUIRED.

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

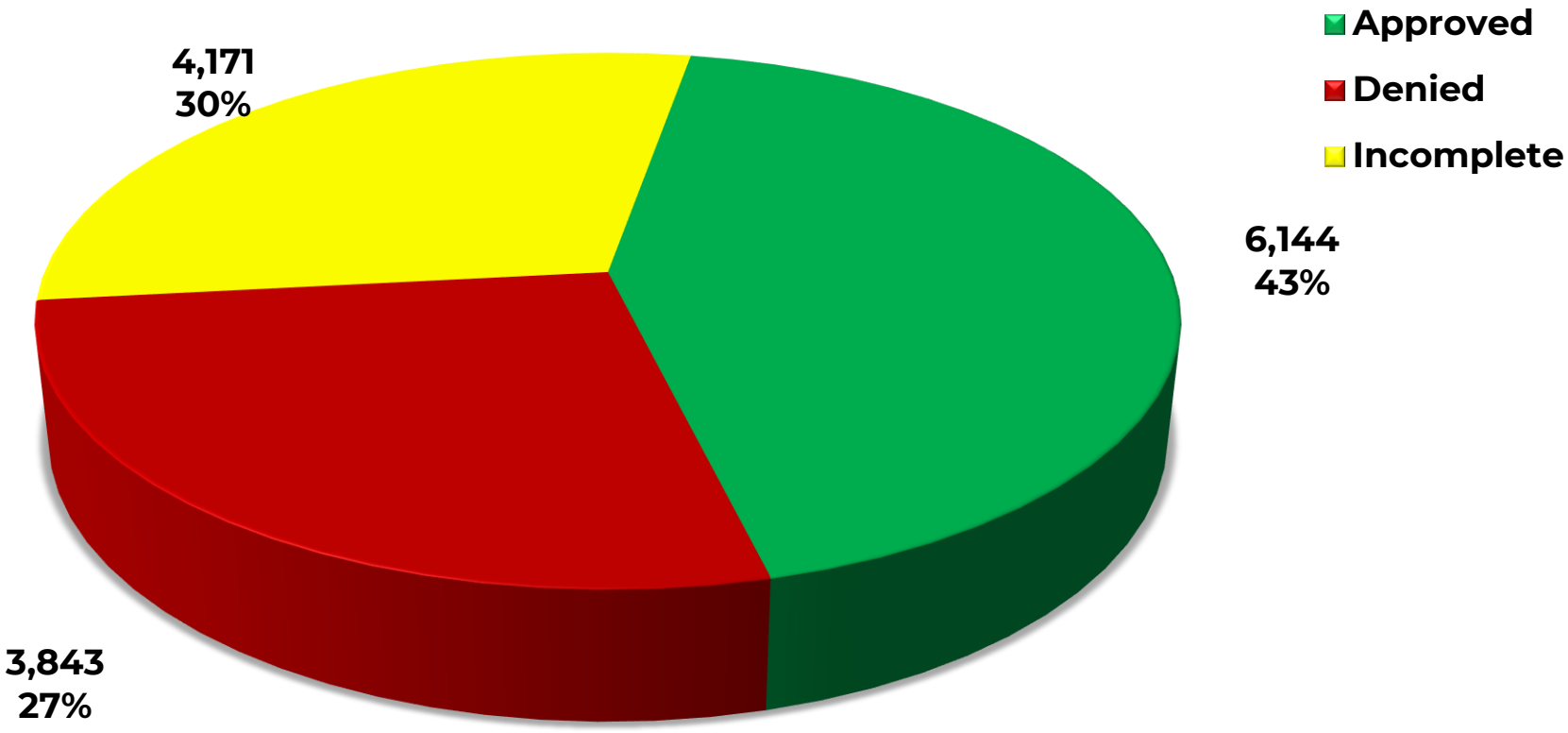
NO ACTION REQUIRED.

Recommendation 18: Future Business

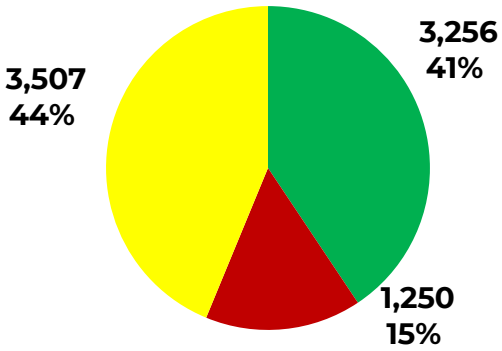
NO ACTION REQUIRED.

Appendix B

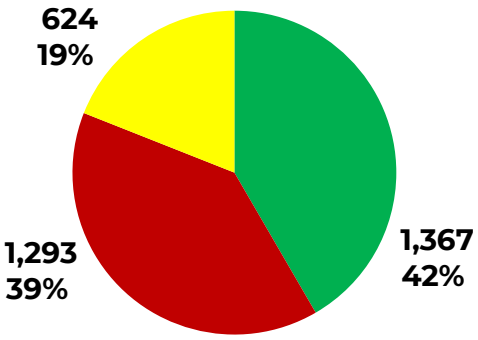
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JUNE 2024



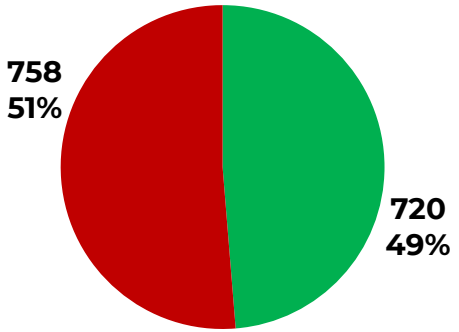
SoonerCare FFS



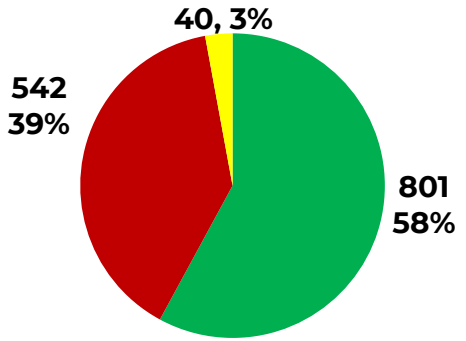
SoonerSelect Aetna



SoonerSelect Humana

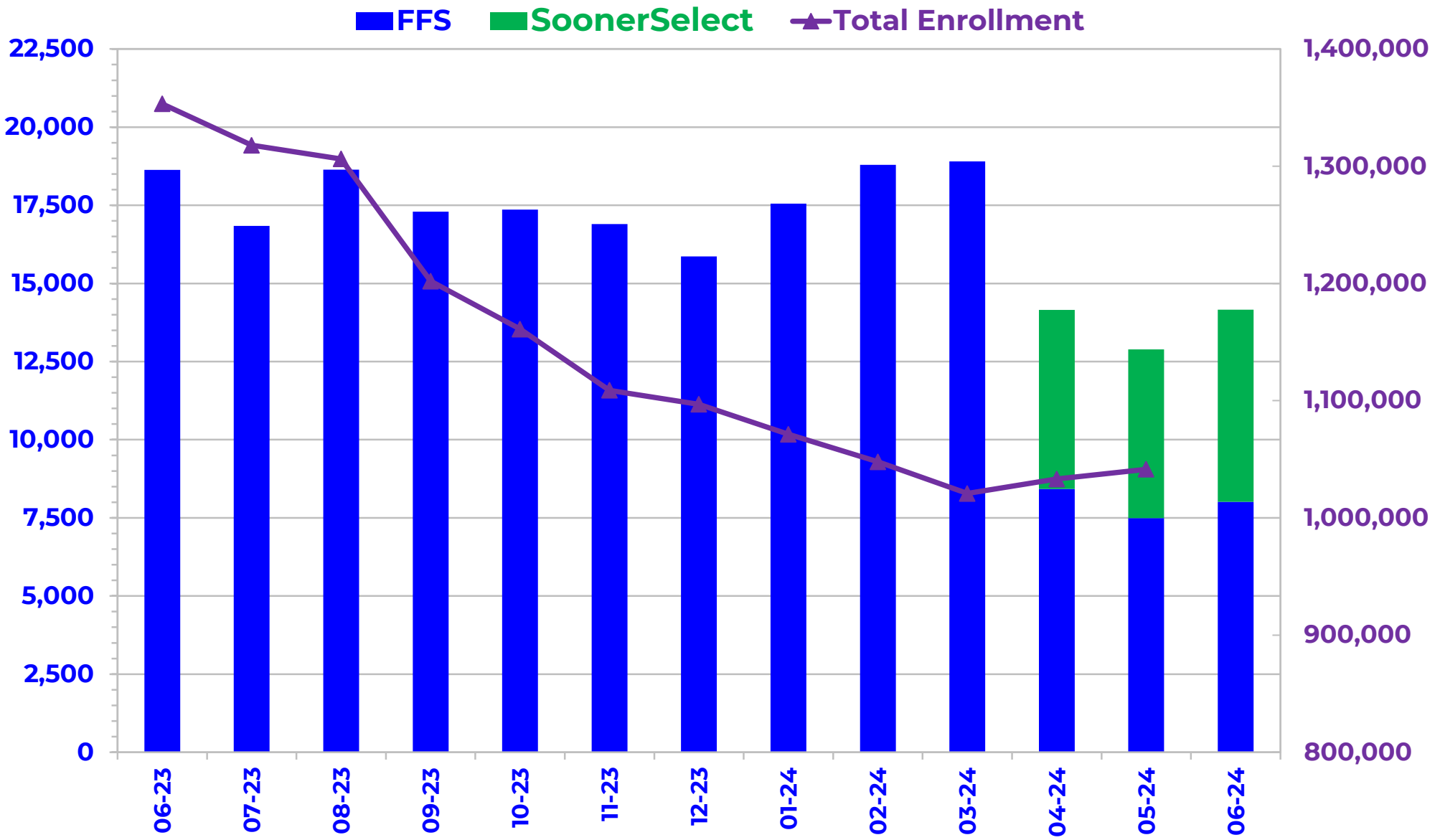


SoonerSelect OK Complete Health



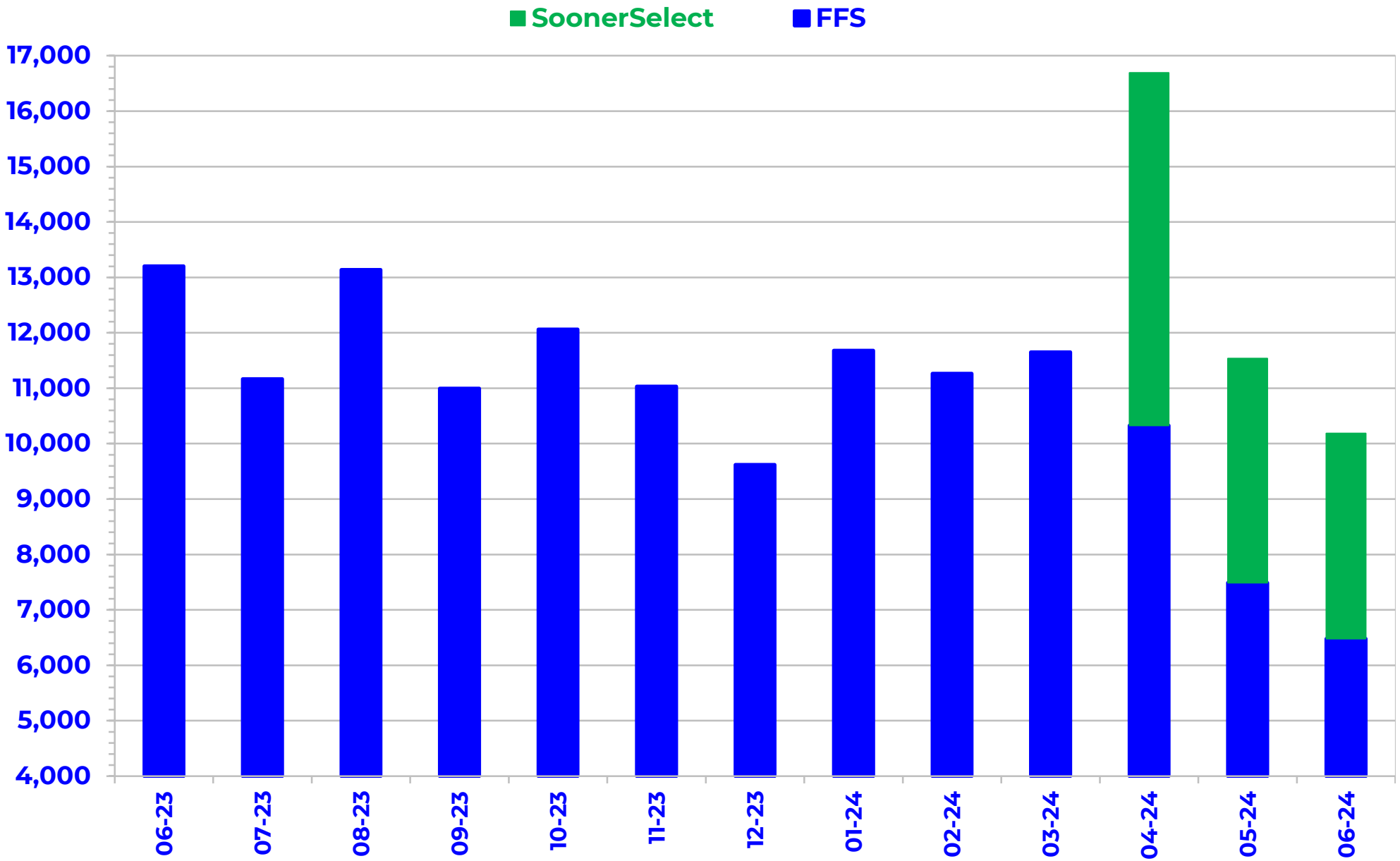
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JUNE 2023 – JUNE 2024



SoonerCare FFS Prior Authorization Activity

6/1/2024 Through 6/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	91	37	5	49	359
Analgesic - NonNarcotic	10	1	3	6	178
Analgesic, Narcotic	196	89	11	96	122
Antiasthma	49	13	12	24	239
Antibiotic	31	16	0	15	254
Anticonvulsant	171	94	5	72	311
Antidepressant	182	35	26	121	292
Antidiabetic	1,262	388	294	580	358
Antihemophilic Factor	10	5	0	5	127
Antihistamine	20	2	6	12	359
Antimigraine	291	53	113	125	256
Antineoplastic	169	109	6	54	177
Antiobesity	29	1	25	3	35
Antiparasitic	11	3	1	7	15
Antiulcers	32	7	3	22	139
Anxiolytic	16	0	2	14	0
Atypical Antipsychotics	259	88	19	152	356
Benign Prostatic Hypertrophy	11	0	5	6	0
Biologics	226	103	34	89	316
Bladder Control	92	13	20	59	338
Blood Thinners	12	2	1	9	359
Botox	47	30	7	10	360
Buprenorphine Medications	51	18	6	27	105
Calcium Channel Blockers	16	5	2	9	197
Cardiovascular	98	36	9	53	349
Chronic Obstructive Pulmonary Disease	203	41	45	117	346
Constipation/Diarrhea Medications	181	33	49	99	199
Contraceptive	34	15	4	15	339
Dermatological	284	91	83	110	268
Diabetic Supplies	236	88	45	103	214
Endocrine & Metabolic Drugs	69	21	8	40	272
Erythropoietin Stimulating Agents	21	10	3	8	94
Estrogen Derivative	11	2	1	8	360
Gastrointestinal Agents	100	23	11	66	193
Glaucoma	14	1	3	10	356
Gonadotropin-releasing Hormone Agonist	13	10	0	3	308
Growth Hormones	73	39	11	23	144
Hematopoietic Agents	10	5	1	4	322
Hepatitis C	21	7	5	9	9
Insomnia	52	5	9	38	159

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Insulin	216	120	8	88	312
Miscellaneous Antibiotics	13	1	2	10	25
Multiple Sclerosis	56	24	9	23	234
Muscle Relaxant	49	4	12	33	101
Nasal Allergy	13	2	3	8	360
Neurological Agents	183	56	45	82	173
Neuromuscular Agents	13	5	0	8	260
NSAIDs	11	0	3	8	0
Ocular Allergy	16	4	4	8	223
Ophthalmic	16	7	1	8	359
Ophthalmic Anti-infectives	16	8	1	7	8
Osteoporosis	36	6	4	26	358
Other*	329	74	63	192	314
Otic Antibiotic	65	4	11	50	22
Respiratory Agents	13	6	0	7	359
Statins	43	9	7	27	190
Stimulant	766	471	28	267	353
Testosterone	54	12	10	32	358
Thyroid	28	7	5	16	321
Topical Antifungal	27	3	10	14	40
Topical Corticosteroids	11	0	2	9	0
Vitamin	95	11	65	19	189
Pharmacotherapy	95	86	1	8	310
Emergency PAs	0	0	0	0	
Total	**6,868**	**2,459**	**1,187**	**3,222**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	20	15	1	4	336
Compound	13	9	0	4	5
Dosage Change	216	195	1	20	16
Ingredient Duplication	3	3	0	0	20
Lost/Broken Rx	69	63	4	2	19
MAT Override	20	13	1	6	80
NDC vs Age	193	124	22	47	285
NDC vs Sex	17	12	2	3	270
Nursing Home Issue	63	56	0	7	17
Opioid MME Limit	67	19	3	45	117
Opioid Quantity	24	12	4	8	183
Other	38	34	2	2	18
Quantity vs. Days Supply	343	208	19	116	260
STBS/STBSM	12	7	1	4	86
Step Therapy Exception	11	6	2	3	171
Stolen	3	1	1	1	41
Third Brand Request	33	20	0	13	28
Overrides Total	**1,145**	**797**	**63**	**285**	
Total Regular PAs + Overrides	**8,013**	**3,256**	**1,250**	**3,507**	

Denial Reasons	
Unable to verify required trials.	3,007
Does not meet established criteria.	1,281
Lack required information to process request.	508
Other PA Activity	
Duplicate Requests	832
Letters	31,674
No Process	1
Changes to existing PAs	461
Helpdesk Initiated Prior Authorizations	348
PAs Missing Information	424

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

SoonerSelect Aetna Prior Authorization Activity

6/1/2024 Through 6/30/2024

	Total	Approved	Denied	Incomplete	Void	Average Length of Approvals in Days
ACE Inhibitors	3	0	0	0	3	0
Advair/Symbicort/Dulera	53	21	22	0	10	361
Analgesic - NonNarcotic	7	1	6	0	0	365
Analgesic, Narcotic	126	57	35	0	34	235
Angiotensin Receptor Antagonist	6	3	0	0	3	365
Anorectal	1	0	0	0	1	0
Antiasthma	34	7	8	0	19	292
Antibiotic	15	3	2	0	10	244
Anticoagulant	2	0	1	0	1	0
Anticonvulsant	45	18	23	0	4	343
Antidepressant	171	58	54	0	59	330
Antidiabetic	665	280	326	0	59	355
Antidiarrheal	1	1	0	0	0	365
Antifungal	5	0	2	0	3	0
Antigout	7	3	2	0	2	274
Antihemophilic Factor	1	1	0	0	0	365
Antihistamine	17	8	9	0	0	324
Anti-inflammatory	1	0	0	0	1	0
Antimigraine	167	44	109	0	14	228
Antineoplastic	20	9	0	0	11	252
Antiobesity	4	0	0	0	4	0
Antiparasitic	7	4	3	0	0	10
Antiparkinsons	10	0	1	0	9	0
Antipsychotic	1	0	0	0	1	0
Antiulcers	41	8	4	0	29	285
Antiviral	2	1	1	0	0	92
Anxiolytic	25	5	7	0	13	320
Atypical Antipsychotics	153	42	75	0	36	352
Benign Prostatic Hypertrophy	6	1	4	0	1	365
Biologics	162	122	28	0	12	311
Bladder Control	26	11	13	0	2	345
Blood Thinners	2	1	0	0	1	183
Buprenorphine Medications	67	35	28	0	4	90
Calcium Channel Blockers	12	3	4	0	5	365
Cardiovascular	42	15	5	0	22	266
Cephalosporins	2	1	1	0	0	30
Chronic Obstructive Pulmonary Disease	76	21	46	0	9	363
Constipation/Diarrhea Medications	43	26	16	0	1	135
Contraceptive	21	6	10	0	5	365
Corticosteroid	2	0	0	0	2	0
Dermatological	161	68	77	0	16	226
Diabetic Supplies	115	51	36	0	28	346
Diuretic	7	0	0	0	7	0
Endocrine & Metabolic Drugs	21	9	8	1	3	335
Estrogen Derivative	12	3	8	0	1	365

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

	Total	Approved	Denied	Incomplete	Void	Average Length of Approvals in Days
Fibric Acid Derivatives	1	0	0	0	1	0
Fibromyalgia	11	0	2	0	9	0
Fish Oils	1	0	1	0	0	0
Gastrointestinal Agents	45	5	29	0	11	152
Genitourinary Agents	6	0	1	0	5	0
Glaucoma	7	5	1	0	1	274
Gonadotropin-releasing Hormone Agonist	1	1	0	0	0	7
Growth Hormones	19	12	5	0	2	183
Hematopoietic Agents	1	0	0	0	1	0
Hepatitis C	4	3	1	0	0	62
HFA Rescue Inhalers	15	0	1	0	14	0
Insomnia	28	5	13	0	10	320
Insulin	90	36	35	0	19	294
Miscellaneous Antibiotics	9	5	2	0	2	191
Multiple Sclerosis	4	1	1	0	2	365
Muscle Relaxant	28	0	11	0	17	0
Nasal Allergy	14	2	5	0	7	274
Neurological Agents	14	6	6	0	2	165
Non-Classified	30	8	21	0	1	347
NSAIDs	21	1	8	0	12	365
Ocular Allergy	8	1	7	0	0	365
Ophthalmic	14	5	3	0	6	262
Ophthalmic Anti-infectives	4	2	1	0	1	67
Ophthalmic Corticosteroid	2	0	2	0	0	0
Ophthalmic NSAIDs	1	0	1	0	0	0
Osteoporosis	3	2	1	0	0	365
Otic Antibiotic	41	4	37	0	0	138
Pediculicide	1	0	1	0	0	0
Prenatal Vitamins	7	6	0	0	1	365
Respiratory Agents	3	3	0	0	0	365
Smoking Cess.	2	0	2	0	0	0
Statins	28	4	6	0	18	122
Stimulant	301	233	41	0	27	360
Testosterone	75	28	46	0	1	365
Thyroid	6	3	2	0	1	365
Topical Antibiotic	2	0	2	0	0	0
Topical Antifungal	15	5	9	0	1	275
Topical Corticosteroids	13	4	4	0	5	320
Toradol	2	0	2	0	0	0
Vitamin	40	30	9	0	1	319
****Total**	**3,284**	**1,367**	**1,293**	**1**	**623**	

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

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

	Total	Approved	Denied	Incomplete	Void	Average Length of Approvals in Days
Overrides						
Brand	3	3	0	0	0	365
Quantity Limit	5	5	0	0	0	256
Step Therapy Exception	1	1	0	0	0	365
Other	629	2	0	0	627	365
Overrides Total	**638**	**11**	**0**	**0**	**627**	

Denial Reasons	
Benefit	66
Experimenta/Investigational	134
Lack required information to process request	351
Medical Necessity	742
Other PA Activity	
Duplicate Requests	15
Letters	4021
No Process	235
Changes to exisitng PAs	28
Helpdesk initiated PA	5
Missing information	17

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

SoonerSelect Humana Prior Authorization Activity

6/1/2024 Through 6/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	19	0	19	0	10
Analgesic - NonNarcotic	1	0	1	0	0
Analgesic, Narcotic	39	20	19	0	167
Antiasthma	17	12	5	0	153
Antibiotic	5	3	2	0	228
Anticonvulsant	7	5	2	0	274
Antidepressant	12	3	9	0	243
Antidiabetic	127	71	56	0	236
Antifungal	2	1	1	0	183
Antigout	2	1	1	0	204
Antimigraine	36	18	18	0	122
Antineoplastic	21	19	2	0	194
Antiparasitic	1	1	0	0	365
Antiulcers	2	0	2	0	0
Benign Prostatic Hypertrophy	1	0	1	0	0
Biologics	79	61	18	0	251
Bladder Control	8	1	7	0	97
Botox	28	17	11	0	282
Buprenorphine Medications	34	19	15	0	70
Cardiovascular	35	22	13	0	306
Chronic Obstructive Pulmonary Disease	33	12	21	0	122
Constipation/Diarrhea Medications	17	14	3	0	257
Contraceptive	16	3	13	0	39
Corticosteroid	1	1	0	0	365
Dermatological	74	48	26	0	202
Diabetic Supplies	26	15	11	0	365
Endocrine & Metabolic Drugs	11	2	9	0	119
Erythropoietin Stimulating Agents	3	3	0	0	117
Estrogen Derivative	3	1	2	0	122
Gastrointestinal Agents	9	3	6	0	51
Gonadotropin-releasing Hormone Agonist	11	9	2	0	268
Growth Hormones	6	1	5	0	75
Hematopoietic Agents	5	4	1	0	150
Hepatitis C	6	1	5	0	14
HFA Rescue Inhalers	1	0	1	0	0
Insomnia	6	0	6	0	73
Insulin	26	4	22	0	89
Miscellaneous Antibiotics	2	0	2	0	1

*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
Multiple Sclerosis	5	1	4	0	151
Muscle Relaxant	18	12	6	0	161
Nasal Allergy	1	1	0	0	365
Neurological Agents	7	2	5	0	109
Non-Classified	8	4	4	0	210
Ophthalmic	4	1	3	0	27
Ophthalmic Anti-infectives	3	1	2	0	183
Ophthalmic Corticosteroid	10	1	9	0	53
Osteoporosis	6	4	2	0	236
Respiratory Agents	8	5	3	0	249
Statins	4	2	2	0	259
Stimulant	17	12	5	0	305
Testosterone	30	7	23	0	146
Thyroid	5	0	5	0	58
Topical Corticosteroids	2	0	2	0	189
Vitamin	38	7	31	0	126
Total	**898**	**455**	**443**	**0**	
Overrides					
High Dose	1	0	1	0	0
Ingredient Duplication	54	35	19	0	279
MAT Override	9	7	2	0	429
NDC vs Age	172	119	53	0	251
Opioid Quantity	7	4	3	0	196
Other	151	11	140	0	25
Quantity vs Days Supply	78	44	34	0	251
STBS/STBSM	41	18	23	0	178
Step Therapy Exception	67	27	40	0	190
Overrides Total	**580**	**265**	**315**	**0**	
Total Regular PAs + Overrides	**1,478**	**720**	**758**	**0**	
Denial Reasons					
Benefit					297
Medical Necessity					462

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

SoonerSelect OK Complete Health Prior Authorization Activity

6/1/2024 Through 6/30/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
ACE Inhibitors	3	3	0	0	306
Advair/Symbicort/Dulera	36	17	18	1	281
Analgesic - NonNarcotic	2	0	2	0	0
Analgesic, Narcotic	121	85	35	1	291
Angiotensin Receptor Antagonist	1	0	0	1	0
Anorectal	1	0	1	0	0
Antiasthma	22	12	10	0	281
Antibiotic	1	1	0	0	180
Anticonvulsant	31	22	8	1	285
Antidepressant	44	22	18	4	233
Antidiabetic	221	119	95	7	357
Antidiarrheal	1	0	1	0	0
Antifungal	3	2	1	0	195
Antihemophilic Factor	1	1	0	0	457
Antihistamine	2	1	1	0	365
Anti-inflammatory	1	0	1	0	0
Antimalarial Agent	1	1	0	0	365
Antimigraine	54	17	37	0	270
Antineoplastic	15	13	2	0	293
Antiobesity	26	0	26	0	0
Antiulcers	6	4	1	1	277
Antiviral	1	1	0	0	189
Anxiolytic	20	11	8	1	255
Atypical Antipsychotics	49	26	20	3	313
Benign Prostatic Hypertrophy	3	0	3	0	0
Biologics	77	61	16	0	364
Bladder Control	6	2	3	1	365
Blood Thinners	2	1	1	0	194
Buprenorphine Medications	24	12	12	0	237
Calcium Channel Blockers	11	5	6	0	227
Cardiovascular	44	29	14	1	282
Chronic Obstructive Pulmonary Disease	15	7	8	0	316
Constipation/Diarrhea Medications	15	8	7	0	225
Contraceptive	2	2	0	0	206
Dermatological	129	72	57	0	288
Diabetic Supplies	53	34	17	2	340
Diuretic	3	2	0	1	199
Endocrine & Metabolic Drugs	8	2	6	0	187
Erythropoietin Stimulating Agents	1	1	0	0	112

*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
Estrogen Derivative	3	1	2	0	200
Fibromyalgia	4	3	1	0	249
Fish Oils	1	0	1	0	0
Gastrointestinal Agents	8	5	2	1	329
Glaucoma	3	2	0	1	284
Gonadotropin-releasing Hormone Agonist	1	1	0	0	365
Growth Hormones	7	4	3	0	319
Hematopoietic Agents	3	1	1	1	365
Hepatitis C	8	1	6	1	84
HFA Rescue Inhalers	1	1	0	0	365
Insomnia	10	6	4	0	286
Insulin	30	20	8	2	315
Miscellaneous Antibiotics	1	0	1	0	0
Multiple Sclerosis	3	1	2	0	180
Muscle Relaxant	4	1	3	0	365
Neurological Agents	4	1	3	0	365
Non-Classified	25	13	11	1	292
NSAIDs	5	2	3	0	195
Ophthalmic	1	1	0	0	365
Ophthalmic Anti-infectives	1	0	1	0	0
Ophthalmic Corticosteroid	3	2	0	1	196
Osteoporosis	1	0	1	0	0
Otic Antibiotic	3	1	2	0	365
Pediculicide	1	1	0	0	366
Prenatal Vitamins	1	1	0	0	365
Respiratory Agents	3	3	0	0	365
Smoking Cess.	1	0	1	0	0
Statins	16	7	9	0	188
Stimulant	143	112	24	7	344
Testosterone	13	4	9	0	365
Thyroid	5	3	2	0	197
Topical Antifungal	1	0	1	0	0
Topical Corticosteroids	1	0	1	0	0
Toradol	1	0	1	0	0
Vitamin	11	7	4	0	365
****Total**	**1,383**	**801**	**542**	**40**	

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

*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
Overrides					
Concurrent Use	15	8	7	0	253
Days Supply	15	0	15	0	0
Default	133	66	67	0	188
DRUG NOT COVERED-FORMULARY	128	81	45	2	227
Drug-Drug Interaction	121	64	55	2	203
Duplicate Therapy	16	11	3	2	335
Exceeds Adult Maximum Dosage Guidelines	1	0	1	0	0
Exceeds Opioid Initial Fill Limit	153	132	21	0	260
Morphine Equivalent Dose Threshold	7	6	1	0	253
Generic Drugs Excluded	76	2	73	1	13
Injectable Excluded	1	0	1	0	0
Not Covered	7	1	6	0	73
Obsolete	1	0	1	0	0
Quantity Limit	26	21	5	0	289
Safety	202	163	37	2	294
Step Therapy	55	29	26	0	253
Override Total	**957**	**584**	**364**	**9**	

Denial Reasons	
Benefit	64
Medical Necessity	478

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

Chronic Medication Adherence (CMA) Program Update

Oklahoma Health Care Authority
July 2024

Prescriber Mailing: Diabetes and Cardiovascular (CV) Maintenance Medications[1]

In mid-2015, the College of Pharmacy initiated the CMA program as an educational mailing which is processed quarterly and is sent to prescribers with members on chronic maintenance medications for diabetes mellitus (DM), hypertension (HTN), and cholesterol. The purpose of the CMA mailing is to encourage medication adherence, reduce poor health outcome risk factors, and improve the quality of care for SoonerCare members receiving these medications. The CMA inclusion criteria for each biannual prescriber mailing cohort requires the prescriber to have ≥7 SoonerCare members taking DM, HTN, and cholesterol medications on a regular basis. The review period for each mailing is 1 year, and members are assigned to prescribers and included in the prescriber's patient list if they are the last prescriber of record for a maintenance medication as demonstrated in SoonerCare paid pharmacy claims.

Although criteria for inclusion, frequency of mailing, and types of mailings have changed slightly since program inception, the last substantial change was made in 2018. Since that time, the mailings have included both CV and DM medications in each mailing rather than alternating mailings. Cohort prescribers receive 4 letters per year to better inform them of their SoonerCare members using chronic maintenance medications and as a convenient way to track their members' adherence over time, including any improvements or changes. The consistent prescriber list is updated approximately once every 2 years to account for prescribers who have a change in their patient base or practice setting, move out of state, retire, or no longer contract with SoonerCare. The CMA prescriber list was most recently updated in February 2022.

Each mailing includes a prescriber summary report with a star rating based on the prescriber's overall percentage of members considered adherent to chronic maintenance medications. Adherence is estimated by measuring the proportion of days covered (PDC), or percentage of days in the past year covered by prescription claims. A member is considered adherent if their PDC is ≥80% and is considered non-adherent if their PDC is <80%. A higher prescriber percentage (and corresponding star rating) indicates that more of their SoonerCare members are adherent to chronic maintenance medications. Each mailing also includes a detailed patient list with each member's PDC, specific medication name and strength, total day supply, and

total study days. Prescribers also receive a list of medication adherence resources for patients in hopes they will utilize these methods to improve their patients' adherence.

Mailing Summaries

The following table outlines total letters mailed and total members included in each CMA mailing since February 2022 to the most recent mailing in May 2024:

Date Letter Processed	Total Letters Mailed to Prescribers	Total Members Included
February 2022*	236	7,599
May 2022	235	7,200
August 2022	235	6,942
November 2022	232	6,714
February 2023	231	6,572
May 2023	226	6,304
August 2023	220	6,093
November 2023	217	5,940
February 2024	212	5,709
May 2024	206	5,451

*CMA prescriber list updated

Star Ratings

The star ratings for the percentage of SoonerCare members who are adherent to CV or DM chronic maintenance medications are based on the 2022-24 Medicare Star Ratings. However, a rating of 0 stars is exclusive to SoonerCare. The following descriptions illustrate the star ratings and adherence percentages for each star rating. It is important to note the threshold for each star rating has become increasingly higher with each annual update. Hence the provider star rating may sometimes appear to show a trend towards worsening adherence each February, but this may actually reflect a more rigorous standard being applied.

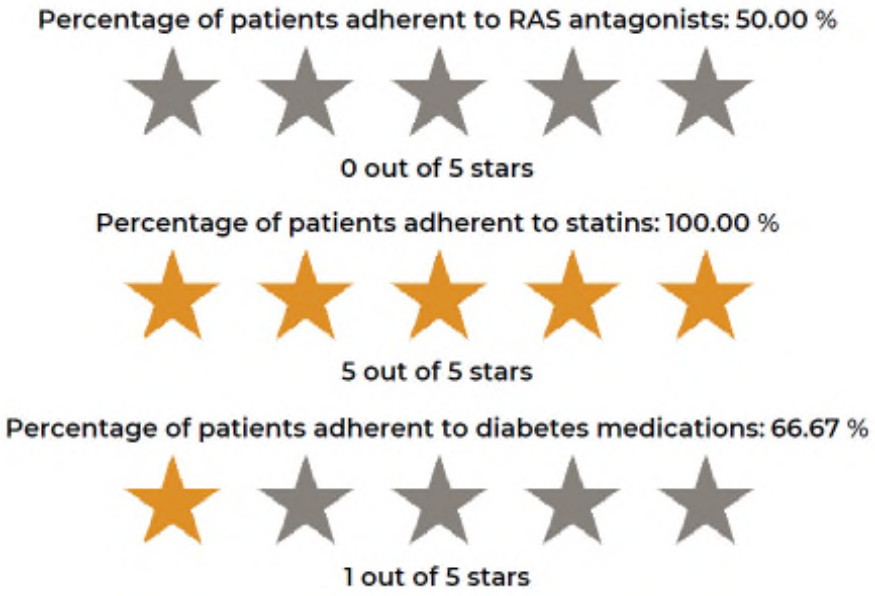
- **CV Star Ratings:**
  CV star ratings address adherence to 2 classes of maintenance medications:
  1. Renin angiotensin system (RAS) antagonists [i.e., angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), direct renin inhibitors]
  2. 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (i.e., statins)

  Adherence is shown in the Provider Summary Report as a percentage for RAS antagonists and as a percentage for statins, with a corresponding star rating for each CV category.

- **DM Star Ratings:**
  DM star ratings address adherence to maintenance medications for DM, excluding insulin and Symlin® (pramlintide). Adherence is shown in the Provider Summary Report as a percentage and corresponding star rating for DM medications.

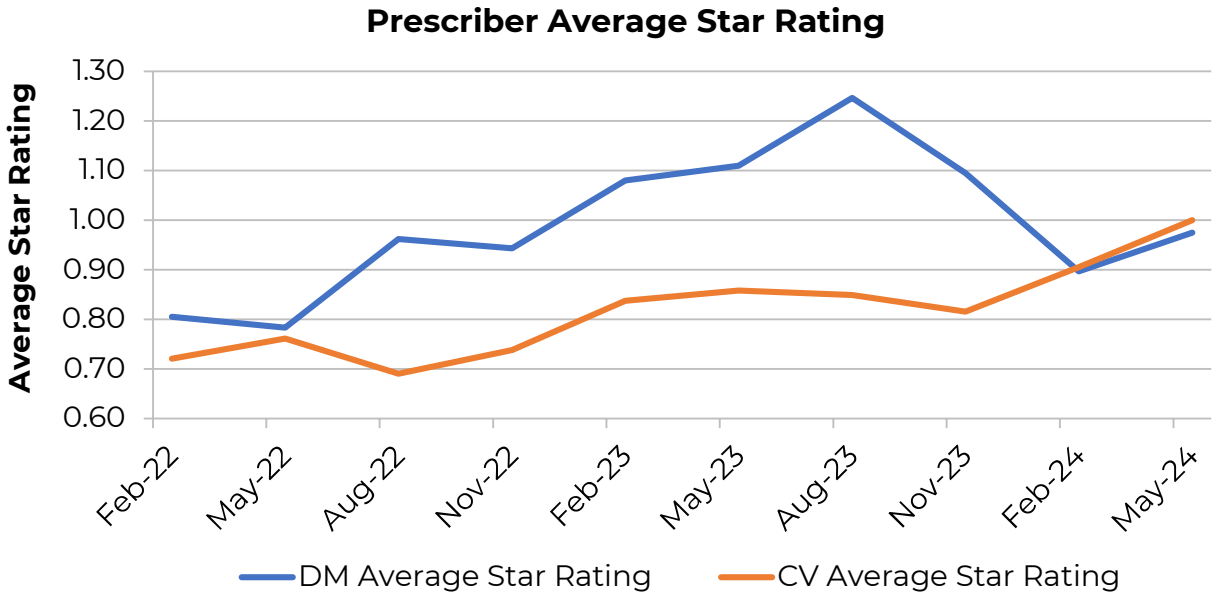
Provider Summary Report

Report date: <Report Date>
Provider: <Provider Name>
NPI: <Prescriber NPI>
SoonerCare Provider ID: <Provider ID>

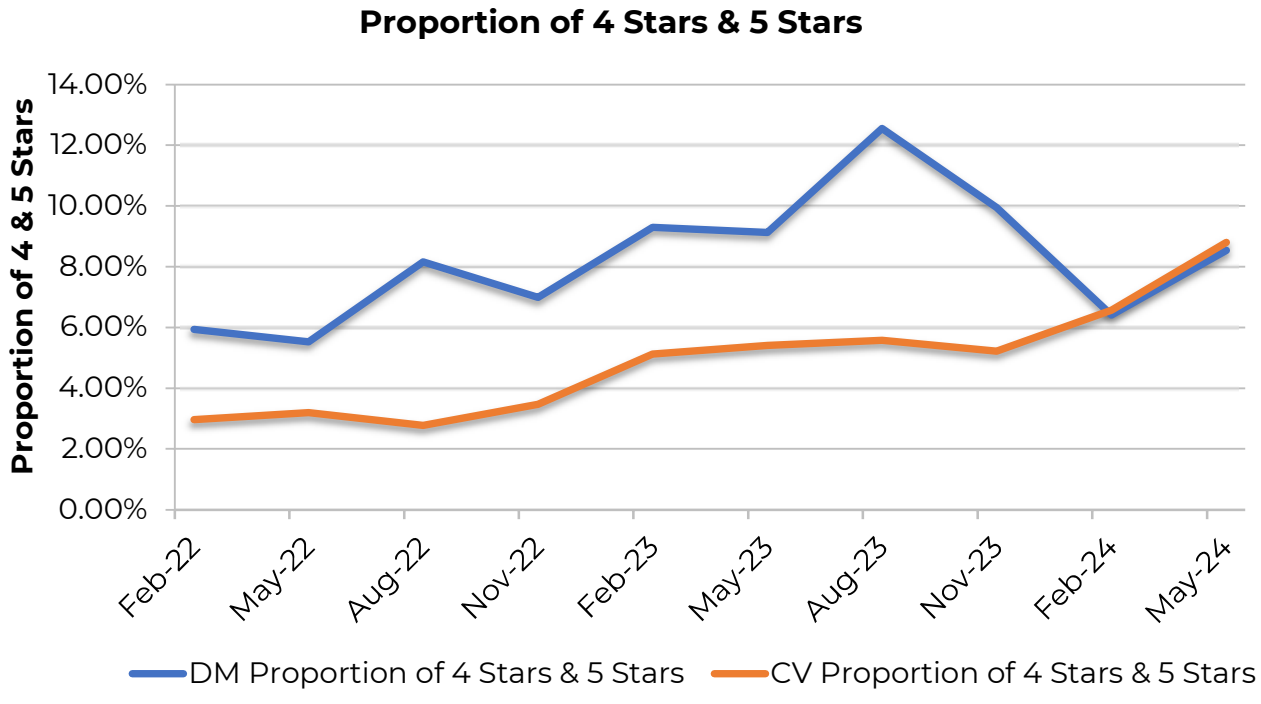


CMA Trends

The following line graph shows trends in the average star rating for prescribers included in the CMA mailing since February 2022. Please note, the vertical axis starts at 0.6 in order to reflect small changes. The mailing list is updated to include prescribers meeting the current CMS criteria and to remove prescribers no longer meeting the criteria. This graph is specific to those prescribers included in the mailings and differentiates between DM and CV (i.e., statins and RAS antagonists) modules. An overall improvement in the average star rating is seen during the analysis period. Since February, 2022, the DM star ratings have been higher than the CV star ratings during the same time period. However, CV star ratings are currently outpacing DM ratings. Approximately 40-45% of the prescribers who received the CMA mailings in a given year continue receiving the CMA mailings when the list is updated. Despite overall favorable increases in the average star ratings, opportunities for further enhancements continue to exist.



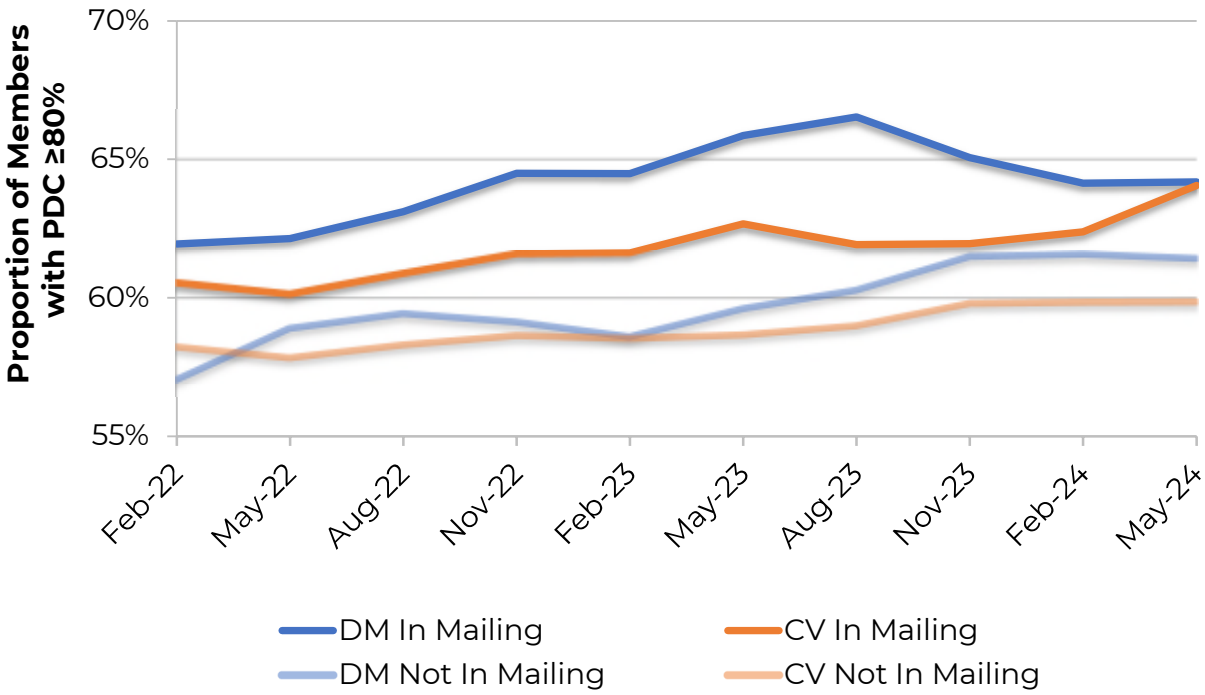
The following line graph shows trends in the proportion of prescribers with 4 star and 5 star ratings included in the CMA mailing since February 2022. An overall increase in the proportion of 4 star and 5 star ratings was seen during the analysis period, similar to the average star ratings above. Also as above, overall favorable increases were seen, but opportunities for further enhancements continue to exist.



The following line graph shows trends in the proportion of members with a PDC ≥80% for those members with prescribers included in the mailing

compared to those with prescribers not included in the mailing since February 2022. A member is considered adherent if their PDC is ≥80%. Please note, the vertical axis starts at 55% in order to reflect small changes.

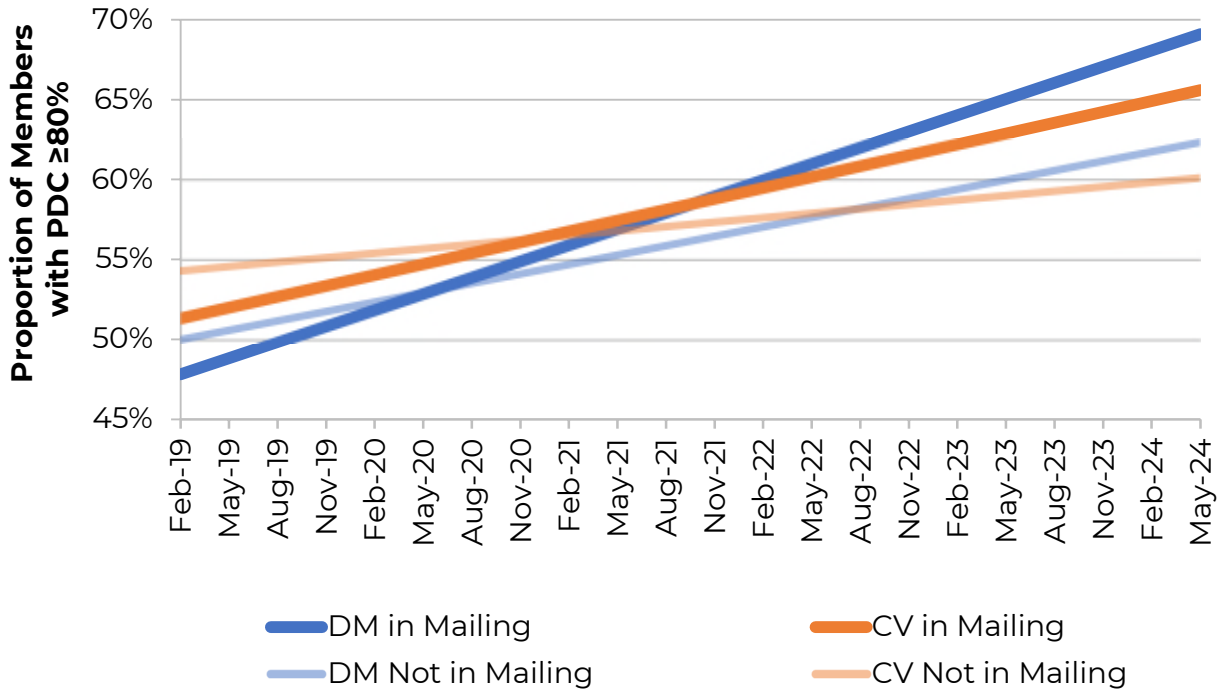
Proportion of Members with PDC ≥80%, 2022-2024



Unlike prescribers included in the mailings, members included in the mailings are not consistent and may change during the calendar year due to medication discontinuations, gaining or losing SoonerCare eligibility, or changing to a prescriber not included in the mailing cohort. Despite member variability, an overall increase in the proportion of members with a PDC ≥80% was seen for both modules for those prescribers included in the recent mailing cohort. The trend is similar when compared to prescribers not included in the mailing. However, prescribers included in the mailing continue to have a higher proportion of members with PDC ≥80% than their peers. This indicates prescriber mailings may have a positive impact on the proportion of members with PDC ≥80%.

The following graph shows the linear trends in the proportion of members with a PDC ≥80% for those members with prescribers included in the mailing compared to those with prescribers not included in the mailing since February 2019. Please note, the vertical axis starts at 45% in order to reflect small changes.

Proportion of Members with PDC ≥80%, 2019-2024



Since February 2019, members included in the CV mailings improved their rates of CV medication adherence by 103% compared to members not included in the CV mailings. During the same time period members included in the DM mailings improved their rates of DM medication adherence by 37% compared to members not included in the DM mailings.

Conclusions

Data specific to prescribers in the CMA mailing shows an overall trend toward higher average star ratings and an increase in the prescriber percentage of adherent members using chronic maintenance DM and CV medications. Trends in prescriber specific measures continue to show improvement, and while favorable increases were seen, opportunities for further enhancements continue to exist. The College of Pharmacy will continue to monitor SoonerCare member adherence with the goal of achieving a member PDC of ≥80% and a 5 star rating for the prescriber percentage of adherent members. New interventions will be implemented where appropriate, and results will be reported to the Drug Utilization Review (DUR) Board when available.

[1] Centers for Medicare and Medicaid Services (CMS): *Medicare 2024 Part C & D Star Rating Technical Notes*. Available online at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData. Last revised 03/13/2024. Last accessed 06/18/2024.

Appendix C

Vote to Prior Authorize Rezdiffra™ (Resmetirom)

Oklahoma Health Care Authority
July 2024

Market News and Updates[1,2]

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

- **March 2024:** The FDA granted accelerated approval to Rezdiffra™ (resmetirom), in conjunction with diet and exercise, for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH[Δ]) 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[3]

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)

[Δ] Please note: The former nomenclature for 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 [metabolic dysfunction-associated steatotic liver dysfunction (MASLD)/metabolic dysfunction-associated steatohepatitis (MASH)] from multinational liver societies, including the American Association for the Study of Liver Diseases (AASLD).

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/m; 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] 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 06/24/2024.
[2] 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.
[3] 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 06/24/2024.

Appendix D

Vote to Prior Authorize Risvan® [Risperidone Intramuscular (IM) Injection] and Update the Approval Criteria for the Atypical Antipsychotic Medications

Oklahoma Health Care Authority
July 2024

Market News and Updates[1]

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.

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) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Use of quetiapine 150mg tablet requires 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.

[1] 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 06/18/2024.

Appendix E

Vote 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 and Update the Approval Criteria for the Various Special Formulations

Oklahoma Health Care Authority
July 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.

Baclofen 15mg Tablet and Ozobax® DS (Baclofen DS 10mg/5mL Oral Solution) Product Summary and Recommendations[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.

The College of Pharmacy recommends the prior authorization of baclofen 15mg tablet and Ozobax® DS 10mg/5mL [baclofen double strength (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 Product Summary and Recommendations[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)	$2.27	$272.40
chlorzoxazone 500mg tablet (generic)	$0.20	$36.00

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 of 750mg orally 4 times daily.

The College of Pharmacy recommends the prior authorization of chlorzoxazone 250mg tablet with placement into the Special Prior Authorization (PA) Tier of the Muscle Relaxant Medications PBPA category with the following additional criteria (shown in red):

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.

Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser) Product Summary and Recommendations[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)	$0.25	$15.00
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.

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.

Combogesic® IV (Acetaminophen/Ibuprofen) Product Summary and Recommendations[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.

The College of Pharmacy recommends the prior authorization of Combogesic® IV (ibuprofen/acetaminophen injection) 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.

Elyxyb™ (Celecoxib Oral Solution) Product Summary and Recommendations[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 ibuprofen and naproxen 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)	**$28.40**	**$1,090.56[α]**
diclofenac potassium 50mg powder (generic Cambia®)	$25.98	$207.84[α]
celecoxib 200mg capsule (generic)	$0.09	$1.44[β]
ibuprofen 400mg tablet (generic)	$0.05	$1.50[+]
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.

The College of Pharmacy recommends the prior authorization of Elyxyb™ (celecoxib oral solution) with placement into the Special PA Tier of the NSAIDs PBPA category with the following additional criteria (shown in red):

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.

Ingrezza® Sprinkle (Valbenazine) Product Summary and Recommendations[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	$265.54	$7,966.20

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 dose 80mg once daily.

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.

Lodoco® (Colchicine) Product Summary and Recommendations[24,25,26,27,28,29,30,31]

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 Behçet'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)	$3.35	$100.50
colchicine 0.6mg tablet (generic)	$0.22	$6.60

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 = capsule, mL, or tablet
*Cost per 30 days is based on a 0.5mg or 0.6mg once daily dose.

The College of Pharmacy 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; and
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 patient-specific, clinically significant reason why the member cannot use the 0.6mg tablet, which is available without a prior authorization, must be provided; and
9. 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.

Millipred™ (Prednisolone 5mg Tablet) Product Summary and Recommendations[32,33]

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.

The College of Pharmacy recommends the prior authorization of Millipred™ (prednisolone) tablet 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 ER Capsule) Product Summary and Recommendations[34,35]

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 IR is indicated in patients 4 years of age or older and the package labeling includes dosing for pediatric patients weighing 11kg or more. Refer to the full package labeling for recommended dosing.
  - The total daily dose for lacosamide IR tablets is the same as Motpoly XR™; however, the IR tablets are dosed twice daily.

Formulation Cost Comparison:

Product	Cost Per Unit	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).
Unit = capsule or tablet
ER = extended-release

The College of Pharmacy recommends the prior authorization of Motpoly XR™ (lacosamide ER) with the following criteria (shown in red):

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.

Neo-Synalar® (Neomycin 0.5%/Fluocinolone 0.025% Cream) Product Summary and Recommendations[36,37,38,39,40,41,42]

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)	$1.07	$64.20
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).

The College of Pharmacy 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.

PoKonza™ (Potassium Chloride 10mEq Packet for Oral Solution) Product Summary and Recommendations[43,44,45,46,47,48]

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)	$0.11	$6.60
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.

The College of Pharmacy 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 of 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.

Suflave™ (PEG-3350/Sodium Sulfate/Potassium Chloride/Magnesium Sulfate/Sodium Chloride) Product Summary and Recommendations[49,50,51,52]

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)	**$119.87**
PEG-3350/sodium sulfate/sodium chloride/potassium chloride/ sodium ascorbate/ascorbic acid powder (generic MoviPrep®)	$58.87
PEG-3350/sodium chloride/sodium bicarbonate/potassium chloride powder (generic NuLYTELY®)	$28.44

Product	Cost Per Treatment*
PEG-3350/sodium sulfate/sodium bicarbonate/sodium chloride/ potassium chloride powder (generic GoLYTELY®)	$16.04

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.

The College of Pharmacy 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®.

Valsartan Oral Solution Product Summary and Recommendations[53,54]

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)	$0.11	$3.30

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.

The College of Pharmacy 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.

Additional Recommendations

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®.~~

[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 06/13/2024.
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Appendix F

Vote to Prior Authorize Qalsody® (Tofersen) and Rilutek® (Riluzole Oral Tablet) and Update the Approval Criteria for the Amyotrophic Lateral Sclerosis (ALS) Medications

Oklahoma Health Care Authority
July 2024

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

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:

- **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[5]

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[6]

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 safe and 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.~~

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Appendix G

Vote to Prior Authorize Liqrev® (Sildenafil Oral Suspension), Opsynvi® (Macitentan/Tadalafil), and Winrevair™ (Sotatercept-csrk) and Update the Approval Criteria for the Pulmonary Arterial Hypertension (PAH) Medications

Oklahoma Health Care Authority
July 2024

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

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

- **April 2023:** The FDA approved Liqrev® (sildenafil oral suspension) for the treatment of 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 (PDE-5) 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[5]

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 based on the initial FDA recommended dosing of 20mg 3 times daily

Cost Comparison: 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 (generic)	$0.31	18.60^{¥}$	223.20^{¥}$
sildenafil 20mg (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 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. 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. Member is currently taking PAH medications from at least 2 of the following categories for ≥90 days or has a contraindication to use of all alternatives:
    a. Phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil, tadalafil) or soluble guanylate cyclase stimulator (e.g., riociguat); or
    b. Endothelin-receptor antagonist (e.g., ambrisentan, bosentan); or
    c. Prostacyclin analogue or receptor agonist (e.g., epoprostenol, treprostinil); and
4. Prescriber must verify that Winrevair™ will be used concurrently with member's current PAH therapies; and
5. Medical supervision by a pulmonary specialist and/or cardiologist; and
6. 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
7. Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and
8. 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
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. 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 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 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.

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[2] 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 06/18/2024.
[3] 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 06/18/2024.
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Appendix H

Vote to Prior Authorize Akeega® (Niraparib/ Abiraterone) and Anktiva® (Nogapendekin Alfa Inbakicept-pmln) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications

Oklahoma Health Care Authority
July 2024

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

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[8]

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[9]

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; and
5. Member has not progressed on prior abiraterone therapy.

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; and
    a. Member has received prior treatment with a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor.

~~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.

[1] U.S. Food and Drug Administration (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 06/25/2024.
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[7] 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 06/25/2024.
[8] 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 06/25/2024.
[9] 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 06/25/2024.

Appendix I

Calendar Year 2023 Annual Review of Testosterone Products

Oklahoma Health Care Authority
July 2024

Current Prior Authorization Criteria

Testosterone Products		
Tier-1*	**Tier-2**	**Special PA**
testosterone cypionate IM inj (Depo Testosterone®)	testosterone enanthate sub-Q auto-injector (Xyosted®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone nasal gel (Natesto®)	testosterone pellets (Testopel®)
testosterone topical gel 1% packet, tube (Testim®, Vogelxo®)	testosterone patch (Androderm®)	testosterone undecanoate oral cap (Jatenzo®, Kyzatrex®, Tlando®)
testosterone topical gel 1.62% pump (Androgel®) – **Brand Preferred**	testosterone topical gel 1%, 1.62% packet (Androgel®)	
testosterone topical solution (Axiron®)	testosterone topical gel 1% pump (Vogelxo®)	
	testosterone topical gel 2% pump (Fortesta®)	
	testosterone undecanoate IM inj (Aveed®)	

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

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis of 1 of the following:
    a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchiectomy; or
    b. Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or
    c. Delayed puberty; or
    d. Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal females with breast cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and

2. The prescriber must verify the member has been evaluated for the presence of a pituitary tumor as the potential cause of low testosterone and the member will receive appropriate follow-up and/or treatment as necessary; and
3. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
4. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
5. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

Testosterone Products Tier-2 Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. Member must have a trial of at least 2 Tier-1 products (must include at least 1 injectable and 1 topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 products must be provided; or
4. Prior stabilization on a Tier-2 product (within the past 180 days); and
5. Approvals will be for the duration of 1 year; and
6. For Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]:
    a. Member must be trained by a health care professional on sub-Q administration and storage of Xyosted® sub-Q auto-injector.

Testosterone Products Special Prior Authorization (PA) Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone must be provided; and
3. Approvals will be for the duration of 1 year.

Utilization of Testosterone Products: 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	453	1,958	$226,594.46	$115.73	$3.36	31,422	67,491
2023	549	2,123	$232,683.44	$109.60	$3.15	39,493	73,879
% Change	**21.20%**	**8.40%**	**2.70%**	**-5.30%**	**-6.30%**	**25.70%**	**9.50%**
Change	**96**	**165**	**$6,088.98**	**-$6.13**	**-$0.21**	**8,071**	**6,388**

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

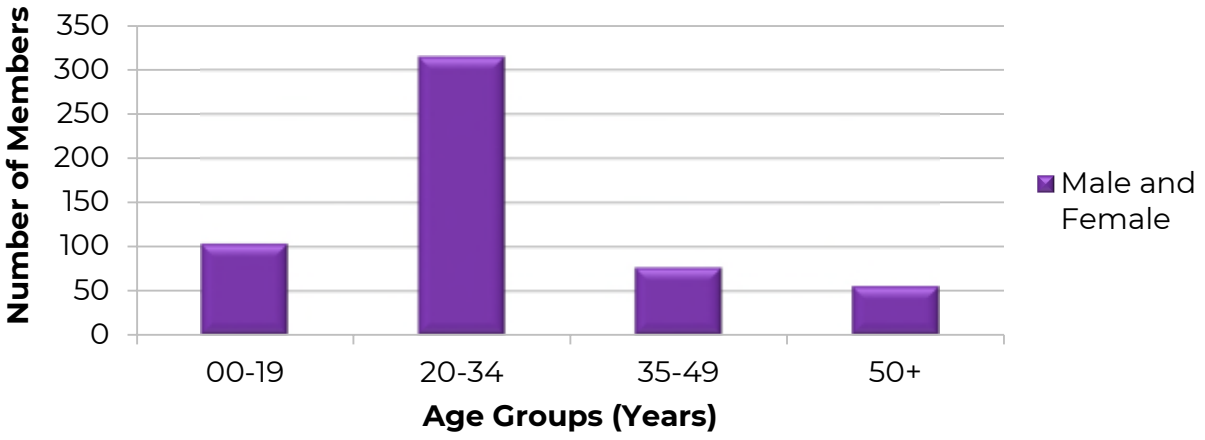
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	14	49	$172.74	$3.53	3.5
2023	16	56	$174.87	$3.12	3.5
% Change	**14.29%**	**14.29%**	**1.23%**	**-11.61%**	**0.00%**
Change	**2**	**7**	**$2.13**	**-$0.41**	**0**

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

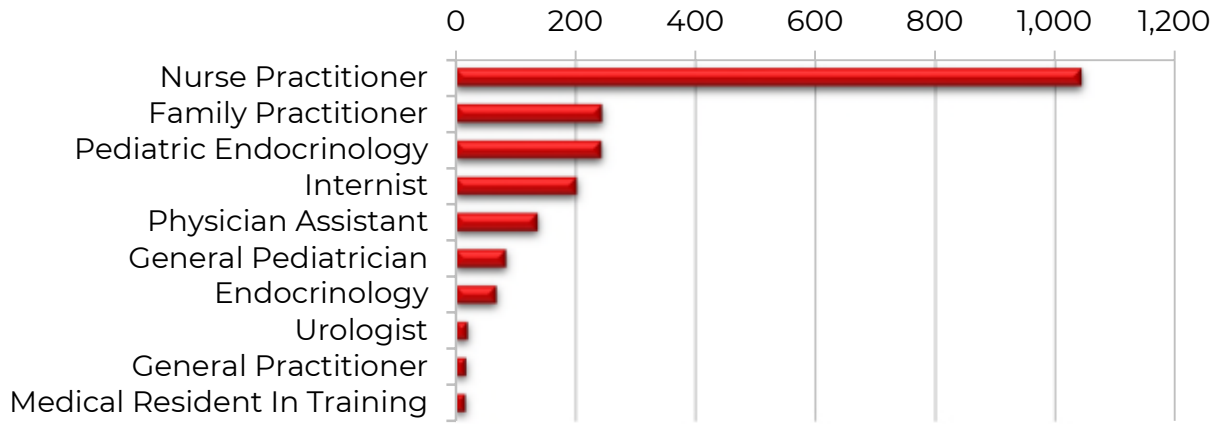
- Aggregate drug rebates collected during calendar year 2023 for testosterone products totaled $156,601.32[Δ]. Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Testosterone Products: Pharmacy 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.

Top Prescriber Specialties of Testosterone Products by Number of Claims: Pharmacy Claims



Prior Authorization of Testosterone Products

There were 2,651 prior authorization requests submitted for testosterone products during calendar year 2023. All testosterone products require prior authorization regardless of tier status in order to evaluate diagnosis and submitted labs. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Androgel® (testosterone topical gel): October 2026
- Aveed® [testosterone undecanoate intramuscular (IM) injection]: May 2027
- Kyzatrex® (testosterone undecanoate oral capsule): March 2033
- Vogelxo® (testosterone topical gel): February 2034
- Natesto® (testosterone nasal gel): March 2034
- Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]: August 2038

- Jatenzo® (testosterone undecanoate oral capsule): April 2039
- Tlando® (testosterone undecanoate oral capsule): April 2041

News:

- **March 2023:** Androderm® (testosterone patch) has been discontinued by the manufacturer.

Recommendations

The College of Pharmacy recommends the following changes to the Testosterone Products Product Based Prior Authorization (PBPA) category based on current product availability and net costs (changes shown in red in the following Tier chart):

1. Moving Aveed® (testosterone undecanoate IM injection) and Natesto® (testosterone nasal gel) from Tier-2 to the Special Prior Authorization (PA) Tier; and
2. Removing the brand preferred status for Androgel® (testosterone topical gel 1.62% pump); and
3. Removing Androderm® (testosterone patch) based on product discontinuation.

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

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

Utilization Details of Testosterone Products: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOSTERONE INJECTABLE PRODUCTS						
TESTOST CYP INJ 200MG/ML	1,693	453	$67,547.20	$39.90	3.74	29.03%
DEPO-TESTOST INJ 200MG/ML	86	46	$3,462.36	$40.26	1.87	1.49%
TESTOST ENAN INJ 200MG/ML	17	12	$1,435.74	$84.46	1.42	0.62%
TESTOST CYP INJ 100MG/ML	17	14	$993.90	$58.46	1.21	0.43%
XYOSTED INJ 100MG/0.5ML	3	2	$1,769.67	$589.89	1.5	0.76%
DEPO-TESTOST INJ 100MG/ML	2	2	$117.18	$58.59	1	0.05%
SUBTOTAL	**1,818**	**477***	**$75,326.05**	**$41.43**	**3.81**	**32.37%**
TESTOSTERONE TOPICAL PRODUCTS						
ANDROGEL GEL 1.62% PUMP	192	69	$129,922.90	$676.68	2.78	55.84%
TESTOSTERONE GEL 1% (50MG)	65	19	$11,513.34	$177.13	3.42	4.95%
TESTOSTERONE GEL 1.62% PUMP	22	13	$1,025.61	$46.62	1.69	0.44%
TESTIM GEL 1% (50MG)	6	2	$3,433.32	$572.22	3	1.48%
TESTOSTERONE SOL 30MG/ACT	6	1	$1,192.18	$198.70	6	0.51%
ANDRODERM DIS 4MG/24HR	1	1	$601.98	$601.98	1	0.26%
TESTOSTERONE GEL 1.62%	1	1	$169.36	$169.36	1	0.07%
SUBTOTAL	**293**	**88***	**$147,858.69**	**$504.64**	**3.33**	**63.54%**
TESTOSTERONE ORAL PRODUCTS						
TLANDO CAP 112.5MG	10	1	$7,550.60	$755.06	10	3.25%
JATENZO CAP 158MG	2	1	$1,948.10	$974.05	2	0.84%
SUBTOTAL	**12**	**1***	**$9,498.70**	**$791.56**	**12**	**4.08%**
TOTAL	**2,123**	**549***	**$232,683.44**	**$109.60**	**3.87**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; CAP = capsule; CYP = cypionate; DIS = patch; ENAN = enanthate; INJ = injection; SOL = solution; TESTOST = testosterone

Medical Claims

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TESTOSTERONE CYPIONATE INJ J1071	56	16	$174.87	$3.12	3.5
TOTAL	**56**	**16**	**$174.87**	**$3.12**	**3.5**

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

[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 06/2023. Last Accessed 06/16/2024.
[2] American Society of Health-System Pharmacists (ASHP). Current Drug Shortages: Testosterone Transdermal System. Available online at: https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=925&loginreturnUrl=SSOCheckOnly. Issued 03/13/2023. Last accessed 06/18/2024.

Appendix J

Calendar Year 2023 Annual Review of Colorectal Cancer (CRC) Medications and 30-Day Notice to Prior Authorize Avzivi® (Bevacizumab-tnjn) and Fruzaqla® (Fruquintinib)

Oklahoma Health Care Authority
July 2024

Current Prior Authorization Criteria

Utilization data for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Opdivo® (nivolumab), and Yervoy® (ipilimumab) and approval criteria for indications other than CRC can be found in the December 2023 Drug Utilization Review (DUR) packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Cyramza® (ramucirumab) and approval criteria for indications other than CRC can be found in the January 2024 DUR packet. This medication and criteria are reviewed annually with the gastrointestinal (GI) cancer medications. Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki), Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), Perjeta® (pertuzumab), Trazimera® (trastuzumab-qyyp), Tukysa® (tucatinib), and Tykerb® (lapatinib) and approval criteria for indications other than CRC can be found in the September 2023 DUR packet. These medications and criteria are reviewed annually with the breast cancer medications.

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

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

Cyramza® (Ramucirumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of CRC; and
2. Subsequent therapy for metastatic disease after progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; and
3. Used in combination with an irinotecan-based regimen.

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

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

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

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with pertuzumab, lapatinib, or tucatinib; and
4. Used in 1 of the following settings:
    a. If first-line therapy, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression; and
5. Preferred trastuzumab products include Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), or Trazimera® (trastuzumab-qyyp)]. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

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

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

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

3. Previously treated with an anti-vascular endothelial growth factor (VEGF) therapy; and
    a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy; and
4. Used as monotherapy or in combination with bevacizumab.

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of metastatic gastric or GEJ adenocarcinoma; and
2. Previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, paclitaxel, docetaxel, or irinotecan; and
3. If human epidermal receptor type 2 (HER2)-positive disease, prior treatment should have included HER2 targeted therapy.

Mvasi® (Bevacizumab-awwb) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Alymsys® (bevacizumab-maly), Avastin® (bevacizumab), Vegzelma® (bevacizumab-adcd), or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

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

Perjeta® (Pertuzumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with trastuzumab; and
4. Used in 1 of the following settings:
    a. If first-line therapy, member should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression.

Stivarga® (Regorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic, recurrent, or unresectable CRC; and
2. Previous treatment with a fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previous treatment with an anti-vascular endothelial growth factor (VEGF) therapy; and
    a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy.

Stivarga® (Regorafenib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic GIST; and
2. Previously treated with imatinib and sunitinib.

Stivarga® (Regorafenib) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Previous treatment with sorafenib.

Stivarga® (Regorafenib) Approval Criteria [Osteosarcoma Diagnosis]:

1. Used for relapsed or refractory disease; and
2. Used in the second line or greater setting; and
3. Used as a single agent.

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

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

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

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

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

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

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 CRC Medications: Calendar Year 2023

The following utilization data includes medications indicated for CRC; however, the data does not differentiate between CRC 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	15	40	$621,974.72	$15,549.37	$555.33	2,634	1,120
2023	25	90	$1,191,747.52	$13,241.64	$472.35	4,686	2,523
% Change	**66.70%**	**125.00%**	**91.60%**	**-14.80%**	**-14.90%**	**77.90%**	**125.30%**
Change	**10**	**50**	**$569,772.80**	**-$2,307.73**	**-$82.98**	**2,052**	**1,403**

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

Calendar Year Comparison: Medical Claims

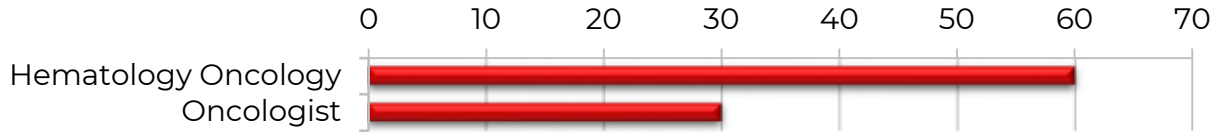
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	899	3,155	$2,954,291.43	$936.38	3.51
2023	1,006	3,407	$3,188,585.64	$935.89	3.39
% Change	**11.90%**	**7.99%**	**7.93%**	**-0.05%**	**-3.50%**
Change	**107**	**252**	**$234,294.21**	**-$0.49**	**-0.12**

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

Demographics of Members Utilizing CRC Medications: Pharmacy Claims

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

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



Prior Authorization of CRC Medications

There were 91 prior authorization requests submitted for CRC 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]

Anticipated Patent Expirations

- Stivarga® (regorafenib): July 2032
- Fruzaqla® (fruquintinib): September 2035
- Lonsurf® (trifluridine/tipiracil): February 2037

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

- **November 2023:** The FDA approved Fruzaqla® (fruquintinib) for the treatment of adult patients with metastatic CRC who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if RAS wild-type and medically appropriate, an anti-epidermal growth factor receptor (EGFR) therapy.
- **December 2023:** The FDA approved Avzivi® (bevacizumab-tnjn), a biosimilar for Avastin® (bevacizumab), for the treatment of the following: metastatic CRC; unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer (NSCLC); recurrent glioblastoma; metastatic renal cell carcinoma; persistent, recurrent, or metastatic cervical cancer; and epithelial ovarian, fallopian tube, or primary peritoneal cancer. Avzivi® contains bevacizumab, which is a VEGF inhibitor. Avzivi® is not indicated for adjuvant treatment of colon cancer.

Fruzaqla® (Fruquintinib) Product Summary[4]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with metastatic CRC who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy

How Supplied: 1mg and 5mg oral capsules

Dosing and Administration: Recommended dose is 5mg once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) is $1,200 per 5mg capsule, resulting in a cost of $25,200 per 28 days or $327,600 per year based on recommended dosing.

Cost Comparison: Bevacizumab Products

Product	Cost Per 10mg	Cost Per 28 Days*	Cost Per Year
Avastin® (bevacizumab) 400mg vial	$72.46	$5,796.80	$75,358.40
Vegzelma® (bevacizumab-adcd) 400mg vial	$61.24	$4,899.20	$63,689.60
Alymsys® (bevacizumab-maly) 400mg vial	$57.72	$4,617.60	$60,028.80
Mvasi® (bevacizumab-awwb) 400mg vial	$26.60	$2,128.00	$27,664.00
Zirabev® (bevacizumab-bvzr) 400mg vial	$20.97	$1,677.60	$21,808.80

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 28 days based on a dose of 5mg/kg every 2 weeks for a member weighing 80kg
Please note: Cost information is not yet available for Avzivi® (bevacizumab-tnjn) to allow for a cost comparison.

Recommendations

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

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

1. Diagnosis of metastatic CRC; and
2. Previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previously treated with an anti-vascular endothelial growth factor (VEGF) therapy; and
4. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy.

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

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

1. A patient-specific, clinically significant reason why the member cannot use ~~Alymsys® (bevacizumab-maly),~~ Avastin® (bevacizumab), Mvasi® (bevacizumab-awwb), ~~Vegzelma® (bevacizumab-adcd),~~ or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Utilization Details of CRC Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRIFLURIDINE/TIPIRACIL PRODUCTS						
LONSURF TAB 20/8.19MG	48	17	$682,117.11	$14,210.77	2.82	57.24%
LONSURF TAB 15/6.14MG	25	9	$187,466.54	$7,498.66	2.78	15.73%
SUBTOTAL	**73**	**20***	**$869,583.65**	**$11,912.10**	**3.65**	**72.97%**
REGORAFENIB PRODUCTS						
STIVARGA TAB 40MG	16	9	$296,956.46	$18,559.78	1.78	24.92%
SUBTOTAL	**16**	**9***	**$296,956.46**	**$18,559.78**	**1.78**	**24.92%**
FRUQUINTINIB PRODUCTS						
FRUZAQLA CAP 5MG	1	1	$25,207.41	$25,207.41	1	2.12%
SUBTOTAL	**1**	**1***	**$25,207.41**	**$25,207.41**	**1**	**2.12%**
TOTAL	**90**	**25***	**$1,191,747.52**	**$13,241.64**	**3.6**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BEVACIZUMAB J9035 (AVASTIN)	2,653	915	$2,015,310.65	$759.63	2.9
BEVACIZUMAB-BVZR Q5118 (ZIRABEV)	663	86	$1,014,823.23	$1,530.65	7.71
BEVACIZUMAB-AWWB Q5107 (MVASI)	86	12	$139,180.06	$1,618.37	7.17
BEVACIZUMAB-ADCD Q5129 (VEGZELMA)	5	2	$19,271.70	$3,854.34	2.5
TOTAL	**3,407**	**1,006**	**$3,188,585.64**	**$935.89**	**3.39**

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2024. Last accessed 06/11/2024.
[2] U.S. FDA. FDA Approves Trifluridine and Tipiracil with Bevacizumab for Previously Treated Metastatic Colorectal Cancer. Available online at: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-trifluridine-and-tipiracil-bevacizumab-previously-treated-metastatic-colorectal-cancer. Issued 08/02/2023. Last accessed 06/18/2024.
[3] Bio-Thera Solutions, Ltd. FDA Approves Bio-Thera Solutions' Avzivi® (Bevacizumab-tnjn), a Biosimilar Referencing Avastin®. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-bio-thera-solutions-avzivi-bevacizumab-tnjn-a-biosimilar-referencing-avastin-302009433.html. Issued 12/07/2023. Last accessed 06/18/2024.
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Appendix K

30-Day Notice to Prior Authorize Wegovy® (Semaglutide)

Oklahoma Health Care Authority
July 2024

Introduction[1,2,3]

Cardiovascular disease (CVD) is one of the leading causes of death in the United States, and it is estimated that 48.6% of Americans 20 years of age or older have CVD, including coronary heart disease, heart failure, or stroke. Overweight and obesity are associated with increased risk of all-cause and CVD mortality by raising the risk of morbidity from risk factors of CVD, including hypertension, dyslipidemia, and type 2 diabetes mellitus (T2DM).

In March 2024, the U.S. Food and Drug Administration (FDA) approved a new indication for Wegovy® (semaglutide) to reduce the risk of major adverse cardiovascular (CV) events in adults with established CVD and either obesity or overweight, used in combination with a reduced calorie diet and increased physical activity.

Wegovy® (Semaglutide) Product Summary[4]

Therapeutic Class: Glucagon-like peptide-1 (GLP-1) receptor agonist

Indication(s): Reduce the risk of major adverse CV events [CV death, non-fatal myocardial infarction (MI), or non-fatal stroke] in adults with established CVD and either obesity or overweight in combination with a reduced calorie diet and increased physical activity[Δ]

- **Limitation(s) of Use:** Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended

How Supplied: 0.25mg, 0.5mg, 1mg, 1.7mg, and 2.4mg pre-filled, single-dose pen

Dosing and Administration:

- Wegovy® should be administered once weekly as an adjunct to a reduced calorie diet and increased physical activity
- Recommended starting dose is 0.25mg once weekly for 4 weeks followed by dose titration every 4 weeks to achieve a maintenance dose of 1.7mg or 2.4mg once weekly

[Δ] Refer to the Wegovy® package labeling for the full FDA approved indications.

Efficacy: The safety and efficacy of Wegovy® was studied in a Phase 3 placebo-controlled double-blind trial in over 17,000 patients who were randomized 1:1 to either Wegovy® or placebo. Patients were titrated every 4 weeks until the target dose of 2.4mg was achieved. If intolerable adverse effects occurred the titration period could be extended or the lower maintenance doses were used. All patients were 45 years of age or older, had a BMI ≥27kg/m^2, had established CVD, and were receiving standard of care therapy for their CVD.

- Primary Endpoint: The primary composite endpoint was the time to first occurrence of a major adverse cardiovascular event (CV death, non-fatal MI, or non-fatal stroke) when added to standard of care therapy including management of CV risk factors and individualized healthy lifestyle counseling (including diet and physical activity).
- Results: Wegovy® was found to be statistically significant for the primary composite endpoint. The primary composite endpoint occurred in 6.5% of patients treated with Wegovy® at 48 months versus 8% of those on placebo with a hazard ratio of 0.8.

Cost: The National Average Drug Acquisition Cost (NADAC) of Wegovy® 2.4mg/0.75mL is $432.98 per mL. This results in an estimated cost of $1,298.94 per 28 days or $16,886.22 per year based on recommended maintenance dosing.

Recommendations

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

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

1. An FDA approved indication to reduce the risk of major adverse cardiovascular (CV) events in members with established CV disease (CVD) and either obesity or overweight; and
    a. Wegovy® will not be approved for obese or overweight members in the absence of established CVD; and
2. Member must be 45 years of age or older; and
3. Member must have established CVD with a history of 1 of the following (documentation must be submitted with the request):
    a. Previous myocardial infarction; or
    b. Previous stroke; or
    c. Symptomatic peripheral arterial disease confirmed by 1 of the following:
        i. Intermittent claudication with ankle-brachial index <0.85 at rest; or
        ii. Peripheral arterial revascularization procedure; or

iii. Amputation due to atherosclerotic disease; and

4. Member has a body mass index (BMI) ≥27kg/m^2; and
5. Member does not have type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM); and
6. Member has a hemoglobin A1C (HbA1c) <6.5%; and
7. Member will not be using Wegovy® in combination with other semaglutide-containing products or any other glucagon-like peptide-1 (GLP-1) receptor agonist; and
8. Member is currently receiving guideline-directed management and therapy (GDMT) for CVD (e.g., antihypertensives, lipid-lowering agents, antiplatelets), as documented in the member's pharmacy claims history, unless contraindicated; and
9. Wegovy® must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and
10. Initial approvals will be for the titration period to allow initial and escalation dosing. A separate prior authorization request must be submitted for each dose; and
    a. Approvals will be for 4 weeks at a time to allow for proper dose escalation; and
    b. An additional 4 weeks for each dose may be approved for those who experience intolerable adverse effects during dose escalation with proper documentation; and
    c. Members who cannot tolerate dose escalation after an additional 4 week approval will not be approved for continuation; and
11. Subsequent approvals for the maintenance dose (1.7mg or 2.4mg) will be approved for 1 year if the prescriber documents the following:
    a. Member is tolerating maintenance dosing; and
    b. Member has not developed T1DM or T2DM; and
    c. Member is continuing all of the following in conjunction with Wegovy®:
        i. Reduced calorie diet; and
        ii. Increased physical activity; and
        iii. GDMT for CVD where applicable; and
12. A quantity limit of 4 pens per 28 days will apply; and
13. Wegovy® should be discontinued in members who cannot tolerate the 1.7mg once weekly maintenance dosing.

[1] Martin S, Aday A, Almarzooq Z, et al. 2024 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association. *Circulation* 2024; 149:e347-e913. doi: 10.1161/CIR.0000000000001209.
[2] Jensen M, Ryan D, Apovian C, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults. *Circulation* 2014; 129:S102-S138. doi: 10.1161/01.cir.0000437739.71477.ee.
[3] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-reduce-risk-serious-heart-problems-specifically-adults-obesity-or. Issued 03/08/2024. Last accessed 06/18/2024.
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Appendix L

Calendar Year 2023 Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Filsuvez® (Birch Triterpenes 10% Topical Gel)

Oklahoma Health Care Authority
July 2024

Current Prior Authorization Criteria

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek® must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and
4. Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering provider via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and
5. Vyjuvek® must be administered by a health care professional (HCP) trained in the administration of Vyjuvek®. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health); and
6. Prescriber must attest that Vyjuvek® gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and
7. Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek® that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings for 24 hours following administration; and
8. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female

members of reproductive potential must be willing to use effective contraception while on therapy; and
9. A maximum approval quantity of 1 carton (2.5mL) per week or 4 cartons (10mL) per 28 days will apply; and
10. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing.

Utilization of EB Medications: Calendar Year 2023

There was no SoonerCare utilization of EB medications during calendar year 2023. Please note the only EB medication available during calendar year 2023 was Vyjuvek® (beremagene geperpavec-svdt), which was approved by the U.S. Food and Drug Administration (FDA) in May 2023.

Prior Authorization of EB Medications

There were 2 prior authorization requests submitted for 1 unique member for Vyjuvek® (beremagene geperpavec-svdt) 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]

Anticipated Patent Expiration(s):

- Filsuvez® (birch triterpenes 10% topical gel): January 2039

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

- **December 2023:** The FDA approved Filsuvez® (birch triterpenes 10% topical gel) for the treatment of partial thickness wounds in patients 6 months and older with junctional epidermolysis bullosa (JEB) and dystrophic epidermolysis bullosa (DEB).

Pipeline:

- **Prademagene Zamikeracel (Pz-cel):** Pz-cel is an autologous, collagen type VII alpha 1 chain (*COL7A1*) gene-corrected epidermal sheet, that is being studied to treat recessive DEB by enabling normal type VII

collagen expression and facilitating wound healing and pain reduction after a one-time application procedure. A Complete Response Letter (CRL) was issued by the FDA in April 2024 in response the Biologics License Application (BLA) for pz-cel, which asked for additional information needed to satisfy Chemistry Manufacturing and Control requirements before the application can be approved. The CRL did not identify any issues related to the clinical safety and efficacy in the data submitted in the BLA. The initial BLA was supported by clinical and safety data from the Phase 3 VIITAL study and Phase 1/2a study, which both showed an improvement in wound healing and pain reduction in large chronic recessive DEB wounds. The manufacturer plans to resubmit the BLA in the third quarter of 2024 with the additional information requested by the FDA in the CRL.

Filsuvez® (Birch Triterpenes 10% Topical Gel) Product Summary[4,5]

Therapeutic Class: Dermatological agent

Indication(s): Treatment of wounds associated with DEB and JEB in adult and pediatric patients 6 months of age and older

How Supplied: 10% birch triterpenes topical gel in a 23.4 gram sterile tube

Dosing and Administration:

- Filsuvez® may be administered by the patient or caregiver.
- Filsuvez® should be applied in a 1mm layer to the affected wound surface and covered with wound dressing or applied directly to the dressing so that the gel is in direct contact with the wound.
- Filsuvez® should not be rubbed into the skin.
- It should be applied to cleansed wounds at wound dressing changes until the wound is healed.
- Each tube of Filsuvez® is for one-time use only. Once the tube is opened, it should be used immediately, and any extra gel should be discarded.
- Filsuvez® is for topical use only and should not be used for oral, intravaginal, intra-anal, or ophthalmic routes.

Efficacy: The safety and efficacy of Filsuvez® for the treatment of wounds associated with EB was studied in EASE, a Phase 3 double-blind, randomized, vehicle-controlled trial.

- Key Inclusion Criteria:
    - Patients ≥6 months of age or older with DEB or JEB
    - Target wound was defined as a partial-thickness wound of 10 to 50cm^2 present for ≥21 days and <9 months prior to screening

- Intervention: Patients were randomized 1:1 to receive Filsuvez® or control topical gel to apply to the target wound with standard of care dressing changes.
- Primary Outcome: Patients with first complete wound closure of target wound by day 45 of the 90-day double-blind phase of the trial
- Results: The Filsuvez®-treated group resulted in 41.3% of patients with first complete wound closure within 45 days compared to 28.9% in the vehicle group [relative risk (RR) 1.44; 95% confidence interval (CI) 1.01, 2.05; P=0.013].

Cost Comparison: EB Medications

Product	Cost Per Unit	Cost Per 28 Days	Cost Per Year
Filsuvez® (birch triterpenes 10% topical gel)	**$76.92**	**$50,397.98α**	**$655,173.79α**
Vyjuvek® (beremagene geperpavec-svdt)	$9,700.00	$97,000.00*	$1,261,000.00*

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 = gram or mL
αCost for Filsuvez® is based on the use of 1 tube (23.4g) daily.
*Cost for Vyjuvek® is based on the FDA maximum recommended weekly dose, which would require 1 carton (2.5mL) per week regardless of dose.

Recommendations

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

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

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB); and
2. Diagnosis must be confirmed by a pathogenic variant in the *COL7A1* gene for DEB or biallelic pathogenic variants in the *COL17A1*, *ITGA3*, *ITGA6*, *ITGB4*, *LAMA3*, *LAMB3*, or *LAMC2* genes for JEB (results of genetic testing must be submitted); and
3. Filsuvez® must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB or JEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB or JEB); and
4. Member must have the presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days; and
5. Filsuvez® must be applied to open partial-thickness wounds at dressing changes at least once every 4 days or up to once daily; and
6. Prescriber must attest that member and/or caregiver has been counseled on the appropriate administration and storage of Filsuvez®

based on package labeling including that each sterile tube is for one-time use only; and
7. Member and/or caregiver has been advised on possible hypersensitivity reactions with Filsuvez® and to discontinue use and contact the prescriber if symptoms of a hypersensitivity reaction develop; and
8. Filsuvez® will not be approved for concomitant use with Vyjuvek® (beremagene geperpavec-svdt); and
9. A maximum approval quantity of 1 tube (23.4 grams) per day or 702 grams per 30 days will apply; and
    a. A quantity limit override will be considered for approval of quantities greater than 1 tube per day if the provider documents the number and size of wounds being treated to justify the need for a larger quantity; and
10. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Filsuvez® will not be applied to closed wounds.

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

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek® must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and
4. Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering provider via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and
5. Vyjuvek® must be administered by a health care professional (HCP) trained in the administration of Vyjuvek®. Approvals will not be granted for self-administration. Prior authorization requests must indicate who

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2024. Last accessed 06/11/2024.
[2] Chiesi Global Rare Diseases. Chiesi Global Rare Diseases Receives FDA Approval for Filsuvez® (Birch Triterpenes) Topical Gel for the Treatment of Epidermolysis Bullosa. Available online at: https://chiesirarediseases.com/media/fda-approval-for-filsuvez-topical-gel. Issued 12/19/2023. Last accessed 06/11/2024.
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[4] Filsuvez® (Birch Triterpenes) Prescribing Information. Chiesi USA, Inc. Available online at: https://resources.chiesiusa.com/Filsuvez/FILSUVEZ_PI.pdf. Last revised 01/2024. Last accessed 06/11/2024.
[5] Kern J, Sprecher E, Fernandez M, et al. Efficacy and Safety of Oleogel-S10 (Birch Triterpenes) for Epidermolysis Bullosa: Results from the Phase III Randomized Double-Blind Phase of the EASE Study. *British Journal of Dermatology* 2023; 188 (1):12–21. doi.org/10.1093/bjd/ljac001.

Appendix M

Calendar Year 2023 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Kisunla™ (Donanemab-azbt)

Oklahoma Health Care Authority
July 2024

Current Prior Authorization Criteria

Alzheimer's Disease Medications Approval Criteria:

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
    a. A patient-specific, clinically significant reason why the special formulation is necessary in place of the standard formulation.
2. An age restriction for ages 0 to 50 years applies to all Alzheimer's medications. Members older than 50 years of age can receive formulations without prior authorization. Members younger than 50 years of age will require prior authorization with the following criteria:
    a. An FDA approved diagnosis; or
    b. Other patient-specific, clinically significant information supporting the use of the medication.

Aduhelm® (Aducanumab-avwa) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 24 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Aduhelm® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and

5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin 325mg per day or less, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Aduhelm®; and
8. Member must not have had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have any pre-treatment localized superficial siderosis, ≥10 brain microhemorrhages, or a brain hemorrhage >1cm within 1 year of treatment initiation as safety with Aduhelm® has not been established in patients with these conditions; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Aduhelm® and prior to the 7th infusion (1st dose of 10mg/kg) and 12th infusion (6th dose of 10mg/kg); and
12. The prescriber must confirm that the member will be monitored for ARIA during the first 8 doses of treatment with Aduhelm®, particularly during titration, and also throughout treatment; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H); and
14. Aduhelm® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and
    a. Aduhelm® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. A patient-specific, clinically significant reason why the member cannot use Leqembi® (lecanemab-irmb) must be provided; and

17. Initial approvals will be for 6 months. Confirmation that MRI has been completed and is acceptable to the provider prior to 7th infusion is required for continuation; and
18. Subsequent approvals will be for 6 months and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy; and
19. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
20. The maximum dose approvable is 10mg/kg per 28 days; and
21. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Leqembi® (Lecanemab-irmb) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 22 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Leqembi® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Leqembi®; and

8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or
    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Leqembi® and prior to the 5th, 7th, and 14th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with Leqembi®; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Leqembi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and
    a. Leqembi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 5th and 7th infusions is required for continuation; and
17. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same

baseline test(s) performed at initiation of therapy for each subsequent approval; and
18. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
19. The maximum dose approvable is 10mg/kg per 14 days; and
20. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Namenda XR® [Memantine Extended-Release (ER) Capsules] Approval Criteria:

1. An FDA approved diagnosis for the treatment of moderate-to-severe Alzheimer's type dementia; and
2. A patient-specific, clinically significant reason why the member cannot use memantine immediate-release tablets must be provided.

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

1. Member must have a patient-specific, clinically significant reason why the separate immediate-release products which do not require prior authorization cannot be used over this combination product; and
2. A quantity limit of 30 capsules per 30 days will apply.

Utilization of Alzheimer's Disease 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	823	5,852	$88,541.44	$15.13	$0.43	309,867	205,146
2023	944	6,122	$90,051.42	$14.71	$0.40	332,446	223,994
% Change	**14.70%**	**4.60%**	**1.70%**	**-2.80%**	**-7.00%**	**7.30%**	**9.20%**
Change	**121**	**270**	**$1,509.98**	**-$0.42**	**-$0.03**	**22,579**	**18,848**

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 Alzheimer's disease medications totaled $2,655.22.[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.

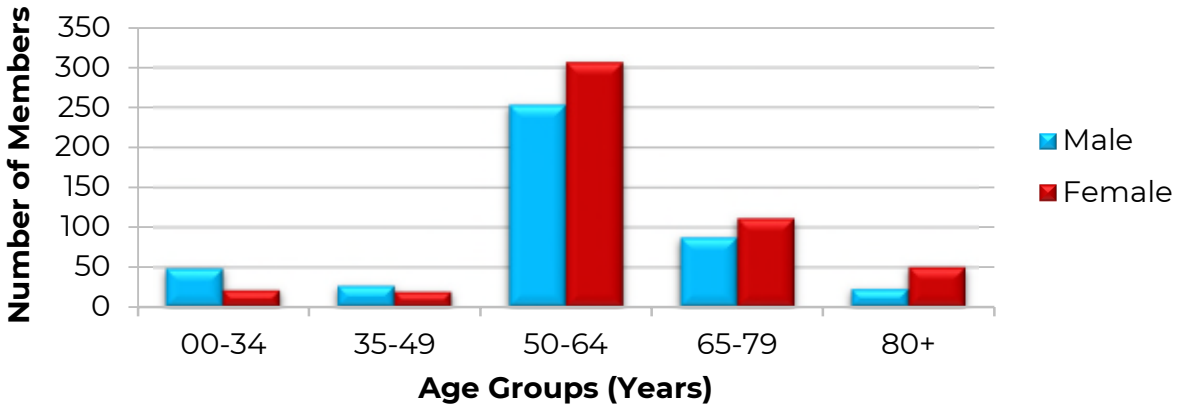
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Calendar Year 2023 Utilization: Medical Claims

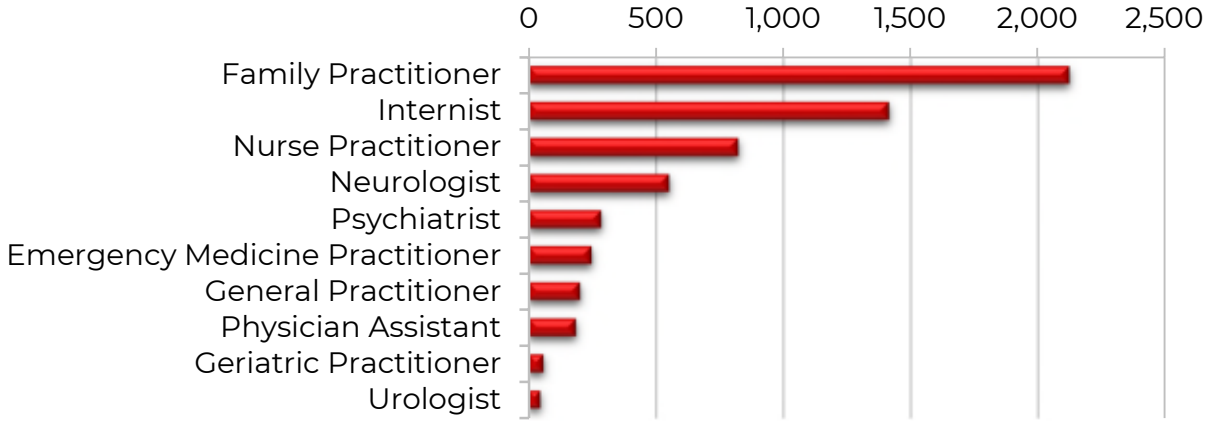
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2023	1	10	$12,700.00	$1,270.00	10

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Please note: There were no paid medical claims for Alzheimer's disease medications during calendar year 2022 to allow for a calendar year comparison.

Demographics of Members Utilizing Alzheimer's Disease Medications

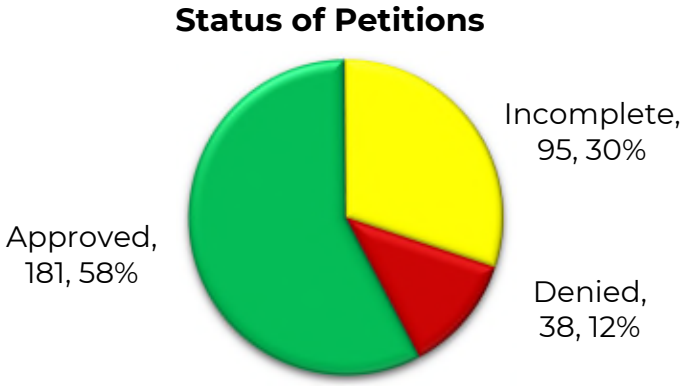


Top Prescriber Specialties of Alzheimer's Disease Medications by Number of Claims



Prior Authorization of Alzheimer's Disease Medications

There were 314 prior authorization requests submitted for Alzheimer's disease 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):

- Namzaric® [memantine extended-release (ER)/donepezil capsules]: December 2029

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

- **July 2024:** The FDA approved Kisunla™ (donanemab-azbt) for the treatment of adults with early symptomatic Alzheimer's disease, which includes patients with mild cognitive impairment (MCI) as well as patients with the mild dementia stage of Alzheimer's disease, with confirmed amyloid pathology. Kisunla™ is the first and only amyloid beta-directed monoclonal antibody with evidence to support discontinuing therapy once amyloid plaques are removed.

News:

- **January 2024:** Biogen announced they will be discontinuing the development and commercialization of Aduhelm® (aducanumab-avwa) and will continue to advance Leqembi® (lecanemab-irmb). The decision was not due to any safety or efficacy reasons but due to the time and investment required for post-marketing studies and the likely advancements in the field by the time Aduhelm® may have received traditional approval from the U.S. Food and Drug Administration (FDA). Biogen also stated that patients receiving Aduhelm® will have it available to them until November 1, 2024.

Pipeline

- **Lecanemab:** Lecanemab (Leqembi®) is an amyloid-beta monoclonal antibody that was approved by the FDA in July 2023 for the treatment of Alzheimer's disease. In June 2024, it was announced that the FDA accepted a Supplemental Biologics License Application (sBLA) for a monthly intravenous (IV) maintenance dosing of lecanemab after the

completion of the biweekly IV initiation phase. A Prescription Drug User Fee Act (PDUFA) date is set for January 25, 2025. A BLA has also been submitted for a lecanemab subcutaneous autoinjector after it was granted Fast Track designation by the FDA in May 2024.

Kisunla™ (Donanemab-azbt) Product Summary[8]

Therapeutic Class: Amyloid beta-directed monoclonal antibody

Indication(s): Treatment of Alzheimer's disease in adults with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials

How Supplied: 350mg/20mL single-dose vial

Dosing and Administration:

- The presence of amyloid beta pathology should be confirmed prior to initiating treatment with Kisunla™.
- A recent (within 1 year) brain magnetic resonance imaging (MRI) should be obtained prior to initiating treatment to evaluate for pre-existing amyloid related imaging abnormalities (ARIA).
- The recommended dose is 700mg administered as an intravenous (IV) infusion over approximately 30 minutes every 4 weeks for the first 3 doses followed by a maintenance dose of 1,400mg IV every 4 weeks.
- Stopping treatment with Kisunla™ should be considered based on reduction of amyloid plaques to minimal levels on amyloid positron emission tomography (PET) imaging.
- An MRI prior to the 2nd, 3rd, 4th, and 7th infusions should be obtained. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms.
- Refer to the full Kisunla™ *Prescribing Information* for the recommended titration and recommendations for patients with ARIA occurrence.

Efficacy: The safety and efficacy of Kisunla™ were studied in the Phase 3 TRAILBLAZER-ALZ 2 trial in patients with early symptomatic Alzheimer's disease and confirmed presence of amyloid pathology. Patients were also required to have confirmation of tau pathology on PET imaging and were categorized as low/medium or high tau. Patients were randomized 1:1 to either placebo or donanemab at doses of 700mg for the first 3 doses and then 1,400mg every 4 weeks. If the amyloid plaque level (assessed at 24 weeks and 52 weeks) was <11 Centiloids on any single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, donanemab-treated patients were blindly switched to placebo.

- <u>Primary Endpoint:</u> The primary efficacy endpoint was a change in the integrated Alzheimer's Disease Rating Scale (iADRS) score from

baseline to 76 weeks in either the low/medium or a combined tau population (low/medium tau and high tau).

- Results:
  - Low/Medium Tau Population:
    - iADRS Score: The donanemab group had a statistically significant change from baseline in the iADRS score of -6.02 versus -9.27 in the placebo group [difference: 3.25; 95% confidence interval (CI): 1.88, 4.62; P<0.001]. These results represented a 35% slowing of disease progression.
    - Amyloid Plaque Levels: Amyloid plaques decreased by 88 Centiloids in the donanemab group versus an increase of 0.2 Centiloids in the placebo group. Some patients also reached amyloid clearance which included 34.2% at 24 weeks and 80.1% at 76 weeks for the donanemab-treated patients.
  - Combined Tau Population:
    - iADRS Score: The donanemab group had a statistically significant change from baseline in the iADRS score of -10.19 versus −13.11 in the placebo group (difference: 2.92; 95% CI: 1.51, 4.33; P<0.001). These results represented a 22% slowing of disease progression.
    - Amyloid Plaque Levels: Amyloid plaques decreased by 87 Centiloids in the donanemab group versus a decrease of 0.67 Centiloids in the placebo group. Some patients also reached amyloid clearance which included 29.7% at 24 weeks and 76.4% at 76 weeks for the donanemab-treated patients.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Kisunla™ (donanemab-azbt) SDV	**$695.65⁺**	**$2,782.60⁺**	**$36,173.80⁺**
Leqembi® (lecanemab-irmb) SDV	$127.40	$2,293.20±	$29,811.60±

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).
SDV = single-dose vial; Unit = mL or vial
⁺The cost per 350mg/20mL vial of Kisunla™ is the estimated cost from the manufacturer. Cost per month and cost per year are based on maintenance dosing (1,400mg every 4 weeks).
±Leqembi® cost is based on use of (2) 200mg/2mL and (1) 500mg/5mL single dose vial for each dose of 10mg/kg every 2 weeks for a member weighing 80kg.
SDV = single dose vial

Recommendations

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

Kisunla™ (Donanemab-azbt) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 20 and 38; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Kisunla™ must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Kisunla™; and
8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or

    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Kisunla™ and prior to the 2nd, 3rd, 4th, and 7th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 12 weeks and throughout treatment with Kisunla™; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Kisunla™ must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and
    a. Kisunla™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 2nd, 3rd, 4th, and 7th infusions is required for continuation; and
16. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
17. Approval quantities will be dependent on dosing based on package labeling; and
18. The maximum approvable dose is 1,400mg per 28 days; and
19. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

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

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

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

Utilization Details of Alzheimer's Disease Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MEMANTINE PRODUCTS						
MEMANTINE TAB HCL 10MG	2,354	369	$35,270.85	$14.98	6.38	39.17%
MEMANTINE TAB HCL 5MG	792	228	$12,135.32	$15.32	3.47	13.48%
MEMANTINE TAB 10MG	304	108	$4,821.73	$15.86	2.81	5.35%
MEMANTINE HCL CAP 28MG ER	137	12	$4,096.12	$29.90	11.42	4.55%
MEMANTINE TAB 5MG	33	20	$468.97	$14.21	1.65	0.52%
MEMANT TITRA PACK 5-10MG	2	2	$56.79	$28.40	1	0.06%
MEMANTINE HCL CAP 14MG ER	2	1	$62.49	$31.25	2	0.07%
MEMANTINE HCL CAP 7MG ER	1	1	$23.41	$23.41	1	0.03%
SUBTOTAL	**3,625**	**741**	**$56,935.68**	**$15.71**	**4.89**	**63.23%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,352	303	$16,264.04	$12.03	4.46	18.06%
DONEPEZIL TAB 5MG	1,000	274	$11,544.62	$11.54	3.65	12.82%
DONEPEZIL TAB 23MG	3	2	$122.89	$40.96	1.5	0.14%
SUBTOTAL	**2,355**	**579**	**$27,931.55**	**$11.86**	**4.07**	**31.02%**
RIVASTIGMINE PRODUCTS						
RIVASTIGMINE CAP 3MG	32	5	$759.49	$23.73	6.4	0.84%
RIVASTIGMINE PATCH 4.6MG/24HR	20	4	$1,444.30	$72.22	5	1.60%
RIVASTIGMINE CAP 1.5MG	16	6	$314.24	$19.64	2.67	0.35%
RIVASTIGMINE CAP 4.5MG	7	3	$144.30	$20.61	2.33	0.16%
RIVASTIGMINE PATCH 9.5MG/24HR	5	3	$370.13	$74.03	1.67	0.41%
RIVASTIGMINE PATCH 13.3MG/24HR	4	2	$220.14	$55.04	2	0.24%
RIVASTIGMINE CAP 6MG	1	1	$26.34	$26.34	1	0.03%
SUBTOTAL	**85**	**24**	**$3,278.94**	**$38.58**	**3.54**	**3.64%**
GALANTAMINE PRODUCTS						
GALANTAMINE TAB 4MG	32	4	$760.48	$23.77	8	0.84%
GALANTAMINE TAB 8MG	22	4	$524.44	$23.84	5.5	0.58%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GALANTAMINE CAP 8MG ER	2	1	$72.82	$36.41	2	0.08%
SUBTOTAL	**56**	**9**	**$1,357.74**	**$24.25**	**6.22**	**1.51%**
MEMANTINE/DONEPEZIL COMBINATION PRODUCTS						
NAMZARIC CAP 7-10MG	1	1	$547.51	$547.51	1	0.61%
SUBTOTAL	**1**	**1**	**$547.51**	**$547.51**	**1**	**0.61%**
TOTAL	**6,122**	**944***	**$90,051.42**	**$14.71**	**6.49**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; HCL = hydrochloride; HR = hour; TAB = tablet; TITRA = titration

Medical Claims

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LECANEMAB-IRMB INJ J0174	10	1	$12,700.00	$1,270.00	10
TOTAL	**10**	**1**	**$12,700.00**	**$1,270.00**	**10**

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2024. Last accessed 06/18/2024.
[2] Eli Lilly. Lilly's Kisunla™ (donanemab-azbt) Approved by the FDA for the Treatment of Early Symptomatic Alzheimer's Disease. Available online at: https://investor.lilly.com/news-releases/news-release-details/lillys-kisunlatm-donanemab-azbt-approved-fda-treatment-early. Issued 07/02/2024. Last accessed 07/03/2024.
[3] Biogen. Biogen to Realign Resources for Alzheimer's Disease Franchise. Available online at: https://investors.biogen.com/news-releases/news-release-details/biogen-realign-resources-alzheimers-disease-franchise. Issued 01/31/2024. Last accessed 06/18/2024.
[4] Alzheimer's Association. Aducanumab to Be Discontinued as an Alzheimer's Treatment. Available online at: https://www.alz.org/alzheimers-dementia/treatments/aducanumab. Last accessed 06/18/2024.
[5] Sims J, Zimmer J, Evans C, et al. Donanemab in Early Symptomatic Alzheimer Disease: The TRAILBLAZER-ALZ 2 Randomized Clinical Trial. *JAMA* 2023; 330(6):512-527. doi: 10.1001/jama.2023.13239.
[6] Eisai Co. FDA Grants Traditional Approval for Leqembi® (Lecanemab-irmb) for the Treatment of Alzheimer's Disease. Available online at: https://investors.biogen.com/news-releases/news-release-details/fda-grants-traditional-approval-leqembir-lecanemab-irmb. Issued 07/06/2023. Last accessed 06/18/2024.
[7] Eisai Co. FDA Accepts Eisai's Filing of Leqembi® (Lecanemab-irmb) Supplemental Biologics License Application for IV Maintenance Dosing for the Treatment of Early Alzheimer's Disease. Available online at: https://investors.biogen.com/news-releases/news-release-details/fda-accepts-eisais-filing-leqembir-lecanemab-irmb-supplemental. Issued 06/09/2024. Last accessed 06/18/2024.
[8] Kisunla™ (Donanemab-azbt) Prescribing Information. Eli Lilly. Available online at: https://pi.lilly.com/us/kisunla-uspi.pdf?s=pi. Last revised 07/2024. Last accessed 07/03/2024.

Appendix N

30-Day Notice to Prior Authorize Defencath® (Taurolidine/Heparin)

Oklahoma Health Care Authority
July 2024

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

Catheter-related bloodstream infections (CRBSIs) are a leading cause of morbidity and mortality in patients receiving hemodialysis (HD) through a central venous catheter (CVC). Up to 80% of patients initiate HD with a CVC, and some patients require long-term CVC use when more permanent types of access (e.g., arteriovenous grafts, fistulas) cannot be established. CRBSIs can lead to hospitalization or death by progressing to severe infections, including osteomyelitis, endocarditis, and sepsis, with reported mortality rates ranging from 12% to 25%. Clinical guidelines recommend primary infection control, such as aseptic technique during insertion, routine hub disinfection before use, and application of topical antimicrobials during dressing changes. Due to multidisciplinary efforts to implement these infection prevention strategies, the burden of central line infections has decreased in recent years. According to the Centers for Disease Control and Prevention (CDC), the incidence of CRBSIs in the United States has decreased approximately 9% between 2021 and 2022. However, even with this reduction, in 2022, there were still over 29,000 CRBSIs associated with central lines in the acute care hospital setting alone.

Another potential infection prevention strategy is the use of antibiotic or antimicrobial catheter lock solutions (CLSs) instilled in the CVC lumens between uses. Currently, there is a paucity of evidence for routine use of this strategy. The most recent (2019) National Kidney Foundation's Disease Outcome Quality Initiatives (KDOQI) Vascular Access guidelines state there is insufficient evidence to recommend the routine use of antibiotic or antimicrobial CLSs for the primary prevention of CRBSI. However, the guidelines suggest that the selective use of specific antibiotic or antimicrobial CLSs (e.g., cefotaxime, gentamicin, sulfamethoxazole/trimethoprim, methylene blue) can be considered in patients in need of long-term CVC use and who are at highest risk of CRBSI (e.g., multiple prior CRBSI despite optimized aseptic technique, in facilities with high rates of CRBSI, *Staphylococcus aureus* nasal carrier). Of note, the recommended antibiotic and antimicrobial CLSs are not commercially available in the United States and must be compounded according to a local facility protocol as there are no standard dosing regimens.

In the setting of CRBSI, removal or exchange of CVCs is typically preferred but always not feasible or desirable, particularly for long-term CVCs. Antibiotic or antimicrobial CLSs are sometimes used in conjunction with systemic antibiotics to treat CRBSI with the goal of catheter salvage; however, evidence for this technique is from observational studies that lack standardization. The KDOQI guidelines state that CLS use as adjunctive therapy for catheter salvage may be considered if the CVC is not to be removed. Randomized controlled studies are needed to further evaluate the role of antibiotic and antimicrobial CLSs in the treatment of CRBSI and in catheter salvage.

In November 2023, Defencath® (taurolidine/heparin) became the first FDA-approved antimicrobial CLS. It is indicated to reduce CRBSIs in adult patients with kidney failure receiving chronic HD through a CVC. The taurolidine component has *in vitro* antimicrobial activity against the most implicated microorganisms in CRBSI, including gram-positive bacteria [i.e., methicillin-resistant *Staphylococcus aureus (*MRSA), *Staphylococcus epidermidis*], gram-negative bacteria (i.e., *Escherichia coli, Pseudomonas aeruginosa*), and fungi [i.e., *Candida albicans, Nakaseomyces glabratus* (formerly *Candida glabrata*)]. Defencath® has only been studied for the prevention of CRBSI in this limited patient population and does not have an FDA-approved indication for treatment of CRBSI or use in catheter salvage.

Defencath® (Taurolidine/Heparin) Product Summary[5,7]

Therapeutic Class: Antimicrobial/anticoagulant

Indication(s): To reduce the incidence of CRBSI in adult patients with kidney failure receiving chronic HD through a CVC

- **Limitation(s) of Use:** The safety and effectiveness of Defencath® have not been established for use in populations other than adult patients with kidney failure receiving chronic HD through a CVC.

How Supplied: Sterile CLS in a single-dose vial (SDV):

- 3mL SDV containing taurolidine 40.5mg/3mL (13.5mg/mL) and heparin 3,000 USP Units/3mL (1,000 USP Units/mL)
- 5mL SDV containing taurolidine 67.5mg/5mL (13.5mg/mL) and heparin 5,000 USP Units/5mL (1,000 USP Units/mL)

Dosing and Administration:

- A sterile needle and syringe should be used to withdraw sufficient volume from the Defencath® vial(s) to fill the CVC lumen.
- Defencath® should be instilled into the lumens of arterial or venous CVCs and dwelled at the conclusion of each HD session. Any unused portion of a vial should be discarded immediately.

- The full volume should be aspirated from the catheter lumens and discarded prior to utilization of the CVC (i.e., prior to initiating the next HD session or administering other therapy).
- Defencath® is not indicated for use as a catheter lock flush product or for systemic administration and is for installation into CVCs only.

Efficacy: The efficacy and safety of Defencath® were evaluated in the Phase 3, randomized, double-blind, multicenter, active control LOCK-IT-100 trial that included a total of 806 patients who were randomized 1:1 to receive taurolidine/heparin or control (heparin) lock solution in CVC.

- Key Inclusion Criteria:
  - Aged ≥18 years of age with kidney failure receiving maintenance HD ≥2 times per week
  - CVC placed in the jugular or subclavian vein ≥14 days and used for successful HD ≥2 times
- Key Exclusion Criteria:
  - Treatment with antibiotics ≤14 days of enrollment
  - Catheter exit-site infection and/or open, non-healing skin ulcers
  - Thrombolytic treatment in current catheter ≤30 days of randomization
  - Systemic, medication-induced immunosuppression
- Primary Endpoint(s):
  - Time to CRBSI
- Results:
  - Study terminated at interim analysis due to clear efficacy
  - Nine (2%) participants developed CRBSI in treatment arm vs. 32 (8%) in the control (heparin) arm
  - Mean length of follow-up was 200 days

Cost: The Wholesale Acquisition Cost (WAC) of Defencath® is $249.99 per 3mL or 5mL SDV, resulting in an estimated cost of $5,999.76 every 28 days or $77,996.88 per year, based on the use of 2 SDVs per HD session and 3 HD sessions per week.

Recommendations

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

Defencath® (Taurolidine/Heparin) Approval Criteria:

1. An FDA approved indication of reducing the incidence of catheter-related bloodstream infections (CRBSIs) in adult members with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC); and
2. Member must be 18 years of age or older; and

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

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Appendix O

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: June 27, 2024

FDA Permits Marketing of First Point-of-Care Hepatitis C RNA Test

The FDA granted marketing authorization to Cepheid for the Xpert HCV test and GeneXpert Xpress System, the first hepatitis C virus (HCV) test that can be used to bring diagnosis to appropriately certified point-of-care settings for individuals at risk for hepatitis C. The test may be performed in settings operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, such as certain substance use disorder treatment facilities, correctional facilities, syringe service programs, doctor's offices, emergency departments and urgent care clinics. Rather than requiring a sample to be sent to a central lab for testing, the test detects HCV RNA and delivers results in about an hour using a blood sample from the fingertip.

The authorization of this test enables a test-and-treat approach where a person can be tested for HCV, and if positive for HCV RNA, be linked to care and potentially receive treatment during the same health care visit. Prior to the availability of a rapid, point-of-care test, HCV testing has been a multi-step process which often results in patients needing follow-up appointments for test results and additional testing, which can lead to patients not receiving a diagnosis and not receiving necessary treatment.

According to the U.S. Centers for Disease Control and Prevention (CDC), hepatitis C is a liver infection caused by the hepatitis C virus. Hepatitis C is spread through contact with blood from a person with hepatitis C. For some people, hepatitis C is a short-term illness, but for more than half of people with HCV infection, it becomes a long-term, chronic infection. It is estimated more than 2.4 million people – and as many as 4 million people – in the United States have hepatitis C, which if left untreated, often leads to serious and sometimes deadly outcomes such as liver cancer and liver failure. The infection contributed to more than 12,000 deaths in 2022 alone.

The Xpert HCV test is indicated for adults with signs or symptoms of, or at risk for hepatitis C and is not intended for use in monitoring patients undergoing treatment or for use in screening blood, plasma or tissue donors. The risks associated with the test include the possibility of false positive and false negative test results. False negative test results can delay effective treatment and potentially increase spread of infection to other persons throughout the community. False positive results could lead to an inappropriate diagnosis of, and unnecessary treatment for hepatitis C. This could cause psychological distress and delay receiving a correct diagnosis, in addition to the expense and risk of side effects from unnecessary treatment.

The FDA reviewed the Xpert HCV test and GeneXpert Xpress System under the FDA's De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing special controls that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type.

FDA NEWS RELEASE

For Immediate Release: June 20, 2024

FDA Expands Approval of Gene Therapy for Patients with Duchenne Muscular Dystrophy

The FDA expanded the approval of Elevidys (delandistrogene moxeparvovec-rokl), a gene therapy for the treatment of Duchenne muscular dystrophy (DMD) for ambulatory and non-ambulatory individuals 4 years of age and older with DMD with a confirmed mutation in the *DMD* gene (except in those with any deletion in exon 8 and/or exon 9 in the *DMD* gene). Elevidys was previously approved under accelerated approval for ambulatory individuals 4 through 5 years of age with DMD with a confirmed mutation in the *DMD* gene.

DMD is a rare and serious genetic condition which worsens over time, leading to weakness and wasting away of the body's muscles. The disease occurs due to a defective gene that results in abnormalities in, or absence of, dystrophin, a protein that helps keep the body's muscle cells intact. As a result of this genetic defect, individuals with DMD may have symptoms such as trouble walking and running, falling frequently, fatigue and learning disabilities/difficulties. They may also experience heart issues as a result of the impact on heart muscle function and breathing problems due to weakening of respiratory muscles involved in lung function.

Symptoms of muscle weakness associated with DMD typically begin in childhood, often between 3 to 6 years of age. DMD mainly affects males and in rare cases may affect females. About 1 in every 3,300 boys are affected by this disorder. As the disease progresses, life-threatening heart and respiratory problems can occur. Although disease severity and life expectancy vary, patients often succumb to the disease in their 20s or 30s because of heart and/or respiratory failure.

Elevidys is a recombinant gene therapy designed to deliver into the body a gene that leads to production of Elevidys micro-dystrophin, a shortened protein (138 kDa, compared to the 427 kDa dystrophin protein of normal muscle cells) that contains selected domains of the dystrophin protein present in normal muscle cells. The product is administered as a single intravenous dose.

The efficacy of Elevidys was evaluated in 2 double-blind, placebo-controlled studies and 2 open-label studies, which enrolled a total of 218 male patients (including those who received placebo) with a confirmed disease-causing mutation in the DMD gene. While the large, randomized study of Elevidys failed to meet its statistical primary endpoint of improvement versus placebo in the North Star Ambulatory Assessment (NSAA), the FDA found the observations regarding the secondary endpoints and exploratory endpoints to be compelling and to indicate clinical benefit compared to placebo. These endpoints include improvements in time to rise from the floor, 10-meter walk/run, time to ascend four steps, and creatine kinase levels. Based on the evidence and given that the mechanism of action of Elevidys is similar for ambulatory and non-ambulatory populations, the FDA determined that increased levels in micro-dystrophin is reasonably likely to predict clinical benefit in the non-ambulatory population. No new safety concerns appear to have been identified.

Current Drug Shortages Index (as of July 3, 2024):

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

Albuterol Sulfate Solution	***Currently in Shortage***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Capecitabine Tablet	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
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***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
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***
Sulfasalazine Tablet	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***
Vitamin A Palmitate Injection	***Currently in Shortage***