OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, September 11, 2024 4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

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

DATE: September 4, 2024

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

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

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Enclosed are the following items related to the September 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/Direct Oral Anticoagulant (DOAC) Health Care System Utilization Following Removal of Prior Authorization (PA) Requirement – Appendix B

Action Item – Vote to Prior Authorize Filsuvez® (Birch Triterpenes Topical Gel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications – Appendix C

Action Item – Vote to Prior Authorize Kisunla™ (Donanemab-azbt) and Update the Approval Criteria for the Alzheimer's Disease Medications – Appendix D

Action Item – Vote to Prior Authorize Defencath® (Taurolidine/Heparin Catheter Lock System) – Appendix E

Action Item – Vote to Prior Authorize Wegovy® (Semaglutide) – Appendix F

Action Item – Vote to Prior Authorize Avzivi® (Bevacizumab-tnjn) and Fruzaqla® (Fruquintinib) and Update the Approval Criteria for the Colorectal Cancer Medications – Appendix G

Action Item – Vote to Prior Authorize Accrufer® (Ferric Maltol) and Update the Approval Criteria for the Iron Products – Appendix H

Action Item – Vote to Prior Authorize Doryx® MPC [Doxycycline Delayed-Release (DR) Tablet], Exblifep® (Cefepime/Enmetazobactam), Meropenem 2g Vial, Pivya™ (Pivmecillinam), Nitrofurantoin 50mg/mL Suspension, Tetracycline 250mg and 500mg Tablet, and Zevtera® (Ceftobiprole Medocaril Sodium) and Update the Approval Criteria for the Various Systemic Antibiotics – Appendix I

Action Item – Vote to Prior Authorize Penicillamine 250mg Tablet and Trientine 500mg Capsule and Update the Approval Criteria for the Wilson's Disease Medications – Appendix J

Action Item – Vote to Prior Authorize Eohilia™ (Budesonide Oral Suspension) and Update the Approval Criteria for the Corticosteroid Special Formulations – Appendix K

Action Item – Vote to Prior Authorize Tramadol 25mg Tablet and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – Appendix L

Action Item – Vote to Update the Approval Criteria for the Topical Corticosteroids – Appendix M

Action Item – Annual Review of Allergen Immunotherapies – Appendix N

Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Hercessi (Trastuzumab-strf) and Truqap™ (Capivasertib) – Appendix O

Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Wainua™ (Eplontersen) – Appendix P

Annual Review of Cystic Fibrosis (CF) Medications – Appendix Q

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – September 11, 2024 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

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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. July 10, 2024 DUR Board Meeting Minutes
   B. July 10, 2024 DUR Board Recommendations Memorandum
   C. August 14, 2024 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Direct Oral Anticoagulant (DOAC) Health Care System Utilization Following Removal of Prior Authorization (PA) Requirement – See Appendix B**
   A. Pharmacy Help Desk Activity for August 2024
   B. Medication Coverage Activity for August 2024
   C. DOAC Health Care System Utilization Following Removal of PA Requirement

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

5. **Action Item – Vote to Prior Authorize Filsuvez® (Birch Triterpenes Topical Gel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications – See Appendix C**
   A. Market News and Updates
   B. Filsuvez® (Birch Triterpenes Topical Gel) 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 Kisunla™ (Donanemab-azbt) and Update the Approval Criteria for the Alzheimer's Disease Medications – See Appendix D**
   A. Market News and Updates
   B. Kisunla™ (Donanemab-azbt) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Defencath® (Taurolidine/Heparin) – See Appendix E**
   A. Market News and Updates
   B. Defencath® (Taurolidine/Heparin) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Wegovy® (Semaglutide) – See Appendix F**
   A. Market News and Updates
   B. Wegovy® (Semaglutide) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Avzivi® (Bevacizumab-tnjn) and Fruzaqla® (Fruquintinib) and Update the Approval Criteria for the Colorectal Cancer (CRC) Medications – See Appendix G**
   A. Market News and Updates
   B. Fruzaqla® (Fruquintinib) Product Summary
   C. Cost Comparison: Bevacizumab Products
   D. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Accrufer® (Ferric Maltol) and Update the Approval Criteria for the Iron Products – See Appendix H**
    A. Market News and Updates
    B. Accrufer® (Ferric Maltol) Product Summary
    C. Cost Comparison: Intravenous (IV) Iron Products
    D. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Doryx® MPC [Doxycycline Delayed-Release (DR) Tablet], Exblifep® (Cefepime/Enmetazobactam), Meropenem 2g Vial, Pivya™ (Pivmecillinam), Nitrofurantoin 50mg/mL Suspension, Tetracycline 250mg and 500mg Tablet, and Zevtera® (Ceftobiprole**

Medocaril Sodium) and Update the Approval Criteria for the Various Systemic Antibiotics – See Appendix I

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

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

12. **Action Item – Vote to Prior Authorize Penicillamine 250mg Tablet and Trientine 500mg Capsule and Update the Approval Criteria for the Wilson's Disease Medications – See Appendix J**

A. Market News and Updates
B. Cost Comparisons
C. College of Pharmacy Recommendations

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

13. **Action Item – Vote to Prior Authorize Eohilia™ (Budesonide Oral Suspension) and Update the Approval Criteria for the Corticosteroid Special Formulations – See Appendix K**

A. Market News and Updates
B. Eohilia™ (Budesonide Oral Suspension) Product Summary
C. College of Pharmacy Recommendations

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

14. **Action Item – Vote to Prior Authorize Tramadol 25mg Tablet and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – See Appendix L**

A. Cost Comparison: Tramadol
B. College of Pharmacy Recommendations

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

15. **Action Item – Vote to Update the Approval Criteria for the Topical Corticosteroids – See Appendix M**

A. College of Pharmacy Recommendations

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

16. **Action Item – Annual Review of Allergen Immunotherapies – See Appendix N**

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

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

17. **Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Hercessi™ (Trastuzumab-strf) and Truqap™ (Capivasertib) – See Appendix O**
    A. Current Prior Authorization Criteria
    B. Utilization of Breast Cancer Medications
    C. Prior Authorization of Breast Cancer Medications
    D. Market News and Updates
    E. Truqap™ (Capivasertib) Product Summary
    F. Cost Comparison: Trastuzumab Products
    G. College of Pharmacy Recommendations
    H. Utilization Details of Breast Cancer Medications

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

18. **Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Wainua™ (Eplontersen) – See Appendix P**
    A. Current Prior Authorization Criteria
    B. Utilization of Amyloidosis Medications
    C. Prior Authorization of Amyloidosis Medications
    D. Market News and Updates
    E. Wainua™ (Eplontersen) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of Amyloidosis Medications

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

19. **Annual Review of Cystic Fibrosis (CF) Medications – See Appendix Q**
    A. Current Prior Authorization Criteria
    B. Utilization of CF Medications
    C. Prior Authorization of CF Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of CF Medications

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

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

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

21. **Future Business* (Upcoming Product and Class Reviews)**
    A. Anemia Medications
    B. Hepatitis C Medications
    C. Synagis® (Palivizumab)
    D. Targeted Immunomodulator Agents

    *Future product and class reviews subject to change.

22. Adjournment

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

Appendix A

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

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

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

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

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

OTHERS PRESENT:	
Rhonda Clark, Indivior	Todd Dickerson, Jazz Pharmaceuticals
Jim Semans, SK Life Science	Lee Stout, Chiesi
John Omick, Travere	Michael DeRemer
Kim Greenberg, Acadia Pharmaceuticals	Lindsey Walter, Novartis
Phil Lohec, Viatris	Glynn Brandon Ross, Merck
Brent Young, BMS	Kristen Winters, Centene
Janie Huff, Madrigal	Brent Parker, Merck
Melissa Abbott, Eisai	Deidra Williams, Humana
Tara McKinley, Madrigal	Logan Poole, Novo Nordisk
Bryan Steffan, Boehringer	Irene Chung, Aetna
David Prather, Novo Nordisk	Shellie Keast, ADURS
Dr. John Kingrey, Integris	

PRESENT FOR PUBLIC COMMENT:	
Dr. John Kingrey, Integris	

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. 9 DR. JOHN KINGREY

ACTION: NONE REQUIRED

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

3A: JUNE 12, 2024 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/CHRONIC MEDICATION ADHERENCE (CMA) PROGRAM UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR JUNE 2024

4B: MEDICATION COVERAGE ACTIVITY FOR JUNE 2024

4C: CMA PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Metts, Dr. Travers

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE REZDIFFRA™ (RESMETIROM)**

5A: MARKET NEWS AND UPDATES

5B: REZDIFFRA™ (RESMETIROM) PRODUCT SUMMARY

5C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE RISVAN® (RISPERIDONE EXTENDED-RELEASE INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: RISVAN® (RISPERIDONE EXTENDED-RELEASE INJECTION) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Haymore
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> 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
7A: MARKET NEWS AND UPDATES
7B: PRODUCT SUMMARIES
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Regarding the approval criteria for Millipred™, Dr. Muchmore recommended to update the criteria to require "a patient-specific, clinically significant reason why the member cannot use prednisone 5mg tablets, methylprednisolone 4mg tablets, or alternative oral corticosteroids that are available without a prior authorization must be provided". The DUR Board voted on the amended criteria.
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE QALSODY™ (TOFERSEN) AND RILUTEK® (RILUZOLE) AND UPDATE THE APPROVAL CRITERIA FOR THE AMYOTROPHIC LATERAL SCLEROSIS (ALS) MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> 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

9A: MARKET NEWS AND UPDATES
9B: PRODUCT SUMMARIES
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Regarding the approval criteria for Uptravi®, the DUR Board recommended removing criteria 3.c. (Orenitram® trial) based on clinical practice and PAH guidelines. The DUR Board voted on the amended criteria.
Dr. West moved to approve; seconded by Dr. Haymore
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE AKEEGA™ (NIRAPARIB/ABIRATERONE ACETATE) AND UPDATE THE APPROVAL CRITERIA FOR THE GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: AKEEGA™ (NIRAPARIB/ABIRATERONE ACETATE) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF TESTOSTERONE PRODUCTS
11C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF COLORECTAL CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AVZIVI® (BEVACIZUMAB-TNJN) AND FRUZAQLA® (FRUQUINTINIB)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF COLORECTAL CANCER MEDICATIONS
12C: PRIOR AUTHORIZATION OF COLORECTAL CANCER MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: PRODUCT SUMMARIES
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF COLORECTAL CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 13: 30-DAY NOTICE TO PRIOR AUTHORIZE WEGOVY® (SEMAGLUTIDE)
13A: INTRODUCTION
13B: MARKET NEWS AND UPDATES
13C: WEGOVY® (SEMAGLUTIDE) PRODUCT SUMMARY
13D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 14: **ANNUAL REVIEW OF EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE FILSUVEZ® (BIRCH TRITERPENES TOPICAL GEL)**

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF EB MEDICATIONS
14C: PRIOR AUTHORIZATION OF EB MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: FILSUVEZ® (BIRCH TRITERPENES TOPICAL GEL) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF EB MEDICATIONS

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

AGENDA ITEM NO. 15: **ANNUAL REVIEW OF ALZHEIMER'S DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KISUNLA™ (DONANEMAB-AZBT)**

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
15C: PRIOR AUTHORIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: KISUNLA™ (DONANEMAB-AZBT) PRODUCT SUMMARY
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ALZHEIMER'S DISEASE MEDICATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 16: **30-DAY NOTICE TO PRIOR AUTHORIZE DEFENCATH® (TAUROLIDINE/HEPARIN CATHETER LOCK SYSTEM)**

16A: INTRODUCTION
16B: MARKET NEWS AND UPDATES
16C: DEFENCATH® (TAUROLIDINE/HEPARIN CATHETER LOCK SYSTEM) PRODUCT SUMMARY
16D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 17: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES**

Materials included in agenda packet; presented by Dr. Metts
ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

18A: NO LIVE DUR BOARD MEETING SCHEDULED FOR AUGUST 2024. AUGUST 2024 WILL BE A PACKET ONLY MEETING.
18B: CORTICOSTEROID SPECIAL FORMULATIONS
18C: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
18D: TOPICAL CORTICOSTEROIDS
18E: VARIOUS SYSTEMIC ANTIBIOTICS

*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: **ADJOURNMENT**

The meeting was adjourned at 5:38pm.

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

Memorandum

Date: August 16, 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 Packet Meeting on August 14, 2024

Recommendation 1: U.S. Food and Drug Administration (FDA) Safety Alerts

NO ACTION REQUIRED.

Recommendation 2: Annual Review of Wilson's Disease Medications and 30-Day Notice to Prior Authorize Penicillamine 250mg Tablet and Trientine Hydrochloride 500mg Capsule

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

Recommendation 3: Annual Review of Corticosteroid Special Formulations and 30-Day Notice to Prior Authorize Eohilia™ (Budesonide Oral Suspension)

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

Recommendation 4: Annual Review of Iron Products and 30-Day Notice to Prior Authorize Accrufer® (Ferric Maltol)

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

Recommendation 5: Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Tramadol 25mg Tablet

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

Recommendation 6: Annual Review of Topical Corticosteroids

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

Recommendation 7: Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Doryx® MPC [Doxycycline Delayed-Release (DR) Tablet], Exblifep® (Cefepime/Enmetazobactam), Meropenem 2g Vial, Pivya™ (Pivmecillinam), Nitrofurantoin 50mg/mL Suspension, Tetracycline 250mg and 500mg Tablet, Zevtera® (Ceftobiprole Medocaril Sodium)

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

Recommendation 8: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

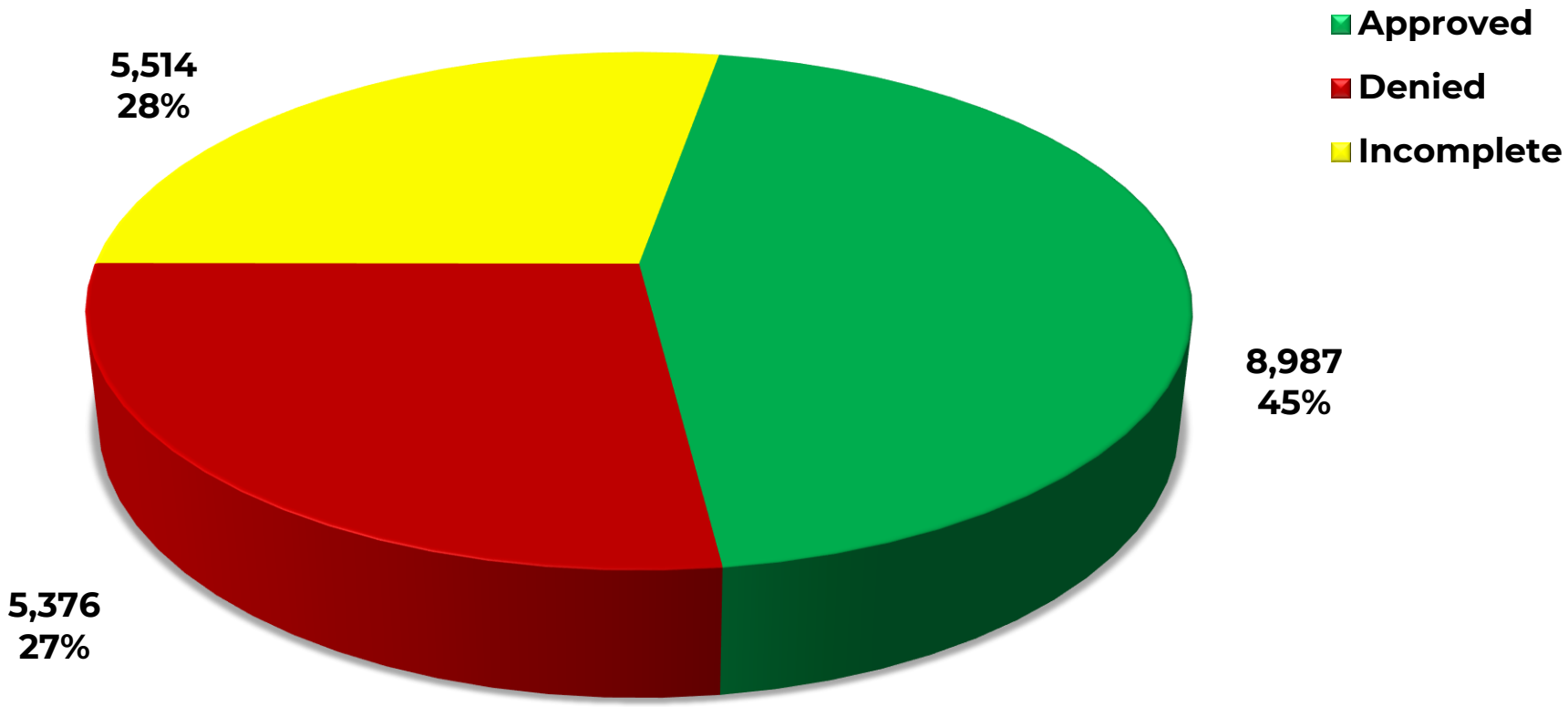
NO ACTION REQUIRED.

Recommendation 9: Future Business

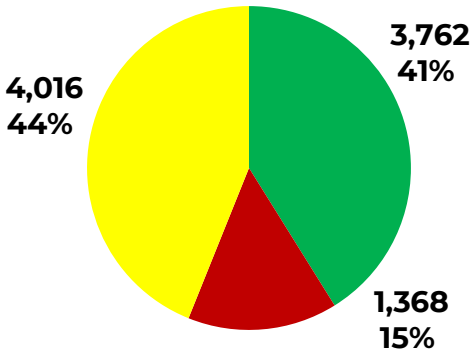
NO ACTION REQUIRED.

Appendix B

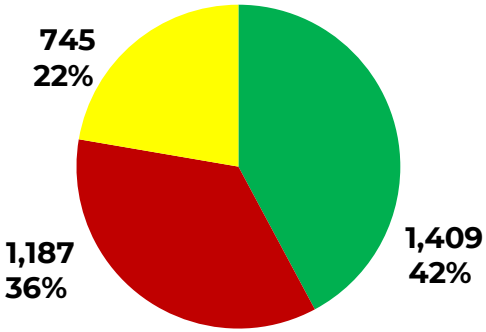
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: AUGUST 2024



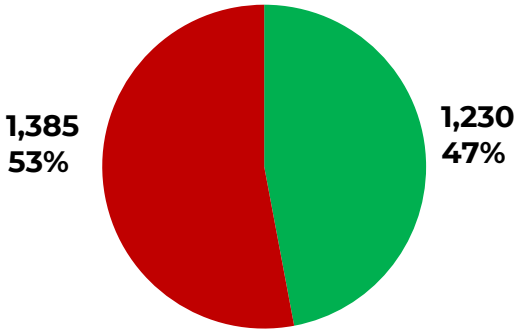
SoonerCare FFS



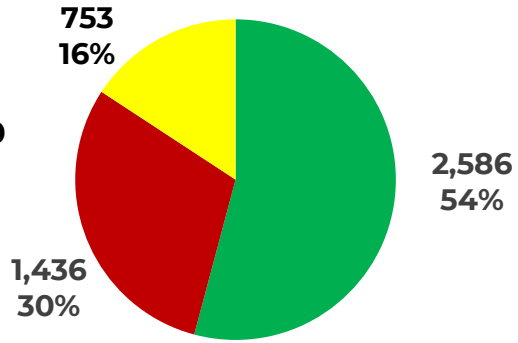
SoonerSelect Aetna



SoonerSelect Humana

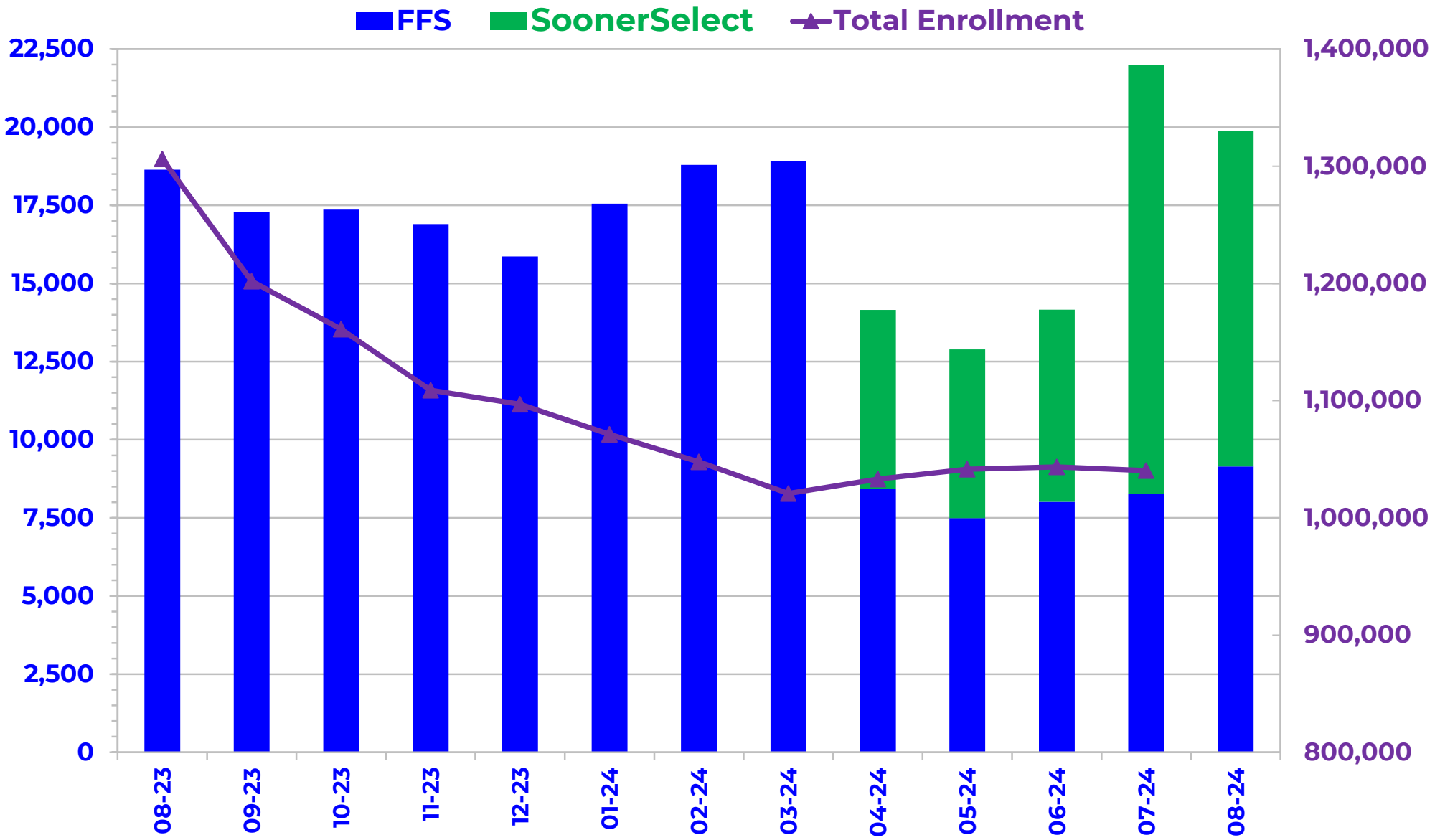


SoonerSelect OK Complete Health



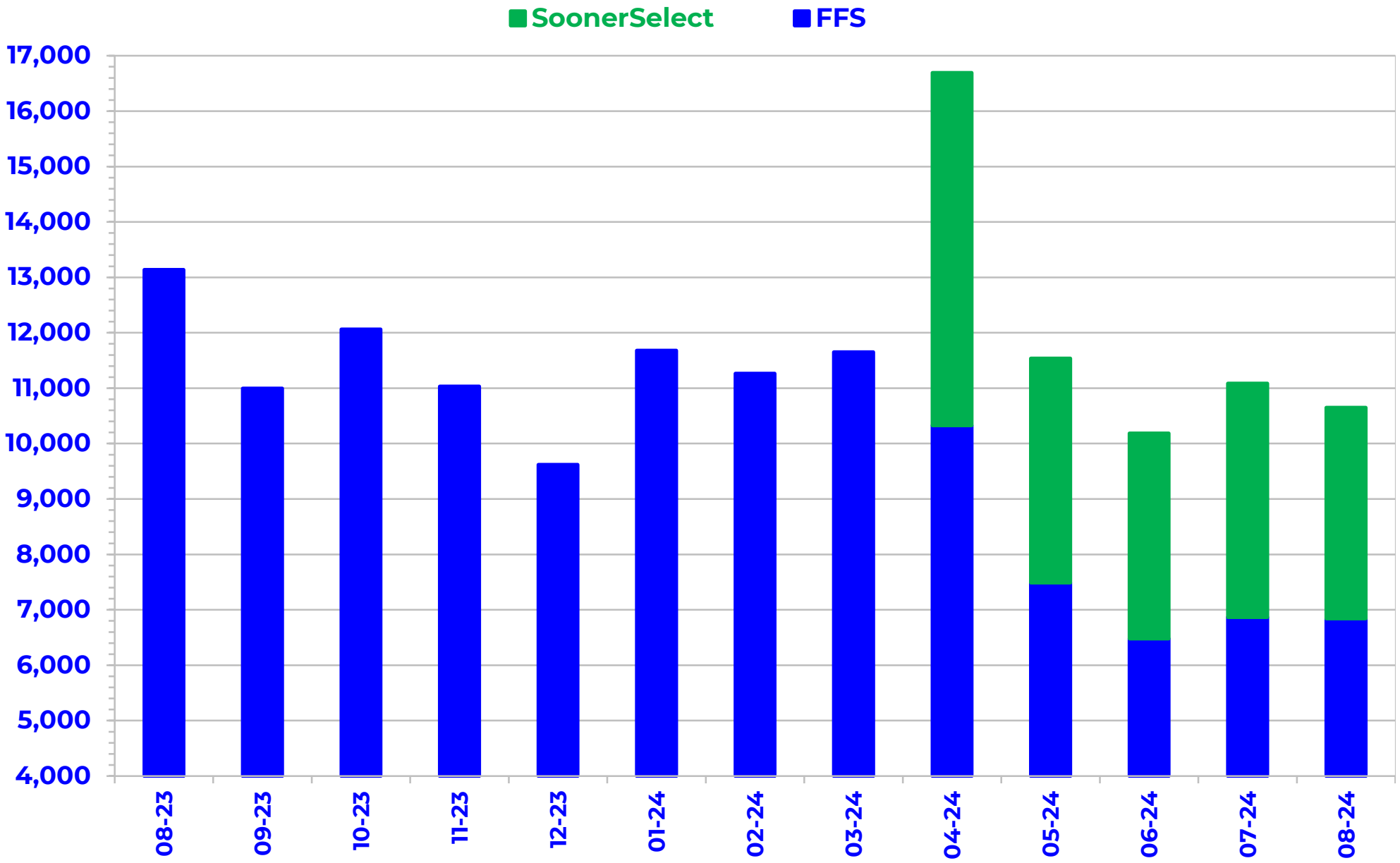
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: AUGUST 2023 – AUGUST 2024



SoonerCare FFS Prior Authorization Activity

8/1/2024 Through 8/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	134	65	3	66	359
Analgesic, Narcotic	261	117	23	121	122
Antiasthma	50	12	9	29	278
Antibiotic	28	11	2	15	346
Anticonvulsant	196	108	12	76	322
Antidepressant	213	38	43	132	252
Antidiabetic	1,389	449	289	651	355
Antifungal	17	3	2	12	85
Antigout	11	7	0	4	229
Antihemophilic Factor	10	5	0	5	292
Antihistamine	20	4	8	8	360
Antimigraine	345	74	130	141	287
Antineoplastic	212	144	8	60	186
Antiobesity	17	0	15	2	0
Antiparasitic	16	6	0	10	20
Antiparkinsons	13	3	2	8	353
Antiulcers	34	4	5	25	293
Anxiolytic	41	2	4	35	292
Atypical Antipsychotics	360	117	40	203	353
Biologics	254	123	21	110	316
Bladder Control	102	9	26	67	360
Blood Thinners	19	0	2	17	0
Botox	46	29	11	6	359
Buprenorphine Medications	79	29	13	37	145
Cardiovascular	103	57	10	36	333
Chronic Obstructive Pulmonary Disease	222	42	42	138	349
Constipation/Diarrhea Medications	194	38	48	108	256
Contraceptive	29	11	6	12	359
Corticosteroid	13	2	5	6	252
Dermatological	345	112	99	134	253
Diabetic Supplies	287	95	48	144	232
Endocrine & Metabolic Drugs	88	23	18	47	275
Erythropoietin Stimulating Agents	24	8	2	14	112
Estrogen Derivative	12	3	1	8	360
Fibric Acid Derivatives	11	3	2	6	359
Gastrointestinal Agents	95	26	20	49	233
Gonadotropin-releasing Hormone Agonist	11	9	0	2	338
Growth Hormones	70	46	11	13	155
Hematopoietic Agents	23	7	4	12	247
Hepatitis C	12	8	1	3	8
HFA Rescue Inhalers	11	2	1	8	360
Insomnia	68	2	13	53	255

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Insulin	186	80	13	93	293
Miscellaneous Antibiotics	21	3	5	13	16
Multiple Sclerosis	43	28	0	15	241
Muscle Relaxant	48	7	7	34	177
Nasal Allergy	23	1	5	17	87
Neurological Agents	189	61	33	95	186
Neuromuscular Agents	18	7	4	7	293
NSAIDs	19	1	6	12	360
Ocular Allergy	17	2	7	8	86
Ophthalmic	18	5	6	7	359
Osteoporosis	24	9	5	10	360
Other*	370	94	63	213	281
Otic Antibiotic	60	2	12	46	26
Pediculicide	13	4	6	3	11
Respiratory Agents	34	17	1	16	298
Statins	60	14	20	26	155
Stimulant	1,056	645	42	369	352
Testosterone	81	14	25	42	357
Thyroid	23	3	2	18	251
Topical Antifungal	31	5	5	21	188
Topical Corticosteroids	20	2	7	11	193
Vitamin	73	12	41	20	133
Pharmacotherapy	101	91	0	10	306
Emergency PAs	0	0	0	0	
Total	**8,013**	**2,960**	**1,314**	**3,739**	

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	17	10	0	7	243
Compound	13	9	0	4	13
Dosage Change	180	167	0	13	16
High Dose	1	1	0	0	358
Ingredient Duplication	2	1	0	1	1
Lost/Broken Rx	56	48	3	5	19
MAT Override	21	15	1	5	105
NDC vs Age	194	142	17	35	283
NDC vs Sex	17	15	0	2	280
Nursing Home Issue	50	41	1	8	12
Opioid MME Limit	63	26	0	37	144
Opioid Quantity	24	14	2	8	167
Other	37	19	13	5	23

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Quantity vs Days Supply	399	259	13	127	266
STBS/STBSM	16	12	1	3	102
Step Therapy Exception	11	7	1	3	312
Stolen	3	3	0	0	14
Third Brand Request	29	13	2	14	16
Overrides Total	**1,133**	**802**	**54**	**277**	
Total Regular PAs + Overrides	**9,146**	**3,762**	**1,368**	**4,016**	

Denial Reasons	
Unable to verify required trials.	3,467
Does not meet established criteria.	1,400
Lack required information to process request.	618
Other PA Activity	
Duplicate Requests	1,256
Letters	34,415
No Process	0
Changes to existing PAs	604
Helpdesk Initiated Prior Authorizations	420
PAs Missing Information	475

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

SoonerSelect Aetna Prior Authorization Activity

08/01/2024 Through 08/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
ACE Inhibitors	14	1	0	13	46
Advair/Symbicort/Dulera	37	10	7	20	97
Analgesic - NonNarcotic	5	0	4	1	0
Analgesic, Narcotic	136	62	43	31	137
Angiotensin Receptor Antagonist	4	0	2	2	0
Anti-inflammatory	1	0	1	0	0
Antiallergic	2	2	0	0	53
Antiasthma	43	13	13	17	118
Antibiotic	13	3	5	5	4
Anticonvulsant	49	20	24	5	161
Antidepressant	187	48	79	60	111
Antidiabetic	472	177	228	67	189
Antifungal	4	2	1	1	87
Antigout	7	5	0	2	243
Antihemophilic Factor	2	2	0	0	365
Antihistamine	22	6	15	1	81
Antimalarial Agent	1	0	0	1	0
Antimigraine	132	45	74	13	131
Antineoplastic	45	21	0	24	180
Antiobesity	12	0	4	8	0
Antiparasitic	3	1	2	0	3
Antiparkinsons	7	0	4	3	0
Antiulcers	49	10	8	31	69
Antiviral	1	0	0	1	0
Anxiolytic	38	16	12	10	164
Atypical Antipsychotics	165	68	61	36	184
Benign Prostatic Hypertrophy	8	1	6	1	30
Biologics	94	75	14	5	252
Bladder Control	10	4	5	1	209
Blood Thinners	6	3	0	3	244
Buprenorphine Medications	91	51	34	6	67
Calcium Channel Blockers	17	3	5	9	100
Cardiovascular	42	13	5	24	101
Chronic Obstructive Pulmonary Disease	46	14	29	3	232
Constipation/Diarrhea Medications	47	21	26	0	122
Contraceptive	12	4	3	5	95
Corticosteroid	6	1	4	1	6

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

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
Cough/Cold/Allergy	3	1	1	1	365
Dermatological	224	116	79	29	103
Diabetic Supplies	157	76	43	38	281
Diuretic	10	0	0	10	0
Ear/Nose/Throat	1	0	0	1	0
Endocrine & Metabolic Drugs	10	4	5	1	274
Erythropoietin Stimulating Agents	2	0	2	0	0
Estrogen Derivative	9	5	3	1	228
Fibric Acid Derivatives	3	0	1	2	0
Fibromyalgia	15	1	2	12	30
Fish Oils	3	1	2	0	122
Gastrointestinal Agents	36	12	13	11	41
Genitourinary Agents	10	0	6	4	0
Glaucoma	3	0	3	0	0
Gonadotropin-releasing Hormone Agonist	5	3	0	2	275
Growth Hormones	32	22	9	1	158
Hematopoietic Agents	9	1	4	4	4
Hepatitis C	2	0	2	0	0
HFA Rescue Inhalers	16	0	0	16	0
Insomnia	14	5	6	3	81
Insulin	87	21	24	42	138
Miscellaneous Antibiotics	8	4	1	3	28
Multiple Sclerosis	20	12	3	5	214
Muscle Relaxant	41	0	14	27	0
Nasal Allergy	13	2	8	3	49
Neurological Agents	15	6	7	2	68
Neuromuscular Agents	1	1	0	0	365
Non-Classified	69	24	28	17	148
NSAIDs	22	1	11	10	2
Ocular Allergy	5	1	4	0	18
Ophthalmic	10	3	4	3	76
Ophthalmic Anti-infectives	3	1	1	1	21
Ophthalmic Corticosteroid	3	1	1	1	122
Osteoporosis	3	0	3	0	0
Otic Antibiotic	31	3	25	3	10
Pediculicide	7	3	2	2	127
Prenatal Vitamins	2	2	0	0	365
Respiratory Agents	1	1	0	0	184
Smoking Cess.	1	0	1	0	0
Statins	31	5	6	20	34

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

	Total	Approved	Denied	Void	Average Length of Approval in Days
Stimulant	419	310	69	40	280
Testosterone	76	29	45	2	228
Thyroid	5	4	0	1	292
Topical Antibiotic	3	0	0	3	0
Topical Antifungal	22	6	13	3	19
Topical Corticosteroids	21	5	10	6	95
Vitamin	28	15	8	5	196
****Total**	**3,341**	**1,409**	**1,187**	**745**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
Overrides					
Brand	3	3	0	0	365
Quantity Limit	49	49	0	0	310
Other	750	5	0	745	365
Overrides Total	**802**	**57**	**0**	**745**	

Denial Reasons	
Benefit	30
Experimental/Investigational	135
Lack Required Information to Process Request	130
Medical Necessity	891
Other	1
Other PA Activity	
Duplicate Requests	15
Letters	3,838
No Process	284
Changes to Existing PAs	33
Helpdesk Initiated PAs	10
PAs Missing Information	15

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

SoonerSelect Humana Prior Authorization Activity

8/1/2024 Through 8/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
Advair/Symbicort/Dulera	40	0	40	0	5
Analgesic - NonNarcotic	4	0	4	0	0
Analgesic, Narcotic	50	26	24	0	176
Anorectal	2	1	1	0	73
Antiallergic	1	1	0	0	184
Antiasthma	20	12	8	0	196
Antibiotic	5	2	3	0	228
Anticonvulsant	13	11	2	0	306
Antidepressant	49	27	22	0	201
Antidiabetic	242	97	145	0	190
Antigout	1	0	1	0	0
Antihistamine	1	1	0	0	365
Antimigraine	124	57	67	0	142
Antineoplastic	16	15	1	0	202
Antiparasitic	3	3	0	0	365
Antiparkinsons	3	0	3	0	0
Antiulcers	8	2	6	0	122
Anxiolytic	2	0	2	0	0
Biologics	79	58	21	0	239
Bladder Control	26	4	22	0	49
Botox	13	10	3	0	318
Buprenorphine Medications	36	21	15	0	78
Cardiovascular	20	14	6	0	262
Cephalosporins	1	0	1	0	0
Chronic Obstructive Pulmonary Disease	67	18	49	0	34
Constipation/Diarrhea Medications	63	28	35	0	95
Contraceptive	14	6	8	0	162
Corticosteroid	2	1	1	0	183
Dermatological	116	79	37	0	198
Endocrine & Metabolic Drugs	29	10	19	0	101
Erythropoietin Stimulating Agents	3	2	1	0	84
Estrogen Derivative	6	1	5	0	37
Fish Oils	2	0	2	0	0
Gastrointestinal Agents	41	11	30	0	137
Genitourinary Agents	2	0	2	0	0
Glaucoma	4	0	4	0	0
Gonadotropin-releasing Hormone Agonist	14	12	2	0	298
Growth Hormones	15	13	2	0	154
Hematopoietic Agents	3	2	1	0	246

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

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
Hepatitis C	7	1	6	0	8
HFA Rescue Inhalers	5	1	4	0	73
Insomnia	6	2	4	0	73
Insulin	45	13	32	0	100
Miscellaneous Antibiotics	12	6	6	0	237
Multiple Sclerosis	14	9	5	0	230
Muscle Relaxant	26	8	18	0	151
Nasal Allergy	2	0	2	0	0
Neurological Agents	15	7	8	0	107
Neuromuscular Agents	2	0	2	0	0
Non-Classified	37	22	15	0	194
NSAIDs	7	0	7	0	0
Ophthalmic	12	4	8	0	42
Ophthalmic Anti-infectives	3	3	0	0	365
Ophthalmic Corticosteroid	11	1	10	0	18
Osteoporosis	2	1	1	0	183
Pediculicide	2	1	1	0	183
Respiratory Agents	4	2	2	0	167
Statins	13	7	6	0	173
Stimulant	44	24	20	0	194
Testosterone	64	19	45	0	89
Thyroid	2	1	1	0	183
Topical Antifungal	11	2	9	0	33
Topical Corticosteroids	13	1	12	0	46
Vitamin	40	18	22	0	262
Total	**1,539**	**698**	**841**	**0**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
Overrides					
Ingredient Duplication	75	32	43	0	172
MAT Override	8	5	3	0	502
NDC vs Age	195	142	53	0	264
Opioid MME Limit	3	3	0	0	133
Opioid Quantity	7	4	3	0	265
Other	194	23	171	0	44
Quantity vs Days Supply	221	144	77	0	251
STBS/STBSM	56	28	28	0	189
Step Therapy Exception	317	151	166	0	179
Overrides Total	**1,076**	**532**	**544**	**0**	
Total Regular PAs + Overrides	**2,615**	**1,230**	**1,385**	**0**	

Denial Reasons	
Benefit	372
Medical Necessity	1,013

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

SoonerSelect OK Complete Health Prior Authorization Activity

08/01/2024 Through 08/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
ACE Inhibitors	31	27	0	4	155
Advair/Symbicort/Dulera	139	92	31	16	176
Allergen Immunotherapy	1	0	1	0	0
Analgesic - NonNarcotic	3	0	2	1	0
Analgesic, Narcotic	250	99	118	33	237
Angiotensin Receptor Antagonist	26	18	1	7	152
Anorectal	4	0	3	1	0
Anti-inflammatory	1	0	1	0	0
Antiasthma	53	21	17	15	199
Antibiotic	13	3	7	3	288
Anticoagulant	1	1	0	0	365
Anticonvulsant	255	196	25	34	165
Antidepressant	399	272	60	67	181
Antidiabetic	800	444	234	122	323
Antifungal	1	0	1	0	0
Antigout	3	1	1	1	365
Antihistamine	23	8	12	3	337
Antihyperlipidemic	1	1	0	0	146
Antimigraine	168	48	103	17	298
Antineoplastic	16	12	4	0	303
Antiobesity	30	0	28	2	0
Antiparasitic	9	6	2	1	309
Antiparkinsons	2	0	0	2	0
Antipsychotic	1	1	0	0	132
Antiulcers	100	65	12	23	163
Antiviral	2	0	2	0	0
Anxiolytic	111	76	18	17	155
Atypical Antipsychotics	237	140	58	39	227
Benign Prostatic Hypertrophy	11	6	4	1	175
Biologics	110	64	23	23	360
Bladder Control	37	11	23	3	181
Blood Thinners	8	4	1	3	200
Botox	4	0	2	2	0
Buprenorphine Medications	24	10	11	3	259
Calcium Channel Blockers	27	20	0	7	171
Cardiovascular	149	107	14	28	180
Cephalosporins	3	0	3	0	0
Chronic Obstructive Pulmonary Disease	76	19	49	8	222
Constipation/Diarrhea Medications	61	23	28	10	244

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

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
Contraceptive	16	8	8	0	335
Corticosteroid	3	1	1	1	138
Dermatological	212	86	94	32	266
Diabetic Supplies	154	107	30	17	349
Diuretic	46	39	0	7	159
Endocrine & Metabolic Drugs	17	1	13	3	180
Erythropoietin Stimulating Agents	2	0	1	1	0
Estrogen Derivative	8	3	4	1	210
Fibric Acid Derivatives	3	1	2	0	365
Fibromyalgia	72	57	1	14	148
Fish Oils	13	4	7	2	190
Gastrointestinal Agents	33	10	22	1	211
Genitourinary Agents	3	0	2	1	0
Glaucoma	10	5	2	3	187
Gonadotropin-releasing Hormone Agonist	4	4	0	0	365
Growth Hormones	27	13	11	3	308
Hematopoietic Agents	3	1	2	0	180
Hepatitis C	4	0	0	4	0
HFA Rescue Inhalers	7	3	2	2	143
Insomnia	24	10	11	3	272
Insulin	122	79	29	14	192
Miscellaneous Antibiotics	7	3	2	2	365
Multiple Sclerosis	19	5	11	3	291
Muscle Relaxant	17	2	10	5	365
Nasal Allergy	21	4	17	0	249
Neurological Agents	30	5	17	8	328
Neuromuscular Agents	2	0	1	1	0
Non-Classified	77	14	37	26	231
NSAIDs	13	3	7	3	210
Ocular Allergy	3	1	2	0	365
Ophthalmic	1	1	0	0	365
Ophthalmic Anti-infectives	1	1	0	0	132
Ophthalmic Corticosteroid	5	2	0	3	149
Ophthalmic NSAIDs	3	1	1	1	365
Osteoporosis	3	2	1	0	137
Otic Antibiotic	51	24	18	9	252
Passive Immunizing Agents	1	0	0	1	0
Pediculicide	12	5	3	4	271
Prenatal Vitamins	6	4	0	2	365
Respiratory Agents	6	3	3	0	365
Smoking Cess.	1	1	0	0	134

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

	Total	Approved	Denied	Incomplete	Average Length of Approval in Days
Statins	50	33	11	6	186
Stimulant	264	168	59	37	225
Testosterone	104	24	63	17	365
Thyroid	50	35	6	9	150
Topical Antifungal	21	4	13	4	365
Topical Corticosteroids	9	0	6	3	0
Vaccine	3	1	0	2	365
Vitamin	22	13	7	2	365
Total	**4,775**	**2,586**	**1,436**	**753**	

Denial Reasons	
Benefit	101
Medical Necessity	1,335

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

Direct Oral Anticoagulant (DOAC) Health Care System Utilization Following Prior Authorization (PA) Removal

Oklahoma Health Care Authority
September 2024

Introduction[1,2,3]

In the United States, it is estimated that 600,000 venous thromboembolism (VTE) events happen each year. VTE manifest most commonly as a deep vein thrombosis (DVT) or less commonly as a pulmonary embolism (PE). When left untreated, VTE has been linked to early recurrences and death in various landmark studies.

It is recommended that patients with an acute PE or DVT receive anticoagulant treatment as soon as possible. Direct oral anticoagulants (DOACs) are the agents of choice for the treatment of acute VTE in the majority of patients. DOACs can be given in fixed doses without laboratory monitoring and have been found to be noninferior to the conventional anticoagulation treatment options (parenteral anticoagulants followed by vitamin K antagonists). Currently available DOACs include Eliquis® (apixaban), Pradaxa® (dabigatran), Savaysa® (edoxaban), and Xarelto® (rivaroxaban). Eliquis® and Xarelto® do not require initial treatment with a parenteral anticoagulant and therefore tend to be the treatment of choice.

Multiple guidelines, including the American Society of Hematology (ASH) and the American College of Chest Physicians (CHEST), recommend treatment initiation as soon as possible, and outpatient treatment is now considered a viable option in most patients with acute DVT and in select patients with acute PE.

Prior Authorization (PA) Removal of Eliquis® and Xarelto®

Prior to May 2023, all DOAC medications required the submission of a PA request for SoonerCare members to ensure appropriate and safe use. Various providers reached out to the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) to request the DOAC PA process be adjusted to allow for the outpatient treatment of acute VTE. SoonerCare has a 24-hour turnaround time for PAs; however, the time needed to process the PA request may have resulted in some providers needing to use the emergency department (ED) or other hospital resources to initiate immediate anticoagulation for members who may have otherwise been candidates for outpatient treatment. The COP performed an analysis of medical claims for calendar year 2022 and found a total cost of $221,208 could be directly linked

to the need for immediate anticoagulation, with 87% of those claims being for DVT and/or PE diagnoses.

In an effort to improve access for immediate outpatient treatment and reduce the related medical costs, the PA requirement was removed from Eliquis® and Xarelto®.

SoonerCare Impact Post-PA Removal

In August 2024, a claims analysis was performed to assess the impact of the removal of the PA requirement from Eliquis® and Xarelto®. The claims were reviewed from 05/01/2022 to 04/30/2023 and 05/01/2023 to 04/30/2024 to allow for a full year comparison pre- and post-PA removal.

The results of the medical claims analysis can be seen below in Figure 1. This cohort included members with a DVT and/or PE diagnosis and assessed the percent change pre- and post-PA removal for inpatient (IP) and/or ED visits.

Figure 1: Medical IP and ED Claims for DVT/PE

	Pre-PA Removal	Post-PA Removal	% Change
Members with a DVT/PE diagnosis	11,517*	11,544*	0.23%
Members with an IP and/or ED visit	2,974*	2,833*	-4.74%
Number of claims for an IP and/or ED visit	5,253	5,005	-4.72%
Total IP and/or ED cost	$45,002,711.93	$43,771,524.33	-2.74%

*Unduplicated members
DVT = deep vein thrombosis; ED = emergency department; IP = inpatient; PA = prior authorization; PE = pulmonary embolism
Pre-PA Removal = 05/01/2022 to 04/30/2023; Post-PA Removal = 05/01/2023 to 04/30/2024

Figure 2 shows the results for the pharmacy claims analysis for Eliquis® and Xarelto®. Pharmacy claims were included if members had at least 1 occurrence of a DVT and/or PE.

Figure 2: Pharmacy Claims for Eliquis® or Xarelto®

	Pre-PA Removal	Post-PA Removal	% Change
Members with ≥1 paid pharmacy claim	5,226*	7,939*	51.91%
Number of paid claims	20,726	36,233	74.82%
Total pharmacy cost	$14,398,394.32	$18,183,307.44	26.29%
Cost per member	$2,755.15	$2,290.38	-16.78%
Cost per claim	$694.70	$501.84	-27.76%

Costs do not reflect rebated prices or net costs.
*Unduplicated members
PA = prior authorization
Pre-PA Removal = 05/01/2022 to 04/30/2023; Post-PA Removal = 05/01/2023 to 04/30/2024

Conclusions

The results showed an overall 3% decrease in the medical cost (IP and/or ED visit) related to DVT and/or PE diagnoses after removing the PA from Eliquis® and Xarelto®. Additionally, a 5% decrease was seen in the number of members and number of claims for an IP and/or ED visit related to DVT or PE. Pharmacy claims post-PA removal showed a 27% increase in total cost and a 75% and 52% increase in number of claims and total members, respectively. However, it's important to note that Eliquis® and Xarelto® are heavily rebated medications, and these results do not include rebated prices or net costs.

These results demonstrate the benefit of removing the PA from Eliquis® and Xarelto® by decreasing the total IP and ED costs for DVT and/or PE diagnoses. Although there was an increase in pharmacy costs by 27%, the total cost for both pharmacy and medical claims increased only by about 4%, and the medical claims costs are expected to continue to decrease with providers being able to start immediate outpatient anticoagulation. The COP will continue to work with OHCA to improve the quality of care for SoonerCare members requiring immediate anticoagulation, and results will be reported to the DUR Board when available.

[1] American Heart Association. What is Venous Thromboembolism? Available online at: https://www.heart.org/en/health-topics/venous-thromboembolism/what-is-venous-thromboembolism-vte. Last reviewed 11/13/2023. Last accessed 08/14/2024.
[2] Becattini C, Agenelli G. Acute Treatment of Venous Thromboembolism. *Blood* 2020; 135: 305-316. doi: 10.1182/blood.2019001881.
[3] Stevens S, Woller S, Kreuziger L, et.al. Executive Summary Antithrombotic Therapy for VTE Disease: Second Update of the CHEST Guideline and Expert Panel Report. *Chest* 2021; 160: 2247-2259. doi: 10.1016/j.chest.2021.07.056.

Appendix C

Vote to Prior Authorize Filsuvez® (Birch Triterpenes 10% Topical Gel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications

Oklahoma Health Care Authority
September 2024

Market News and Updates[1]

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).

Filsuvez® (Birch Triterpenes 10% Topical Gel) Product Summary[2,3]

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)	$9,894.00	$98,940.00*	$1,286,220.00*

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] 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 08/20/2024.

[2] Filsuvez® (Birch Triterpenes) Prescribing Information. Chiesi USA, Inc. Available online at: https://resources.chiesiusa.com/Filsuvez/FILSUVEZ_PI.pdf. Last revised 05/2024. Last accessed 08/20/2024.

[3] 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 D

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

Oklahoma Health Care Authority
September 2024

Market News and Updates[1]

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.

Kisunla™ (Donanemab-azbt) Product Summary[2]

Therapeutic Class: Amyloid beta-directed monoclonal antibody

Indication(s): Treatment of Alzheimer's disease in adults with MCI 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.

- Primary Endpoint: 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 mL	Cost Per Month	Cost Per Year
Kisunla™ (donanemab-azbt) SDV	**$34.78⁺**	**$2,782.40⁺**	**$36,171.20⁺**
Leqembi® (lecanemab-irmb) SDV	$127.40	$2,038.40±	$26,499.20±

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).
SDV = single-dose vial
⁺Kisunla™ cost is based on use of (4) 350mg/20mL SDVs for a maintenance dosing of 1,400mg every 4 weeks.
±Leqembi® cost is based on use of (4) 200mg/2mL SDVs for each dose of 10mg/kg every 2 weeks for a member weighing 80kg.

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 28; or
   b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
   c. Montreal Cognitive Assessment (MoCA) score ≥19; or
   d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Kisunla™ must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing intracerebral hemorrhage with the

concomitant use have been discussed and are acceptable to the member prior to initiating Kisunla™; and

8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or
    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Kisunla™ and prior to the 2nd, 3rd, 4th, and 7th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 12 weeks and throughout treatment with Kisunla™; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Kisunla™ must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration; and
    a. Kisunla™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 2nd, 3rd, 4th, and 7th infusions is required for continuation; and
16. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and

17. Approval quantities will be dependent on dosing based on package labeling; and
18. The maximum approvable dose is 1,400mg per 28 days; and
19. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

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

Leqembi® (Lecanemab-irmb) Approval Criteria:

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

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

20. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Finally, the College of Pharmacy recommends the following changes to the Namzaric® (memantine 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.

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[1] 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 08/20/2024.

[2] 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 08/20/2024.

Appendix E

Vote to Prior Authorize Defencath® (Taurolidine/ Heparin)

Oklahoma Health Care Authority
September 2024

Market News and Updates[1]

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

- **November 2023:** Defencath® (taurolidine/heparin) became the first FDA-approved antimicrobial catheter lock solution (CLS). It is indicated to reduce catheter-related blood stream infections (CRBSIs) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC). Defencath® has only been studied for the prevention of CRBSI in this limited patient population and does not have an FDA-approved indication for the treatment of CRBSI or for use in catheter salvage.

Defencath® (Taurolidine/Heparin) Product Summary[2,3]

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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[1] U.S. Food and Drug Administration (FDA). FDA Approves New Drug Under Special Pathway for Patients Receiving Hemodialysis. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-new-drug-under-special-pathway-patients-receiving-hemodialysis. Issued 11/15/2023. Last accessed 08/09/2024.

[2] Agarwal AK, Roy-Chaudhury P, Mounts P. Taurolidine/Heparin Lock Solutions and Cather-Related Bloodstream Infection in Hemodialysis: A Randomized, Double-Blind, Active-Control, Phase 3 Study. *Clin J Am Soc Nephrol* 2023; 18(11):1446-1455. doi: 10.2215/CJN0000000000000278.

[3] Defencath® (Taurolidine/Heparin) Prescribing Information. CorMedix, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/214520s000lbl.pdf. Issued 11/2023. Last accessed 08/09/2024.

Appendix F

Vote to Prior Authorize Wegovy® (Semaglutide)

Oklahoma Health Care Authority
September 2024

Market News and Updates[1]

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

- **March 2024:** The FDA approved a new indication for Wegovy® (semaglutide) to reduce the risk of major adverse cardiovascular (CV) events in adults with established cardiovascular disease (CVD) and either obesity or overweight, used in combination with a reduced calorie diet and increased physical activity.

Wegovy® (Semaglutide) Product Summary[2]

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

Indication(s): Reduction in 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

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

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

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 $433.24 per mL. This results in an estimated cost of $1,299.72 per 28 days or $16,896.36 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 at least the 1.7mg once weekly maintenance dosing.

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[1] 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 08/12/2024.
[2] Wegovy® (Semaglutide) Prescribing Information. Novo Nordisk. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215256s011lbl.pdf. Last revised 03/2024. Last accessed 08/12/2024.

Appendix G

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

Oklahoma Health Care Authority
September 2024

Market News and Updates[1,2]

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[3]

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.

[1] U.S. Food and Drug Administration (FDA). FDA Approves Fruquintinib in Refractory Metastatic Colorectal Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-fruquintinib-refractory-metastatic-colorectal-cancer. Issued 11/08/2023. Last accessed 09/04/2024.

[2] 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 08/27/2024.

[3] Fruzaqla® (Fruquintinib) Prescribing Information. Takeda Pharmaceuticals America, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217564s000lbl.pdf. Last revised 11/2023. Last accessed 08/27/2024.

Appendix H

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

Oklahoma Health Care Authority
September 2024

Market News and Updates[1]

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

- **July 2019:** The FDA approved Accrufer® (ferric maltol), an oral iron replacement product, for the treatment of iron deficiency in adults.

Accrufer® (Ferric Maltol) Product Summary[2,3,4]

Therapeutic Class: Iron replacement product

Indication(s): Treatment of iron deficiency in adults

How Supplied: 30mg oral capsules

Dosing and Administration:

- The recommended dose is 30mg twice daily on an empty stomach (1 hour before or 2 hours after a meal).
- Treatment duration will depend on the severity of iron deficiency but generally at least 12 weeks of treatment is required.
- Treatment should be continued as long as necessary until ferritin levels are within the normal range.

Efficacy: The efficacy of Accrufer® was evaluated in clinical trials only in adult patients (18 years of age or older) with iron deficiency anemia (IDA) who also had either inflammatory bowel disease (IBD; e.g., Crohn's disease, ulcerative colitis) or chronic kidney disease (CKD). Two randomized, double-blind, placebo-controlled trials were conducted in IDA patients with IBD and 1 trial was conducted in IDA patients with CKD.

- Key Inclusion Criteria (IBD Trials):
  - Prior discontinuation of oral ferrous product due to lack of efficacy or intolerance
  - IDA confirmed by hemoglobin (Hb) ≥9.5g/dL and <12g/dL (for women) or <13g/dL (for men) and ferritin <30mcg/L
- Key Inclusion Criteria (CKD Trial):
  - CKD with estimated glomerular filtration rate (eGFR) ≥15 and <60mL/min/1.73m^2
  - Not receiving dialysis (patients on dialysis or for whom initiation of dialysis was considered likely during the study were excluded)

        - IDA confirmed by Hb ≥8g/dL and <11g/dL and 1 of the following:
            - Ferritin <250mcg/L and transferrin saturation (TSAT) <25%; or
            - Ferritin <500mcg/L and TSAT <15%
- Primary Endpoint(s):
    - IBD Trials: Least square mean (LSM) difference in Hb from baseline to week 12
    - CKD Trial: LSM difference in Hb from baseline to week 16
- Results:
    - IBD Trials: LSM difference in Hb at week 12 was 2.18g/dL, in favor of Accrufer® treatment, relative to placebo (P <0.0001)
    - CKD Trial: LSM difference in Hb at week 16 was 0.52g/dL, in favor of Accrufer® treatment, relative to placebo (P = 0.0149)

Cost: The National Average Drug Acquisition Cost (NADAC) is $8.98 per capsule, resulting in a cost of $538.80 per 30 days or $6,465.60 per year based on recommended dosing.

Cost Comparison: Intravenous (IV) Iron Products

Product	Cost Per mg	Cost Per Treatment Course*
Monoferric® (ferric derisomaltose) 1,000mg/10mL inj	$2.07	$2,070.00
Injectafer® (ferric carboxymaltose) 1,000mg/20mL inj	$1.13	$1,130.00
Infed® (iron dextran) 100mg/2mL inj	$0.36	$360.00
Feraheme® (ferumoxytol) 510mg/17mL inj	$0.33	$336.60
Venofer® (iron sucrose) 200mg/2mL inj	$0.23	$230.00

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 treatment course based on 1,000mg for Monoferric®, Injectafer®, and Infed®, (2) 510mg doses for Feraheme®, and (5) 200mg doses for Venofer®.
inj = injection

Recommendations

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

Accrufer® (Ferric Maltol) Approval Criteria:

1. Diagnosis of iron deficiency anemia (IDA); and
2. Lab results verifying IDA must be submitted; and
3. Member must be 18 years of age or older; and
4. Member must have a documented diagnosis of chronic kidney disease (CKD) or inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis); and

5. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
6. A recent, failed trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
7. A patient-specific clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided; and
8. Initial approvals will be for the duration of 3 months of treatment. Subsequent approvals (for 3 months of treatment) will require updated recent laboratory results documenting continued IDA.

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

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

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

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

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

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

1. An FDA approved indication of iron deficiency in adult members with New York Heart Association (NYHA) class II-III heart failure (HF) to improve exercise capacity; and
2. Member must be 18 years of age or older; and
3. Documented lab results verifying iron deficiency; and
4. Prescriber must verify member is already receiving optimal background therapy for HF; and
5. Member must have left ventricular ejection fraction (LVEF) <45%; and
6. Member's current weight (kg) and hemoglobin (Hb) (g/dL) must be provided to ensure appropriate dosing according to package labeling; and
7. A recent trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
8. Initial approvals will be for 1 or 2 doses only (depending on member's weight and Hb) according to package labeling; and
9. Subsequent requests for maintenance doses at weeks 12, 24, and 36 will require submission of updated lab results verifying continued iron deficiency for each dose and will be approved for (1) 500mg dose at a time.

Monoferric® (Ferric Derisomaltose) Approval Criteria:

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

[1] Accrufer® (Ferric Maltol) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapprovals_accrufer_2019-0729.pdf. Issued 07/26/2019. Last accessed 08/27/2024.
[2] Accrufer® (Ferric Maltol) Prescribing Information. Shield Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212320s015lbl.pdf. Last revised 03/2022. Last accessed 08/27/2024.
[3] Gasche C, Ahmad T, Tulassay Z, et al. Ferric Maltol is Effective in Correcting Iron Deficiency Anemia in Patients with Inflammatory Bowel Disease: Results from a Phase-3 Clinical Trial Program. *Inflamm Bowel Dis* 2015; 21(3):579-88. doi: 10.1097/MIB.0000000000000314.
[4] Pergola PE and Kopyt NP. Oral Ferric Maltol for the Treatment of Iron-Deficiency Anemia in Patients with CKD: A Randomized Trial and Open-Label Extension. *Am J Kidney Dis* 2021; 78(6):846-856.e1. doi: 10.1053/j.ajkd.2021.03.020.

Appendix I

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

Oklahoma Health Care Authority
September 2024

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

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

- **July 2023:** The FDA approved the first meropenem 2 gram vial for the treatment of bacterial meningitis in patients 3 months of age and older. Meropenem was previously only available as 500mg and 1 gram vials or ready-to-use intravenous (IV) piggyback formulations.
- **January 2024:** Based on a recent supplemental New Drug Application (sNDA) for Avycaz® (ceftazidime/avibactam) injection, the FDA approved the addition of the pediatric population from birth (at least 31 weeks gestational age) to younger than 3 months of age for all current FDA-approved indications.
- **February 2024:** Exblifep® (cefepime/enmetazobactam) was FDA approved for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, in patients 18 years of age and older.
- **April 2024:** The FDA approved Pivya™ (pivmecillinam) tablets for the treatment of adult females with uncomplicated urinary tract infections (uUTI) caused by susceptible isolates of *Escherichia coli, Proteus mirabilis,* and *Staphylococcus saprophyticus.* Although the 2010 Infectious Disease Society of America (IDSA) Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women has recommended pivmecillinam as a first line option for treatment of uUTI, this medication had not been available in the United States until this FDA approval. Of note, the FDA-approved dose of Pivya™ is 185mg (equivalent to 200mg pivmecillinam hydrochloride) 3 times daily which differs from the IDSA-recommended dose of 400mg pivmecillinam hydrochloride twice daily.
- **April 2024:** The FDA approved Zevtera® (ceftobiprole medocaril sodium) injection for the treatment of adults with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB), including those with

right-sided infective endocarditis; adults with acute bacterial skin and skin structure infections (ABSSSIs); and adult and pediatric patients (at least 3 months to younger than 18 years of age) with community-acquired bacterial pneumonia (CABP).

News:

- **January 2023:** Doryx® MPC 60mg modified polymer-coated DR tablets were launched and are equivalent to 50mg of the conventional DR tablets (e.g., Doryx®). Doryx® MPC was previously available in a 120mg modified polymer-coated DR tablet; however, this formulation was discontinued as of June 30, 2024. Per the Federal Register, this formulation was not discontinued due to safety or efficacy concerns.
- **January 2024:** Tetracycline 250mg and 500mg tablets were brought to market under an Abbreviated New Drug Application (ANDA). Tetracycline was previously only available as 250mg and 500mg capsules.
- **February 2024:** Nitrofurantoin 50mg/5mL suspension was brought to market under a New Drug Application (NDA). Nitrofurantoin has been available as a less concentrated 25mg/5mL suspension and as capsules of various strengths and release formulations.

Guideline Update(s):

- **Infectious Disease Society of America (IDSA) Guideline Update(s):** In July 2024, the IDSA released updated guidance on the treatment of antimicrobial resistant gram-negative infections. This was an update from the 2023 version of these guidelines. Notable updates include the recommendation that Zerbaxa® (ceftolozane/tazobactam) should be reserved for the treatment of *Pseudomonas aeruginosa* with difficult-to-treat resistance (DTR *P. aeruginosa*) or polymicrobial infections [e.g., DTR *P. aeruginosa* and extended-spectrum β-lactamase-producing Enterobacterales (ESBL-E)]. The IDSA also suggests that when treating ESBL-E infections, Avycaz® (ceftazidime/avibactam), Fetroja® (cefiderocol), Recarbrio™ (imipenem/cilastatin/relebactam), and Vabomere® (meropenem/vaborbactam) preferably should be reserved for infections exhibiting resistance to carbapenems. Additionally, Xacduro® (sulbactam/durlobactam), in combination with imipenem/cilastatin or meropenem, was recommended as the preferred agent for carbapenem-resistant *Acinetobacter baumannii* (CRAB) infections.

Exblifep® (Cefepime/Enmetazobactam) Product Summary[13,14]

Therapeutic Class: Cephalosporin antibacterial and beta-lactamase inhibitor combination

Indication(s): Treatment of patients 18 years of age and older with cUTI, including pyelonephritis, caused by designated susceptible microorganisms

How Supplied: 2.5 gram single-dose vial (SDV) containing 2 grams of cefepime and 0.5 grams of enmetazobactam

Dosing and Administration: The recommended dose of Exblifep® is 2.5 grams every 8 hours via IV infusion in adults with an estimated glomerular filtration rate (eGFR) between 60 to 129mL/min/1.73m^2.

- See package labeling for dose adjustments for patients with eGFR <60mL/min/1.73m^2 or ≥130 mL/min/1.73m^2.
- The treatment duration is for 7 days (up to 14 days for patients with concurrent bacteremia).

Efficacy: Exblifep® was evaluated in a Phase 3, multinational, double blind, randomized, active-controlled, non-inferiority trial.

- Key Inclusion Criteria:
  - 18 years of age and older
  - Diagnosed with cUTI with pyuria caused by a gram-negative pathogen and required hospitalization and treatment with ≥7 days of IV antibiotics
- Intervention(s):
  - Exblifep® 2.5 grams IV vs. piperacillin/tazobactam 4.5 grams IV every 8 hours for 7 days (up to 14 days for concurrent bacteremia)
- Primary Endpoint(s):
  - Composite outcome of clinical cure (complete resolution of signs and symptoms present at baseline) and microbiological eradication [qualifying baseline pathogen <10^3 colony-forming units (CFU)/mL in urine] at day 14
  - 10% prespecified non-inferiority margin
- Results:
  - Primary endpoint occurred in 79.1% (273/345) in Exblifep® group vs. 58.9% (196/333) in piperacillin/tazobactam group [difference: 21.2%; 95% confidence interval (CI): 14.3%, 27.9%]

Cost: The Wholesale Acquisition Cost (WAC) of Exblifep® is not available at this time to allow for a cost analysis.

Pivya™ (Pivmecillinam) Product Summary[15]

Therapeutic Class: Penicillin antibacterial

Indication(s): Treatment of female patients 18 years of age and older with uUTI caused by susceptible isolates of *Escherichia coli, Proteus mirabilis,* and *Staphylococcus saprophyticus*

How Supplied: 185mg film-coated tablet (equivalent to 200mg pivmecillinam hydrochloride)

Dosing and Administration: The recommended dose of Pivya™ is 185mg orally 3 times daily with or without food for 3 to 7 days as clinically indicated.

Efficacy: The safety and efficacy of Pivya™ were evaluated in 3 trials comparing various dosing regimens to placebo, cephalexin, or ibuprofen (designated by the package labeling as Trial 1, Trial 2, and Trial 4, respectively). All trials were multi-center, randomized, double-blind, controlled studies.

- Key Inclusion Criteria (All Trials):
  - Female 18 years of age or older
  - Presented with symptoms of uUTI
- Key Exclusion Criteria (All Trials):
  - Urine culture containing more than 2 species of pathogen
- Intervention(s):
  - Trial 1: Pivya™ (185mg 3 times daily for 7 days, 185mg twice daily for 7 days, or 370mg twice daily for 3 days) vs. placebo
  - Trial 2: Pivya™ 185mg 3 times daily for 3 days vs. active control (cephalexin 250mg 4 times daily for 7 days)
  - Trial 4: Pivya™ 185mg 3 times daily for 3 days vs. inactive control (ibuprofen 600mg 3 times daily for 3 days)
- Primary Endpoint(s):
  - Trial 1: Composite outcome of clinical cure (complete resolution of signs and symptoms present at baseline) and microbiological eradication (qualifying baseline pathogen $<10^3$ CFU/mL in urine) at days 8-10
  - Trial 2: Composite outcome of clinical cure and microbiological eradication at day 10
  - Trial 4: Composite outcome of clinical cure at day 7 and 14 and microbiological eradication at day 14
- Results:
  - Trial 1: Primary endpoint occurred in 62% (85/137) of patients in the Pivya™ groups combined vs. 10% (14/134) in the placebo group (difference: 52%; 95% CI: 41%, 62%)
  - Trial 2: Primary endpoint occurred in 72% (91/127) of patients in the Pivya™ group vs. 76% (100/132) in the cephalexin group (difference: -4%; 95% CI: -16%, 7%)
  - Trial 4: Primary endpoint occurred in 66% (69/105) of patients in the Pivya™ group vs. 22% (26/119) in the ibuprofen group (difference: 44%; 95% CI: 31%, 57%)

Cost: The WAC of Pivya™ is not available at this time to allow for a cost analysis.

Zevtera® (Ceftobiprole Medocaril Sodium) Product Summary[16,17,18,19]

Therapeutic Class: Cephalosporin antibacterial

Indication(s): Treatment of:

- Adult patients with SAB, including those with right-sided infective endocarditis
- Adult patients with ABSSSI
- Adult and pediatric patients (3 months to younger than 18 years of age) with CABP

How Supplied: 667mg SDV (equivalent to 500mg ceftobiprole)

Dosing and Administration: The recommended dose of Zevtera® is dependent upon indication.

- SAB: 667mg via IV infusion every 6 hours on days 1 to 8 and every 8 hours from day 9 and up to 42 days
- ABSSSI and CABP: 667mg via IV infusion every 8 hours for 5 to 14 days
- See package labeling for pediatric dosing for CABP and renal dose adjustments for creatinine clearance (CrCl) ≤50mL/min or ≥150mL/min

Efficacy: The safety and efficacy of Zevtera® were evaluated in Phase 3, non-inferiority trials for each approved indication.

- **SAB Indication:**
  - Key Inclusion Criteria:
    - 18 years of age and older
    - Diagnosis of SAB based on ≥1 positive blood cultures ≤72 hours prior to randomization
    - Symptoms of bacteremia (e.g., fever, leukocytosis, tachycardia, hypotension)
  - Key Exclusion Criteria:
    - Treatment with anti-staphylococcal systemic antibacterial treatment for ≥48 hours within the last 7 days
    - Left-sided infective endocarditis
    - Implanted prosthetic cardiac devices
  - Intervention(s):
    - Zevtera® 667mg IV every 6 hours on days 1-8 and then every 8 hours thereafter vs. daptomycin 6-10mg/kg IV every 24 hours plus optional aztreonam 1 gram IV every 12 hours
  - Primary Endpoint(s):
    - Overall treatment success (survival, symptom improvement, negative blood cultures, no new SAB complications) as assessed by an independent drug review committee
    - 15% prespecified non-inferiority margin

- Results:
    - Primary endpoint occurred in 69.8% (132/189) in Zevtera® group vs. 68.7% (136/198) in daptomycin ± aztreonam group (difference*: 2%; 95% CI: -7.1%, 11.1%)
      *Between-group difference using Cochran-Mantel-Haenszel weights method adjusted for actual stratum (dialysis status and prior antibacterial treatment use)

- **ABSSSI Indication:**
    - Key Inclusion Criteria:
        - 18 years of age and older
        - Diagnosis of ABSSSI with regional or systemic symptoms presenting ≤7 days before screening
        - Requirement for IV antibacterial treatment
    - Key Exclusion Criteria:
        - Systemic antibacterial treatment ≤14 days or topical antibacterial treatment ≤96 hours before first study infusion
        - Primary ABSSSI due to or associated with a diabetic foot infection/gangrene/perianal abscess, concomitant infection, infected burns, chronic or necrotizing wound, or vascular catheter infection
    - Intervention(s):
        - Zevtera® 667mg IV every 8 hours vs. vancomycin 15mg/kg IV every 12 hours plus aztreonam 1 gram IV every 12 hours for 5 to 14 days
    - Primary Endpoint(s):
        - Early clinical response (reduction in primary lesion ≥20%, survival ≥72 hours, and absence of additional treatment requirements) within 48 to 72 hours
        - 10% prespecified non-inferiority margin
    - Results:
        - Primary endpoint occurred in 91.3% (306/335) patients in the Zevtera® group vs. 88.1% (303/344) in the vancomycin plus aztreonam group (difference*: 3.3%; 95% CI: -1.2%, 7.8%)
          *Between-group difference using Cochran-Mantel-Haenszel weights method adjusted for geographic region and actual type of ABSSSI

- **CABP Indication (Adult):**
    - Key Inclusion Criteria:
        - 18 years of age and older
        - Diagnosis of CABP requiring hospitalization
    - Intervention(s):
        - Zevtera® 667mg IV every 8 hours vs. ceftriaxone 2 gram IV every 24 hours plus optional linezolid 600mg IV every 12 hours for 5 to 14 days

- Primary Endpoint(s):
  - Clinical cure (survival with resolution of signs and symptoms or antibacterial treatment no longer required) 7 to 14 days after end of treatment
  - 10% prespecified non-inferiority margin
- Results:
  - Primary endpoint occurred in 76.4% (240/314) of patients in the Zevtera® group vs. 79.3% (257/324) in the ceftriaxone ± linezolid group (difference: -2.9%; 95% CI: -9.3%, 3.6%)

- **CABP Indication (Pediatric):** An additional trial was completed in pediatric patients (3 months to younger than 18 years of age) with CABP; however, the primary objective of the trial was to evaluate safety and it was not powered for an efficacy analysis.

Cost: The WAC of Zevtera® is not available at this time to allow for a cost analysis.

Cost Comparison: Doxycycline Products

Product	Cost Per Unit	Cost Per Day
Doryx® MPC (doxycycline DR) 60mg tab	**$17.95**	**$35.90***
doxycycline monohydrate 100mg tab (generic)	$0.28	$0.56⁺
doxycycline monohydrate 100mg cap (generic)	$0.24	$0.48⁺

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 day is based on the FDA approved maintenance dosing of 120mg per day.
⁺Cost per day is based on the FDA approved dosing of 100mg twice daily.
cap = capsule; DR = delayed-release; tab = tablet

Cost Comparison: Meropenem Products

Product	Cost Per Vial	Cost Per 2-Gram Dose	Cost Per Day*
meropenem 2 gram vial	**$32.90**	**$32.90**	**$98.70**
meropenem 1 gram vial (generic)	$6.60	$13.20	$39.60
meropenem 500mg vial (generic)	$2.87	$11.48	$34.44

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 day is based on the maximum FDA approved dosing of 2 grams every 8 hours.

Cost Comparison: Nitrofurantoin Suspensions

Product	Cost Per mL	Cost Per 100mg Dose	Cost Per Day*
nitrofurantoin 50mg/5mL	**$36.63**	**$366.30**	**$1,465.20**
nitrofurantoin 25mg/5mL (generic)	$9.50	$190.00	$760.00

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 day is based on the maximum FDA approved dosing of 100mg every 6 hours.

Recommendations

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

Exblifep® (Cefepime/Enmetazobactam) Approval Criteria:

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

Meropenem 2 Gram Vial Approval Criteria:

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

Pivya™ (Pivmecillinam) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection caused by designated susceptible isolates of *Escherichia coli, Proteus*

mirabilis, and *Staphylococcus saprophyticus* (culture/sensitivity results must be submitted); and
2. Member must be a female 18 years of age or older; and
3. Member must not have any of the following contraindications:
    a. Serious hypersensitivity reactions (e.g., anaphylaxis, Stevens-Johnson syndrome) to Pivya™ or to other beta-lactam antibacterial drugs (e.g., penicillins, cephalosporins); and
    b. Primary or secondary carnitine deficiency resulting from inherited disorders of mitochondrial fatty acid oxidation and carnitine metabolism and other inborn errors of metabolism (e.g., methylmalonic aciduria, propionic acidemia); and
    c. Acute porphyria; and
4. Provider must verify that concurrent treatment with valproic acid, valproate, or other pivalate-generating drugs will be avoided due to increased risk of carnitine depletion; or
    a. If concomitant use is necessary, member must be counseled to monitor for and report adverse reactions associated with carnitine depletion (e.g., hypoglycemia, muscle aches, fatigue, confusion); and
5. Pivya™ must not be used when prolonged antibacterial treatment (i.e., longer than the FDA-approved treatment duration of up to 7 days) is necessary; and
6. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
7. A quantity limit of 21 tablets per 7 days will apply.

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

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

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

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

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

1. An FDA approved diagnosis of SAB caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and
2. Member must be 18 years of age or older; and
3. For methicillin-resistant *Staphylococcus aureus* (MRSA), a patient-specific, clinically significant reason why the member cannot use vancomycin or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. For methicillin-susceptible *Staphylococcus aureus* (MSSA), a patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., nafcillin, oxacillin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

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

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

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

2. For the tablet formulation, approval also requires a patient-specific, clinically significant reason why the member requires the tablet formulation and cannot use the capsule formulation.

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

Oral Antibiotic Special Formulation Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.
2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:
   - Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)
   - Cephalexin 250mg and 500mg tablets
   - Cephalexin 750mg capsules
   - Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)
   - Doxycycline hyclate 50mg tablet (Targadox®)
   - Doxycycline hyclate delayed-release (DR) tablets (Doryx®, Doryx® MPC)
   - Doxycycline monohydrate 75mg capsules
   - Doxycycline monohydrate 150mg capsules and tablets
   - Doxycycline monohydrate DR 40mg capsules (Oracea®)
   - Minocycline ER capsules (Ximino®)
   - Minocycline ER tablets (Minolira™)
   - Minocycline ER tablets (Solodyn®)
   - Nitrofurantoin 50mg/5mL suspension

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

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or

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

Fetroja® (Cefiderocol) Approval Criteria:

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

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

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI); or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or

c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. A quantity limit of 56 vials per 14 days will apply.

Vabomere® (Meropenem/Vaborbactam Injection) Approval Criteria:

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

Xacduro® (Sulbactam/Durlobactam) Approval Criteria:

1. An FDA approved diagnosis of hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (culture/sensitivity results must be submitted); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use a carbapenem, ampicillin/sulbactam, polymyxin B, or other cost effective therapeutic equivalent alternative(s) must be provided; ~~and~~ or
   a. A clinical exception will apply for infections caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB), in which case Xacduro® will be approved; and
~~4. For members with carbapenem-resistant *Acinetobacter baumannii* (CRAB), a patient-specific, clinically significant reason why the member cannot us high dose ampicillin/sulbactam in combination with polymyxin B, minocycline, or tigecycline must be provided; and~~
5. The prescriber must confirm that the member will be treated for other pathogens present, if applicable; and
6. Approval quantity will be based on Xacduro® package labeling and FDA approved dosing regimen(s).

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

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

[1] WG Critical Care, LLC. New 2-gram Meropenem for Injection, USP Vial Exclusive from WG Critical Care, LLC. *PRNewswire*. Available online at: https://www.prnewswire.com/news-releases/new-2-gram-meropenem-for-injection-usp-vial-exclusive-from-wg-critical-care-llc-302005176.html. Issued 12/05/2023. Last accessed 08/20/2024.

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Appendix J

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

Oklahoma Health Care Authority
September 2024

Market News and Updates[1]

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

- **November 2023:** The FDA approved a new strength of trientine hydrochloride in a 500mg capsule through an Abbreviated New Drug Application (ANDA).

Cost Comparison: Penicillamine Products

Product	Cost Per Unit	Cost Per Month*	Cost Per Year*
penicillamine 250mg tablet (generic)	**$46.53**	**$11,167.20**	**$134,006.40**
penicillamine 250mg capsule (generic)	$9.29	$2,229.60	$26,755.20

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 = tablet or capsule
*Cost per month and year based on the maximum recommended dosage of 2,000mg/day

Cost Comparison: Trientine Hydrochloride Products

Product	Cost Per Capsule	Cost Per Month*	Cost Per Year*
trientine hydrochloride 500mg (generic)	**$56.96**	**$6,835.20**	**$82,022.40**
trientine hydrochloride 250mg (generic)	$8.61	$2,066.40	$24,796.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month and year based on the maximum recommended dosage of 2,000mg/day

Recommendations

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

Penicillamine 250mg Tablet Approval Criteria:

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

Trientine Hydrochloride (HCl) 500mg Capsule Approval Criteria:

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

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

Cuvrior® (Trientine Tetrahydrochloride) Approval Criteria:

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

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Appendix K

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

Oklahoma Health Care Authority
September 2024

Market News and Updates[1]

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

- **February 2024:** The FDA approved Eohilia™ (budesonide oral suspension) for 12 weeks of treatment in patients 11 years of age and older with eosinophilic esophagitis (EoE).

Eohilia™ (Budesonide Oral Suspension) Product Summary[2,3]

Therapeutic Class: Corticosteroid

Indication(s): For 12 weeks of treatment in adults and pediatric patients 11 years of age and older with EoE

- **Limitation(s) of Use:** Eohilia™ has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

How Supplied: 2mg/10mL oral suspension supplied as single-dose stick packs

Dosing and Administration:

- The recommended dose is 2mg orally twice daily for 12 weeks.
- The Eohilia™ stick pack should be shaken for at least 10 seconds prior to opening, then the packet should be squeezed from the bottom to the top directly into the mouth until the packet is empty, then swallowed completely.
- Food and drink should not be consumed for at least 30 minutes after Eohilia™ has been swallowed.
- After 30 minutes, the mouth should be rinsed with water and the medication should be spit out without swallowing.

Efficacy: The safety and efficacy of Eohilia™ were studied in 2 multicenter, randomized, double-blind, parallel group, placebo-controlled 12-week trials.

- <u>Key Inclusion Criteria:</u>
  - Patients were 11 to 55 years of age with evidence of EoE, defined as meeting all of the following:
    - ≥15 eosinophils/high-power field (eos/hpf) from at least 2 levels of the esophagus during screening

        - Dysphagia on at least 4 days in any 2 consecutive weeks during screening and in the 2 weeks before randomization measured by the Dysphagia Symptom Questionnaire (DSQ; DSQ scores range from 0-84, with lower scores indicating less frequent or less severe dysphagia symptoms)
        - On a stable diet for at least 3 months prior to screening
        - Dosing with inhaled or nasal corticosteroids or proton pump inhibitors was stable
- Intervention: Eohilia™ or placebo for 12 weeks
- Primary Outcomes:
    - Proportion of stringent histologic responders (≤6eos/hpf across all esophageal levels)
    - Absolute change from baseline in subject-reported DSQ combined score after 12 weeks
- Results:
    - Proportion of patients achieving histological remission:
        - Study 1: 53.1% vs. 1.0% [95% confidence interval (CI): 43.3%, 59.1%]
        - Study 2: 38.0% vs. 2.4% (95% CI: 17.2%, 50.0%)
    - Absolute change from baseline in DSQ combined score, least squares mean (standard error):
        - Study 1: -10.2 (1.5) vs. -6.5 (1.8) (95% CI: -6.8, -0.6)
        - Study 2: -14.5 (1.8) vs. -5.9 (2.1) (95% CI: -13.7, -3.5)

Cost Comparison[4,5]

Product	Cost Per Unit	Cost Per 3-month Treatment Course
Eohilia™ (budesonide 2mg/10mL oral suspension)	**$3.01**	**$5,418.00***
budesonide 1mg/2mL inhalation suspension	$3.45	$2,484.00[+]
fluticasone propionate HFA 220mcg inhalation aerosol[β]	$20.10	$1,447.20[α]

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).
HFA= hydrofluoroalkane; Unit= gram or mL
* Cost is based on the FDA approved dosing for eosinophilic esophagitis of 2mg orally twice daily.
[+] Cost is based on the maximum guideline supported dosing of 2mg twice daily.
[α] Cost is based on the maximum guideline supported dosing of 880mcg twice daily.
[β] Please note: each fluticasone propionate 220mcg inhaler is 12 grams and contains 120 metered actuations that deliver 220mcg per actuation.

Recommendations

The College of Pharmacy recommends the prior authorization of Eohilia™ (budesonide oral suspension) with the following criteria (shown in red):

Eohilia™ (Budesonide Oral Suspension) Approval Criteria:

1. An established diagnosis of eosinophilic esophagitis (EoE) defined as:
   a. The presence of clinical symptoms of EoE ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
   b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf)] in the esophagus; and
2. Member must be 11 years of age or older; and
3. Must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a gastroenterologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. Member must have a documented trial for a minimum of 8 weeks that resulted in failure with 1 high-dose proton pump inhibitor (i.e., omeprazole 20-40mg twice daily or equivalent in adults or 1-2mg/kg of omeprazole daily or equivalent in children) or have a contraindication or documented intolerance; and
5. A patient specific, clinically significant reason why the member cannot use a swallowed respiratory corticosteroid (e.g., budesonide, Flovent®) must be provided; and
6. Approvals will be for (1) 3-month treatment course; and
7. A quantity limit of 600mL per 30 days will apply; and
8. Eohilia™ will not be approved for maintenance treatment. Reauthorization for additional 3-month treatment course(s) may be considered if the prescriber documents the following:
   a. The member had a positive initial response to Eohilia™; and
   b. Is now experiencing recurrent worsening symptoms of EoE after completing the treatment course with Eohilia™; and
   c. A patient specific, clinically significant reason why the member still cannot use a swallowed respiratory corticosteroid (e.g., budesonide, Flovent) must be provided.

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

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

1. Approval of Millipred™ or Veripred™ 20 requires a patient-specific, clinically significant reason why the member cannot use ~~a tablet or~~ an alternative strength liquid formulation of generic prednisolone oral

solution including the 5mg/5mL, 15mg/5mL, and 25mg/5mL strengths which are available without a prior authorization.

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

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

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[1] Takeda Pharmaceuticals America, Inc. FDA Approves Takeda's Eohilia™ (Budesonide Oral Suspension) the First and Only Oral Treatment in the U.S. for Eosinophilic Esophagitis (EoE). Available online: https://www.takeda.com/newsroom/newsreleases/2024/fda-approves-eohilia/. Issued 02/12/2024. Last accessed 08/20/2024.

[2] Eohilia™ (Budesonide Oral Suspension) Prescribing Information. Takeda Pharmaceuticals America, Inc. Available online: https://content.takeda.com/?contenttype=PI&product=EOH&language=ENG&country=USA&documentnumber=1. Last revised 02/2024. Last accessed 08/20/2024.

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Appendix L

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

Oklahoma Health Care Authority
September 2024

Market News and Updates[1,2]

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

- **November 2023:** The FDA approved a new strength of tramadol in a 25mg tablet through an Abbreviated New Drug Application (ANDA).

Guidelines:

- **November/December 2023:** The *Journal of Addiction Medicine* published a clinical considerations document by the American Society of Addiction Medicine (ASAM) that addresses buprenorphine treatment of opioid use disorder (OUD) for individuals using high-potency synthetic opioids (HPSOs) such as fentanyl and its analogs. Some of the notable clinical considerations include:
  - Buprenorphine dosing during stabilization should be individualized and some patients may benefit from doses higher than 16-24mg/day.
  - For patients with HPSO exposure, higher doses ≥24mg/day during treatment stabilization may be needed, but clinical reasoning should be documented.
  - Factors such as "psychosocial vulnerability, concomitant stimulant use, or mental health conditions" may delay stabilization, and these patients may require higher doses of buprenorphine and higher levels of care.
  - Once stabilization is achieved and the patient has no ongoing full-opioid agonist use, doses within the 16-24mg/day range may be effective for long-term treatment.
  - The physiological changes in pregnancy can alter buprenorphine metabolism, so a higher dose (>16mg/day) of buprenorphine and more frequent dosing (2-4 times per day) should be considered.

Cost Comparison: Tramadol[3]

Product	Cost Per Tablet	Cost Per 30 Days*
tramadol 25mg tablet (generic)	**$2.49**	**$298.80**
tramadol 50mg tablet (generic)	$0.02	$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 based on the FDA approved initial dosing of 100mg/day.

Recommendations

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

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

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	**methadone soln (Dolophine®)**
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tapentadol ER tab 50mg (Nucynta® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tapentadol ER tab 100mg, 150mg, 200mg, 250mg (Nucynta® ER)	hydromorphone ER tab (Exalgo®)	
	tramadol ER tab (Ultram ER®, Ryzolt®)	methadone tab **~~& soln~~** (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		oxycodone ER cap (Xtampza® ER)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
APAP/butalbital/ caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)	~~**benzhydrocodone/ APAP tab (Apadaz®)**~~	APAP/butalbital/ caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	dihydrocodeine/ APAP/caff cap (Trezix®)	APAP/codeine elixir & soln
codeine tab		~~**hydrocodone/APAP tab (Xodol®)**~~	celecoxib 56mg/tramadol 44mg (Seglentis®)
codeine/APAP tab (Tylenol® with Codeine)		~~**oxycodone/APAP tab (Nalocet®)**~~	hydrocodone/ APAP soln
hydrocodone/ APAP tab (Norco®)		~~**oxycodone/APAP tab & soln (Prolate®)**~~	**hydrocodone/ APAP tab (Xodol®)**
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)		~~**oxycodone tab (Oxaydo®)**~~	levorphanol tab
hydromorphone tab & soln (Dilaudid®)		oxycodone tab (RoxyBond™)	**oxycodone/APAP tab (Nalocet®)**
meperidine tab & soln (Demerol®)			**oxycodone/APAP tab & soln (Prolate®)**
morphine IR tab & soln (MSIR®)			tramadol **25mg &** 100mg tab
oxycodone/APAP tab & soln (Percocet®)			tramadol soln (Qdolo™)
oxycodone/ASA tab (Percodan®)			
oxycodone IR cap (Oxy IR®)			***Oncology Only:***
oxycodone IR tab & soln (Roxicodone®)			~~**fentanyl buccal film (Onsolis®)**~~

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
tapentadol IR (Nucynta®)			fentanyl buccal tab (Fentora®)
tramadol 50mg tab (Ultram®)			~~**fentanyl SL tab (Abstral®)**~~
tramadol/APAP (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

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

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. ~~Abstral®;~~ Actiq®~~;~~ and Fentora®~~, and Onsolis®~~ are approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
   a. Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use of these products despite the medication being contraindicated for the member's age; or
   b. For members older than 12 years of age, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/ caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.
5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
   a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; ~~and~~ or
   b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior

authorization is required, unless the prescription is written by an otolaryngologist or a dentist; ~~or~~ and
    c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
6. Levorphanol Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
7. Methadone Oral Solution Approval Criteria:
    a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or
    b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.
8. Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and
    b. For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.
9. Oxymorphone ER Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other available extended-release opioid analgesic must be provided.
10. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    c. A quantity limit of 2,400mL per 30 days will apply.
11. Seglentis® (Celecoxib 56mg/Tramadol 44mg Tablet) Approval Criteria:

a. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
b. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
c. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
d. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
e. A quantity limit of 28 tablets for a 7-day supply will apply.

12. Tramadol 25mg and 100mg Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose or split a tramadol 50mg tablet to achieve a 25mg dose must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

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

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

1. Generic buprenorphine/naloxone SL tablet is the preferred product. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why generic buprenorphine/naloxone SL tablets are not appropriate.
2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and
3. Member must have an FDA approved diagnosis of opioid abuse/ dependence; and
4. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and

5. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
6. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of ~~60~~ 90 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of ~~30~~ 60 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of ~~60~~ 90 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of ~~60~~ 90 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg ~~and 11.4mg/2.9mg SL tablets~~: A quantity limit of ~~30~~ 60 SL tablets per 30 days will apply.
    i. Zubsolv® 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

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

1. Each request for ~~>16mg~~ >24mg bioequivalent buprenorphine per day will be evaluated on a case-by-case basis; and
2. A taper schedule, dates of an attempted taper with reason(s) for failure, or a patient-specific, clinically significant reason why a taper attempt is not appropriate for the member should be documented on the prior authorization request; and
3. Opioid urine drug screens should be submitted with high-dose requests that plan to continue high-dose treatment longer than the duration of 1 month; and
    a. Urine drug screens must show the absence of opioid medications other than buprenorphine products for continued approval; or
    b. Prescriber must document a patient-specific reason the member should continue therapy, reason for opioid use, and document a plan for member to discontinue opioid use; and
4. Symptoms associated with withdrawal at lower doses or symptoms requiring high doses should be listed on the prior authorization request; and
5. Each approval will be for the duration of 1 month. If urine drug screen and other documentation are submitted indicating high-dose therapy

is necessary, an approval can be granted for the duration of 3 months; and

6. Continued high-dose authorization after the 3-month approval will require a new (recent) urine drug screen; and
7. For Opioid Treatment Programs (OTPs), high-dose authorization will be approved for 1 year if urine drug screen and other documentation are submitted indicating high-dose therapy is necessary.

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[1] U.S. FDA. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Product Details for Abbreviated New Drug Application (ANDA) 208708. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=208708#43720. Last revised 08/2024. Last accessed 08/20/2024.

[2] Weimer M, Herring A, Kawasaki S, et al. ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids. *J Addict Med* 2023; 17(6): 632-639. doi: 10.1097/ADM.0000000000001202.

[3] Tramadol Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=93b12089-3a0f-4b57-abb1-2429cf31995d. Last revised 02/27/2024. Last accessed 08/20/2024.

Appendix M

Vote to Update the Approval Criteria for the Topical Corticosteroids

Oklahoma Health Care Authority
September 2024

Recommendations

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

1. Ultra-High to High Potency:
    a. Move clobetasol propionate 0.05% (Clobex®) spray from Tier-3 to Tier-2; and
    b. Move halcinonide 0.1% (Halog®) cream, ointment, and solution from Tier-2 to Tier-3; and
    c. Remove clobetasol propionate 0.05% (Impeklo®) lotion due to product discontinuation.
2. Medium-High to Medium Potency:
    a. Move hydrocortisone valerate 0.2% (Westcort®) cream from Tier-3 to Tier-1; and
    b. Move betamethasone dipropionate/calcipotriene 0.064%/0.005% (Taclonex®) ointment, spray, and suspension and clocortolone pivalate 0.1% (Cloderm®) cream from Tier-2 to Tier-3; and
    c. Move hydrocortisone butyrate 0.1% cream and lotion and flurandrenolide 0.05% cream, lotion, and ointment from Tier-2 to Tier-3; and
    d. Move fluticasone 0.05% (Cutivate®) lotion from Tier-2 to Tier-3.
3. Low Potency:
    a. Move alclometasone dipropionate 0.05% (Aclovate®) ointment from Tier-3 to Tier-2; and
    b. Remove hydrocortisone/urea 1%/10% (U-Cort®) cream due to product discontinuation.

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

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

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluocinolone acetonide 0.01% (Capex®)	Sh	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	hydrocortisone/pramoxine 1%/1% (Pramosone®)	C,L	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O				
~~**hydrocortisone/urea 1%/10% (U-Cort®)**~~	~~**C**~~				
triamcinolone acetonide 0.025%	C,L				

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

Appendix N

Calendar Year 2023 Annual Review of Allergen Immunotherapies

Oklahoma Health Care Authority
September 2024

Current Prior Authorization Criteria

Grastek® (Timothy Grass Pollen Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test (labs required) or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies for Timothy grass or cross-reactive grass pollen (cool season grasses); and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of the grass pollen season (November 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

Odactra® (House Dust Mite Allergen Extract) Approval Criteria:

1. Member must be 12 to 65 years of age; and
2. Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or *in vitro* testing for immunoglobulin E (IgE) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each; and
6. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
7. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
8. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
9. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
10. A quantity limit of 1 tablet daily will apply; and
11. Initial approvals will be for the duration of 6 months of therapy, at which time the prescriber must verify the member is responding well to Odactra® therapy. Additionally, compliance will be evaluated for continued approval.

Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to 1 of the 5 grass pollens contained in Oralair®; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):

   a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
   b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥16 weeks prior to the start of the grass pollen season (October 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 16 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

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

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

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

Ragwitek® (Short Ragweed Pollen Allergen Extract) Approval Criteria:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis symptoms; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of ragweed pollen season (May 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

Utilization of Allergen Immunotherapies: Calendar Year 2023

Comparison of Calendar Years

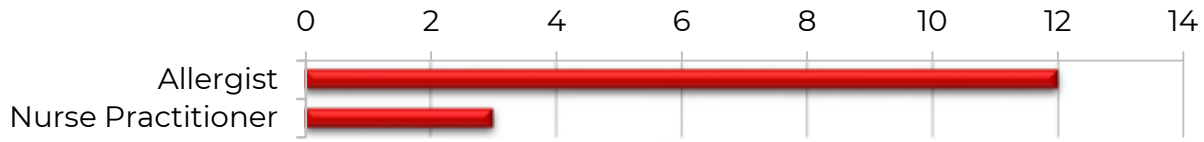
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1	4	$1,796.16	$449.04	$14.97	120	120
2023	5	15	$4,495.18	$299.68	$9.99	450	450
% Change	**400.00%**	**275.00%**	**150.30%**	**-33.30%**	**-33.30%**	**275.00%**	**275.00%**
Change	**4**	**11**	**$2,699.02**	**-$149.36**	**-$4.98**	**330**	**330**

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

Demographics of Members Utilizing Allergen Immunotherapies

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

Top Prescriber Specialties of Allergen Immunotherapies by Number of Claims



Prior Authorization of Allergen Immunotherapies

There were 63 prior authorization requests submitted for 21 unique members for allergen immunotherapies during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions

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

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

- **June 2024:** The FDA approved an age expansion for therapy initiation of Palforzia® (peanut allergen powder-dnfp) down to 1 year of age. The initial FDA approval of Palforzia® in 2020 included therapy initiation in patients 4 to 17 years of age with continuation of maintenance therapy as an option for patients 18 years of age and older.

Pipeline:

- **REGN5713-5714-5715:** Regeneron Pharmaceuticals' birch tree pollen allergen anti-Bet v 1 monoclonal antibodies, given subcutaneously or intravenously as a single dose, are currently in Phase 3 clinical trials.
- **Viaskin™ Milk:** DBV Technologies is investigating cow's milk protein topical patches in Phase 1 and 2 clinical trials for desensitizing immunoglobulin E (IgE)-mediated cow's milk allergy in patients 2 to 17 years of age. Additionally, these patches are being studied for possible treatment of eosinophilic esophagitis (EoE) in patients 4 to 17 years of age, as this diagnosis is thought to be connected to an immune reaction to cow's milk.
- **Viaskin™ Peanut:** DBV Technologies is also investigating peanut protein topical patches in Phase 3 clinical trials. Completed trial results suggest these patches could be a new desensitization option for children with food allergies to peanuts. The trials included patients down to 1 year of age.

Recommendations

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

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

1. Member must be ~~4~~ 1 to 17 years of age to initiate initial dose escalation (maintenance dosing may be continued for members ~~4~~ 1 year~~s~~ of age and older); and
2. Member must have a diagnosis of peanut allergy confirmed by a positive skin test, positive *in vitro* test for peanut-specific immunoglobulin E (IgE), or positive clinician-supervised oral food challenge; and
3. Prescriber must confirm member will use Palforzia® with a peanut-avoidant diet; and
4. Member must not have severe uncontrolled asthma; and
5. Member must not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and

6. Member must not have had severe or life-threatening anaphylaxis within the previous 60 days; and
7. Member or caregiver must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
9. Prescriber, health care setting, and pharmacy must be certified in the Palforzia® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Palforzia® REMS program; and
11. Palforzia® must be administered under the direct observation of a health care provider in a REMS certified health care setting with an observation duration in accordance with the Palforzia® *Prescribing Information*; and
12. After successful completion of initial dose escalation and all levels of up-dosing as documented by the prescriber, initial approvals of maintenance dosing will be for 6 months. For continued approval, the member must be compliant, and prescriber must verify the member is responding well to treatment.

Utilization Details of Allergen Immunotherapies: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ODACTRA 12 SQ-HDM SUB TAB	10	4	$2,703.03	$270.30	2.5	60.13%
RAGWITEK 12 AMB A 1-U SUB TAB	4	1	$1,433.72	$358.43	4	31.89%
GRASTEK 2800 BAU SUB TAB	1	1	$358.43	$358.43	1	7.97%
TOTAL	**15**	**5***	**$4,495.18**	**$299.68**	**3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BAU = bioequivalent allergy units; SQ-HDM = standardized quality-house dust mite; SUB = sublingual; TAB = tablet; U = unit

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[1] Palforzia® (Peanut *Arachis hypogaea* Allergen Powder-dnfp) Prescribing Information. Aimmune Therapeutics, Inc. Available online at: https://www.fda.gov/media/134838/download. Last revised 07/2024. Last accessed 08/16/2024.
[2] Aimmune Therapeutics. FDA Approves U.S. Pediatric Indication Extension for Palforzia® Oral Immunotherapy for the Treatment of Peanut Allergy. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20240730211334/en/FDA-Approves-U.S.-Pediatric-Indication-Extension-for-Palforzia%C2%AE-Oral-Immunotherapy-for-the-Treatment-of-Peanut-Allergy. Issued 07/30/2024. Last accessed 08/27/2024.
[3] Regeneron Pharmaceuticals. Investigational Pipeline. Available online at: https://www.regeneron.com/pipeline-medicines/investigational-pipeline. Last accessed 08/16/2024.
[4] DBV Technologies. Development Program: Viaskin™ Milk. Available online at: https://dbv-technologies.com/pipeline/viaskin-milk/. Last accessed 08/16/2024.
[5] DBV Technologies. Development Program: Viaskin™ Peanut. Available online at: https://dbv-technologies.com/pipeline/viaskin-peanut/. Last accessed 08/16/2024.

Appendix O

Calendar Year 2023 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Hercessi™ (Trastuzumab-strf) and Truqap™ (Capivasertib)

Oklahoma Health Care Authority
September 2024

Current Prior Authorization Criteria

Utilization data for Keytruda® (pembrolizumab) and approval criteria for indications other than breast cancer can be found in the December 2023 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the skin cancer medications. Utilization data for Afinitor® (everolimus) and Lynparza® (olaparib) and approval criteria for indications other than breast cancer can be found in the June 2024 DUR Board packet. These medications and criteria are reviewed annually with the genitourinary and gynecologic cancer medications.

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

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

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

1. Adult members with unresectable or metastatic disease; and
    a. For human epidermal growth factor receptor 2 (HER2)-positive disease, must meet the following:
        i. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and
        ii. Member has received ≥1 prior anti-HER2-based regimen; or
    b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet the following:
        i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

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.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic gastric or GEJ adenocarcinoma; and
2. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
3. Member has received at least 1 prior trastuzumab-based regimen.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of unresectable or metastatic NSCLC; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member must have received a prior systemic therapy.

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

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

Halaven® (Eribulin) Approval Criteria [Liposarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic liposarcoma; and
2. Previously received an anthracycline-containing chemotherapy regimen.

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

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

Herceptin® (Trastuzumab), 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.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), 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.

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

1. Diagnosis of advanced, metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. Used in combination with:
    a. An aromatase inhibitor in female members; or
    b. Fulvestrant in women with disease progression following endocrine therapy; or
    c. An aromatase inhibitor or fulvestrant in male patients.

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

1. Diagnosis of metastatic or locally advanced breast cancer; and
2. Used in combination with capecitabine; and
    a. After failure of an anthracycline and a taxane unless anthracycline contraindicated; or
3. Used as a single agent; and
    a. Used in 1 of the following settings:
        i. After failure of capecitabine, an anthracycline, and a taxane; or
        ii. In members with no response to preoperative systemic therapy; or
        iii. After at least 1 line of therapy for recurrent unresectable (local or regional) disease; or

iv. Disease is human epidermal growth factor receptor 2 (HER2)-negative; or

4. Used in combination with trastuzumab; and
    a. Disease is HER2-positive; and
    b. Third-line or subsequent therapy.

Kadcyla® (Ado-Trastuzumab Emtansine) Approval Criteria [Early Stage or Locally Advanced Breast Cancer Diagnosis]:

1. Diagnosis of early stage or locally advanced breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Used as adjuvant treatment in members with residual invasive disease after neoadjuvant therapy with taxane and trastuzumab-based treatment; and
4. Maximum duration of a total of 14 cycles.

Kadcyla® (Ado-Trastuzumab Emtansine) Approval Criteria [Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Previously received trastuzumab and a taxane, separately or in combination; and
4. Members should also have either:
    a. Received prior therapy for metastatic disease; or
    b. Developed disease recurrence during or within 6 months of completing adjuvant therapy.

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

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

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

1. Hormone receptor (HR) positive; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Used in 1 of the following settings:
    a. Diagnosis of advanced or metastatic breast cancer, as initial therapy; and
        i. In combination with an aromatase inhibitor; or

b. Diagnosis of advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy; and
    i. In combination with fulvestrant; and
    ii. Must be used in postmenopausal women only.

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

1. Diagnosis of advanced or metastatic breast cancer, as initial therapy; and
2. Hormone receptor (HR) positive; and
3. Human epidermal growth factor receptor 2 (HER2)-negative.

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

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

Margenza® (Margetuximab-cmkb) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member has received 2 or more prior anti-HER2 regimens, at least 1 of which was for metastatic disease; and
4. Used in combination with chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine).

Nerlynx® (Neratinib) Approval Criteria [Non-Metastatic Breast Cancer Diagnosis]:

1. For adjuvant treatment in early-stage breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
3. Neratinib must be used to follow 4adjuvant trastuzumab-based therapy.

Nerlynx® (Neratinib) Approval Criteria [Recurrent or Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Member must have human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
3. Used in combination with capecitabine; or
4. Used in combination with capecitabine or paclitaxel if brain metastases are present.

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

1. Diagnosis of advanced or metastatic breast cancer; and
2. Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and
3. Tumor is positive for ESR1-mutation; and
4. Female members must be postmenopausal; and
5. Has progressed after at least 1 prior endocrine therapy.

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

1. Human epidermal growth factor receptor 2 (HER2)-positive; and
2. Used in 1 of the following settings:
    a. Metastatic breast cancer in members who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease:
        i. Used in combination with trastuzumab and chemotherapy; or
    b. Neoadjuvant treatment of members with locally advanced, inflammatory, or early stage breast cancer (either >2cm in diameter or node positive):
        i. Used in combination with trastuzumab and chemotherapy; or
    c. Adjuvant systemic therapy for members with node positive, HER2-positive tumors or members with high-risk node negative tumors [tumor >1cm; tumor 0.5 to 1cm with histologic or nuclear grade 3; estrogen receptor (ER)/progesterone receptor (PR) negative; or younger than 35 years of age]:
        i. Used in combination with trastuzumab and chemotherapy; or
        ii. Used in combination with trastuzumab and docetaxel following doxorubicin/cyclophosphamide (AC); or
        iii. Used in combination with docetaxel/carboplatin/trastuzumab (TCH); or
        iv. Used in combination with trastuzumab following neoadjuvant therapy with paclitaxel/docetaxel/carboplatin/trastuzumab/pertuzumab (pTCHP).

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, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression.

Phesgo® (Pertuzumab/Trastuzumab/Hyaluronidase-zzxf) Approval Criteria [Breast Cancer Diagnosis]:

1. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
2. Used in 1 of the following settings:
    a. Neoadjuvant treatment of members with locally advanced, inflammatory, or early stage breast cancer; or
    b. Adjuvant treatment of members with early breast cancer; or
    c. In combination with docetaxel for members with metastatic disease.

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

1. Diagnosis of advanced or metastatic breast cancer that has progressed on or after an endocrine-based regimen in men or in postmenopausal women; and
2. Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative; and
3. PIK3CA-mutated disease; and
4. In combination with fulvestrant.

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

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Presence of BRCA1/BRCA2-germline mutated disease; and
4. Disease is hormone receptor (HR) negative or is HR positive and endocrine therapy refractory; and
5. Patient has symptomatic visceral disease; and
6. Must be used as a single-agent.

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

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

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

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

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

1. Diagnosis of unresectable locally advanced or metastatic disease; and
2. Member must have previously received a platinum-containing chemotherapy; and
3. Member must have previously received either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

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

1. Diagnosis of advanced unresectable or metastatic breast cancer; and
2. Used in combination with trastuzumab and capecitabine; and
3. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
4. Following progression of ≥1 prior anti-HER2 regimen(s) in the metastatic setting.

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

1. Diagnosis of RAS wild-type, human epidermal growth factor receptor 2 (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 [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic or recurrent breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Lapatinib must be used in combination with 1 of the following:
    a. Trastuzumab; or
    b. Capecitabine; or
    c. An aromatase inhibitor (e.g., exemestane, letrozole, anastrozole) if also estrogen receptor (ER) positive.

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.

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

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

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 Breast Cancer Medications: Calendar Year 2023

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

Calendar Year Comparison: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	89	558	$7,970,940.76	$14,284.84	$505.26	21,943	15,776
2023	114	668	$10,076,759.96	$15,084.97	$536.48	28,248	18,783
% Change	**28.10%**	**19.70%**	**26.40%**	**5.60%**	**6.20%**	**28.70%**	**19.10%**
Change	**25**	**110**	**$2,105,819.20**	**$800.13**	**$31.22**	**6,305**	**3,007**

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

Calendar Year Comparison: Medical Claims

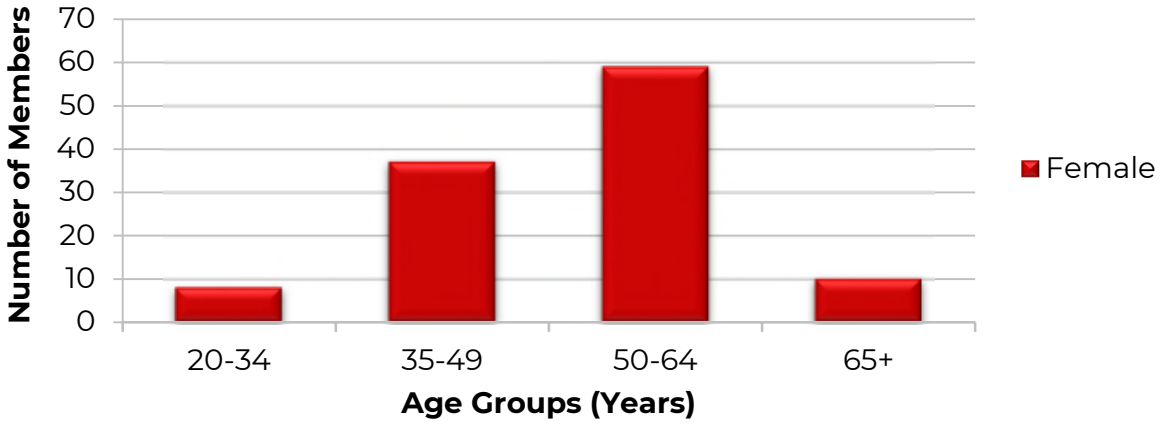
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	136	1,549	$7,417,173.82	$4,788.36	11.39
2023	138	1,596	$9,232,679.10	$5,784.89	11.57
% Change	**1.47%**	**3.03%**	**24.48%**	**20.81%**	**1.58%**
Change	**2**	**47**	**$1,815,505.28**	**$996.53**	**0.18**

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

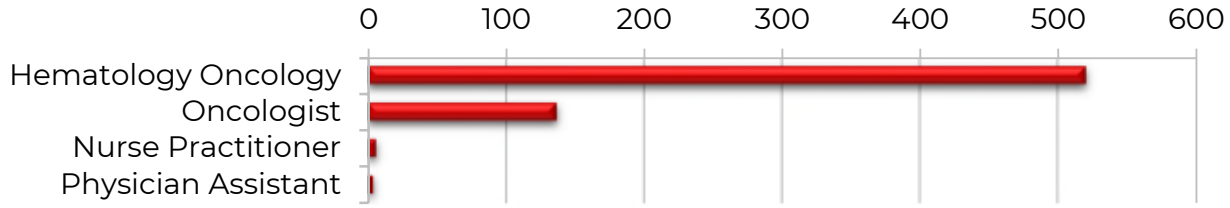
- Aggregate drug rebates collected during calendar year 2023 for Breast Cancer Medications totaled $6,934,011.67.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Breast Cancer Medications: Pharmacy Claims



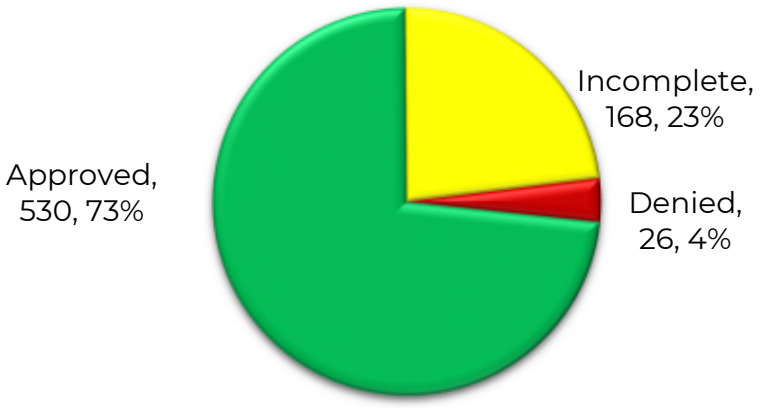
Top Prescriber Specialties of Breast Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Breast Cancer Medications

There were 724 prior authorization requests submitted for breast cancer medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Ixempra® (ixabepilone): February 2025
- Halaven® (eribulin): July 2027
- Tykerb® (lapatinib): September 2029
- Verzenio® (abemaciclib): December 2029
- Nerlynx® (neratinib): July 2031
- Talzenna® (talazoparib): October 2031
- Piqray® (alpelisib): April 2033
- Truqap™ (capivasertib): April 2033
- Ibrance® (palbociclib capsule): February 2034
- Kisqali® (ribociclib): April 2036
- Kisqali® Femara® Co-Pack (ribociclib/letrozole): April 2036
- Ibrance® (palbociclib tablet): August 2036
- Orserdu® (elacestrant): January 2038
- Tukysa® (tucatinib): April 2038

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

- **March 2023:** The FDA approved Verzenio® (abemaciclib) for an expanded indication for the treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, in combination with an aromatase inhibitor as initial endocrine-based therapy. This new indication removes the previous requirement that it be used in postmenopausal women.
- **November 2023:** The FDA approved Truqap™ (capivasertib), in combination with fulvestrant, for the treatment of adult patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer with 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test following progression on at least 1 endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.
- **January 2024:** The FDA approved Piqray® (alpelisib) for an expanded indication, in combination with fulvestrant, for the treatment of adults with HR-positive, HER2-negative, *PIK3CA*-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. This new indication removes the previous requirement that it be used in postmenopausal women, allowing for the use of alpelisib in pre- and perimenopausal women.
- **April 2024:** The FDA granted accelerated approval for Enhertu® (fam-trastuzumab deruxtecan-nxki) for a new indication for the treatment of adult patients with unresectable or metastatic HER2-positive [immunohistochemistry (IHC) 3+] solid tumors who have received prior

systemic treatment and have no satisfactory alternative treatment options.

- **April 2024:** The FDA approved Hercessi™ (trastuzumab-strf), a new biosimilar to Herceptin® (trastuzumab), for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Hercessi™ will be available as a 150mg lyophilized powder in a single-dose vial for reconstitution.
- **July 2024:** The FDA approved Kisqali® (ribociclib) for an expanded indication for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer, in combination with fulvestrant, as initial endocrine-based therapy or with disease progression following endocrine therapy. This new indication removes the previous requirement that it be used in postmenopausal women.

Guideline Update(s):

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

Truqap™ (Capivasertib) Product Summary[16]

Therapeutic Class: Kinase inhibitor

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

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

How Supplied: 160mg and 200mg oral tablets

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

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

Cost Comparison: Trastuzumab Products

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

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

Recommendations

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

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

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

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

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

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

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

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

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

1. Diagnosis of advanced or metastatic breast cancer that has progressed on or after an endocrine-based regimen ~~in men or in postmenopausal women~~; and
2. Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative; and
3. PIK3CA-mutated disease; and
4. In combination with fulvestrant.

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

1. Diagnosis of advanced or metastatic breast cancer; and
    a. Hormone receptor positive disease; and
    b. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in 1 of the following settings:
            1. In combination with an aromatase inhibitor as initial endocrine-based therapy ~~for postmenopausal women~~; or
            2. In combination with fulvestrant with disease progression following endocrine therapy; or

3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or

2. Diagnosis of early-stage breast cancer; and
   a. Hormone receptor positive disease; and
   b. HER2-negative disease; and
   c. Node-positive disease high risk for recurrence; and
   d. Used as adjuvant treatment in combination with endocrine therapy.

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

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

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

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

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

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

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

i. HR negative; or
ii. HR positive with visceral crisis or endocrine therapy refractory.

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

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

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

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

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

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and

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

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

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

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

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

Utilization Details of Breast Cancer Medications: Calendar Year 2023

Pharmacy Claims

BRAND NAME	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PALBOCICLIB PRODUCTS						
IBRANCE TAB 125MG	150	27	$2,263,120.05	$15,087.47	5.56	22.46%
IBRANCE TAB 100MG	81	13	$1,222,097.69	$15,087.63	6.23	12.13%
IBRANCE TAB 75MG	38	10	$573,287.82	$15,086.52	3.8	5.69%
IBRANCE CAP 75MG	26	4	$362,081.98	$13,926.23	6.5	3.59%
IBRANCE CAP 125MG	14	2	$211,243.96	$15,088.85	7	2.10%
IBRANCE CAP 100MG	13	3	$196,114.82	$15,085.76	4.33	1.95%
SUBTOTAL	**322**	**59**	**$4,827,946.32**	**$14,993.62**	**5.46**	**47.91%**
ABEMACICLIB PRODUCTS						
VERZENIO TAB 150MG	98	28	$1,396,414.66	$14,249.13	3.5	13.86%
VERZENIO TAB 100MG	48	13	$698,106.32	$14,543.88	3.69	6.93%
VERZENIO TAB 50MG	17	3	$247,249.03	$14,544.06	5.67	2.45%
SUBTOTAL	**163**	**44**	**$2,341,770.01**	**$14,366.69**	**3.7**	**23.24%**
RIBOCICLIB PRODUCTS						
KISQALI TAB 600MG DOSE	87	21	$1,395,812.47	$16,043.82	4.14	13.85%
KISQALI TAB 400MG DOSE	30	7	$393,314.40	$13,110.48	4.29	3.90%
KISQALI TAB 200MG DOSE	10	2	$65,603.20	$6,560.32	5	0.65%
SUBTOTAL	**127**	**30**	**$1,854,730.07**	**$14,604.17**	**4.23**	**18.41%**
ELACESTRANT PRODUCTS						

BRAND NAME	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORSERDU TAB 345MG	15	3	$322,354.30	$21,490.29	5	3.20%
SUBTOTAL	**15**	**3**	**$322,354.30**	**$21,490.29**	**5**	**3.20%**
NERATINIB PRODUCTS						
NERLYNX TAB 40MG	14	2	$279,149.74	$19,939.27	7	2.77%
SUBTOTAL	**14**	**2**	**$279,149.74**	**$19,939.27**	**7**	**2.77%**
ALPELISIB PRODUCTS						
PIQRAY 300MG TAB DOSE	5	3	$102,088.35	$20,417.67	1.67	1.01%
PIQRAY 250MG TAB DOSE	5	1	$102,091.85	$20,418.37	5	1.01%
SUBTOTAL	**10**	**4**	**$204,180.20**	**$20,418.02**	**2.5**	**2.03%**
LAPATINIB PRODUCTS						
LAPATINIB TAB 250MG	7	2	$50,580.13	$7,225.73	3.5	0.50%
SUBTOTAL	**7**	**2**	**$50,580.13**	**$7,225.73**	**3.5**	**0.50%**
TUCATINIB PRODUCTS						
TUKYSA TAB 150MG	6	3	$129,375.46	$21,562.58	2	1.28%
SUBTOTAL	**6**	**3**	**$129,375.46**	**$21,562.58**	**2**	**1.28%**
RIBOCICLIB/LETROZOLE PRODUCTS						
KISQALI FEMARA PAK 600/2.5MG	3	1	$49,148.25	$16,382.75	3	0.49%
SUBTOTAL	**3**	**1**	**$49,148.25**	**$16,382.75**	**3**	**0.49%**
TALAZOPARIB PRODUCTS						
TALZENNA CAP 1MG	1	1	$17,525.48	$17,525.48	1	0.17%
SUBTOTAL	**1**	**1**	**$17,525.48**	**$17,525.48**	**1**	0.17%
TOTAL	**668**	**114***	**$10,076,759.96**	**$15,084.97**	**5.86**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PERTUZUMAB J9306 (PERJETA)	444	67	$3,010,938.20	$6,781.39	6.63
TRASTUZ-DTTB Q5112 (ONTRUZANT)	295	38	$697,822.53	$2,365.50	7.76
ADO-TRASTUZ EMT J9354 (KADCYLA)	240	26	$2,003,954.35	$8,349.81	9.23
TRASTUZ-QYYP Q5116 (TRAZIMERA)	214	40	$234,979.24	$1,098.03	5.35
FAM-TRASTUZ DER-NXKI J9358 (ENHERTU)	155	20	$1,766,800.28	$11,398.71	7.75
SACITUZ GOV-HZIY J9317 (TRODELVY)	84	9	$1,010,893.40	$12,034.45	9.33
TRASTUZ-DKST Q5114 (OGIVRI)	73	14	$151,451.31	$2,074.68	5.21
ERIBULIN MESYLATE J9179 (HALAVEN)	28	4	$99,406.40	$3,550.23	7
TRASTUZUMAB J9355 (HERCEPTIN)	25	2	$111,757.35	$4,470.29	12.5
TRASTUZ-ANNS Q5117 (KANJINTI)	21	7	$25,995.20	$1,237.87	3
PERTUZ/TRASTUZ/HYAL-ZZXF J9316 (PHESGO)	11	3	$90,256.80	$8,205.16	3.67
MARGETUXIMAB-CMKB J9353 (MARGENZA)	5	1	$28,282.78	$5,656.56	5
TRASTUZ-PKRB Q5113 (HERZUMA)	1	1	$141.26	$141.26	1
TOTAL	**1,596**	**138**	**$9,232,679.10**	**$5,784.89**	**11.57**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
DER = deruxtecan; EMT = emtansine; GOV = govitecan; HYAL = hyaluronidase; PERTUZ = pertuzumab; SACITUZ = sacituzumab; TRASTUZ = trastuzumab

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Appendix P

Calendar Year 2023 Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Wainua™ (Eplontersen)

Oklahoma Health Care Authority
September 2024

Current Prior Authorization Criteria

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

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; or
   b. Genetic confirmation of transthyretin (*TTR*) gene mutation; and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. For Onpattro®, prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
9. Amvuttra® will not be approved for concomitant use with Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), or Vyndamax® (tafamidis); and
10. Authorization for Amvuttra® will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and
11. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine); and

12. For Onpattro®, member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
13. For Amvuttra®, a quantity limit of 0.5mL per 90 days will apply; and
14. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; or
   b. Genetic confirmation of transthyretin (*TTR*) gene mutation; and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Tegsedi® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
13. A quantity limit of 4 syringes per 28 days will apply.

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

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis; and
    b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
    a. Nuclear scintigraphy; or
    b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® or Vyndaqel® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Vyndamax® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), or Tegsedi® (inotersen); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

Utilization of Amyloidosis Medications: Calendar Year 2023

Calendar Year 2023 Utilization: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2023	1	2	$41,757.42	$20,878.71	$695.96	240	60

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

Calendar Year 2023 Utilization: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2023	2	5	$261,181.90	$29,020.21	2.5

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 amyloidosis medications during calendar year 2022 to allow for a calendar year comparison.

Demographics of Members Utilizing Amyloidosis Medications

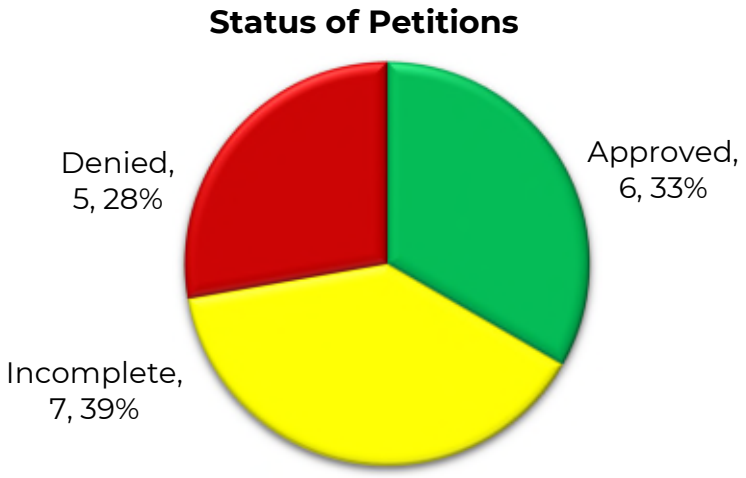
- Due to the limited number of members utilizing amyloidosis medications during calendar year 2023, detailed demographic information could not be provided.

Top Prescriber Specialties of Amyloidosis Medications by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for amyloidosis medications during calendar year 2023 was hematologist/ oncologist.

Prior Authorization of Amyloidosis Medications

There were 18 prior authorization requests submitted for 4 unique members for the amyloidosis medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



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

Anticipated Patent Expiration(s):

- Vyndaqel® (tafamidis meglumine): December 2024
- Tegsedi® (inotersen): April 2031

- Wainua™ (eplontersen): August 2034
- Onpattro® (patisiran): August 2035
- Vyndamax® (tafamidis): August 2035
- Amvuttra® (vutrisiran): July 2036

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

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

Pipeline:

- **Acoramidis (AG10):** On February 5, 2024, BridgeBio Pharma announced that the FDA accepted a New Drug Application (NDA) for acoramidis for the treatment of patients with transthyretin amyloid cardiomyopathy (ATTR-CM). The Prescription Drug User Fee Act (PDUFA) action date is November 29, 2024. The NDA submission was based on positive results from ATTRibute-CM, a Phase 3, double-blind, randomized, controlled trial. In the trial, acoramidis administered orally twice daily demonstrated a statistically significant reduction in the frequency of cardiovascular-related hospitalization, reduction in all-cause mortality, improvements in N-terminal pro-B type natriuretic peptide (NT-proBNP) levels, and improvement in distance walked on the 6-minute walk test (6MWT).
- **NTLA-2001:** Regeneron Pharmaceuticals, in collaboration with Intellia, is evaluating NTLA-2001, a *TTR* gene knockout therapy using CRISPR/Cas9, in Phase 3 clinical trials for the treatment of ATTR-CM.

Wainua™ (Eplontersen) Product Summary[6,7]

Therapeutic Class: Transthyretin-directed antisense oligonucleotide (ASO)

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

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

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

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

- Key Inclusion Criteria:
  - Diagnosis of hATTR-PN with *TTR* gene mutation

    - Neuropathy Impairment Scale (NIS) score ≥10 and ≤130
    - Familial Amyloid Neuropathy (FAP) or Coutinho stage 1 or 2
- Key Exclusion Criteria:
    - Karnofsky Performance Scale status ≤50
    - Prior liver transplant or anticipated liver transplant within 1 year of screening
    - Alternative causes of sensorimotor or autonomic neuropathy
    - New York Heart Association (NYHA) Functional Classification ≥3
    - Current treatment with any approved drug for hATTR
    - Previous treatment with any other ASO or ribonucleic acid (RNA) therapy
        - Treatment with tafamidis, tafamidis meglumine, or diflunisal must have been discontinued ≥2 weeks prior to trial Day 1
- Intervention(s):
    - Wainua™ 45mg sub-Q once every 4 weeks vs. historical placebo group (population attained from NEURO-TTR trial which evaluated inotersen for FDA approval)
    - Patients were also randomized 6:1 to receive Wainua™ vs. inotersen 284mg sub-Q once per week (as a small, cross-trial comparison group)
    - All patients were required to take approximately 3000 IU/day of Vitamin A
- Primary Endpoint(s):
    - Change in modified Neuropathy Impairment Scale+7 (mNIS+7) and Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) from baseline at Week 35
- Results:
    - The least square mean change in mNIS+7 from baseline at Week 35 was 0.2 [standard error of the mean (SEM): 1.9] for the Wainua™ group (n=140) vs. 9.2 (SEM: 1.9) for the placebo group (n=59), resulting in a treatment difference of -9.0 [95% confidence interval (CI): -13.5, -4.5; P <0.001]
    - The least square mean change in Norfold QoL-DN from baseline at Week 35 was -3.1 (SEM: 2.1) for the Wainua™ group (n=140) vs. 8.7 (SEM: 2.1) for the placebo group (n=59), resulting in a treatment difference of -11.8 (95% CI: -16.8, -6.8; P <0.001).

Cost Comparison:

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

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

Recommendations

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

Wainua™ (Eplontersen) Approval Criteria:

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

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

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

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by ~~the following:~~
   ~~a. Tissue (fat pad) biopsy confirming amyloid deposits; or~~
   b. Genetic ~~confirmation of~~ testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. For Onpattro®, prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
9. Amvuttra® will not be approved for concomitant use with Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), or Vyndamax® (tafamidis); and
10. Authorization for Amvuttra® will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and
11. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine); and
12. For Onpattro®, member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
13. For Amvuttra®, a quantity limit of 0.5mL per 90 days will apply; and

14. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by ~~the following:~~
   ~~a. Tissue (fat pad) biopsy confirming amyloid deposits; or~~
   b. Genetic ~~confirmation of~~ testing identifying a transthyretin (*TTR*) gene mutation (e.g., Val30Met) (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Tegsedi® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
13. A quantity limit of 4 syringes per 28 days will apply.

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

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
   a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
   b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
   a. Nuclear scintigraphy; or
   b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® or Vyndaqel® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Vyndamax® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), or Tegsedi® (inotersen); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

Utilization Details of Amyloidosis Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VYNDAQEL CAP 20MG	2	1	$41,757.42	$20,878.71	2	100%
TOTAL	**2**	**1***	**$41,757.42**	**$20,878.71**	**2**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VUTRISIRAN INJ (J0225)	3	1	$255,171.70	$63,792.93	3	97.70%
PATISIRAN INJ (J0222)	2	1	$6,010.20	$1,202.04	2	2.30%
TOTAL	**5†**	**2***	**$261,181.90**	**$29,020.21**	**2.5**	**100%**

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 08/2024. Last accessed 08/12/2024.
[2] Ionis Pharmaceuticals, Inc. Wainua™ (Eplontersen) Granted Regulatory Approval in the U.S. for the Treatment of Adults with Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis. *PRNewswire*. Available online at: https://www.prnewswire.com/news-releases/wainua-eplontersen-granted-regulatory-approval-in-the-us-for-the-treatment-of-adults-with-polyneuropathy-of-hereditary-transthyretin-mediated-amyloidosis-302021385.html. Issued 12/21/2023. Last accessed 08/12/2024.
[3] BridgeBio Pharma, Inc. BridgeBio Announces Consistently Positive Results from Phase 3 ATTRibute-CM Study of Acoramidis for Patients with Transthyretin Amyloid Cardiomyopathy (ATTR-CM). Available online at: https://bridgebio.com/news/bridgebio-announces-consistently-positive-results-from-phase-3-attribute-cm-study-of-acoramidis-for-patients-with-transthyretin-amyloid-cardiomyopathy-attr-cm/. Issued 07/17/2023. Last accessed 08/12/2024.
[4] BridgeBio Pharma, Inc. BridgeBio Announces U.S. Food and Drug Administration (FDA) Acceptance of New Drug Application (NDA) for Acoramidis for the Treatment of Patients with Transthyretin Amyloid Cardiomyopathy (ATTR-CM). Available online at: https://investor.bridgebio.com/news-releases/news-release-details/bridgebio-pharma-announces-us-food-and-drug-administration-fda. Issued 02/05/2024. Last accessed 08/12/2024.
[5] Regeneron Pharmaceuticals. Investigational Pipeline. Available online at: https://www.regeneron.com/pipeline-medicines/investigational-pipeline. Last accessed 08/12/2024.
[6] Wainua™ (Eplontersen) Prescribing Information. Ionis Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217388s000lbl.pdf. Last revised 12/21/2023. Last accessed 08/12/2024.
[7] Coelho T, Marques Jr. W, Dasgupta NR, et. al. Eplontersen for Hereditary Transthyretin Amyloidosis with Polyneuropathy. *JAMA* 2023; 330(15):1448-1458. doi: 10.1001/jama.2023.18688.

Appendix Q

Calendar Year 2023 Annual Review of Cystic Fibrosis (CF) Medications

Oklahoma Health Care Authority
September 2024

Current Prior Authorization Criteria

Bronchitol® (Mannitol Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members 18 years of age or older; and
    a. Bronchitol® will not require a prior authorization and claims will pay at the point of sale if the adult member has a reported diagnosis of CF within the past 12 months of claims history; and
    b. If the member does not have a reported diagnosis, a manual prior authorization will be required for coverage consideration; and
2. A quantity limit of 560 capsules per 28 days will apply

Cayston® (Aztreonam), Pulmozyme® (Dornase Alfa), and Inhaled Tobramycin Products (Bethkis®, Kitabis® Pak, Tobi®, and Tobi® Podhaler®) Approval Criteria:

1. Use of inhaled tobramycin products, Pulmozyme® (dornase alfa), and Cayston® (aztreonam) is reserved for members who have a diagnosis of cystic fibrosis (CF).
    a. Kitabis® Pak and generic tobramycin 300mg/5mL nebulized solution are the preferred inhaled tobramycin products. Authorization of Bethkis® or Tobi® Podhaler® requires a patient-specific, clinically significant reason why the preferred inhaled tobramycin products (Kitabis® Pak and generic tobramycin 300mg/5mL nebulized solution) are not appropriate for the member.
    b. Preferred inhaled tobramycin products (including Kitabis® Pak, and generic tobramycin 300mg/5mL nebulized solution), dornase alfa, and aztreonam inhalation will not require a prior authorization and claims will pay at the point of sale if member has a reported diagnosis of CF within the past 12 months of claims history.
    c. If the member does not have a reported diagnosis, a manual prior authorization will be required for coverage consideration.
2. Use of inhaled tobramycin products and Cayston® (aztreonam) is restricted to 28 days of therapy per every 56 days to ensure cycles of 28 days on therapy followed by 28 days off therapy.
    a. Use outside of this recommended regimen may be considered for coverage via a manual prior authorization submission with a

patient-specific, clinically significant reason why the member would need treatment outside of the FDA approved dosing.
   b. Pharmacies should process the prescription claim with a 56-day supply.

Kalydeco® (Ivacaftor) Approval Criteria:

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

For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
14. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

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

For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
14. Subsequent approvals will be for the duration of 1 year.

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

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

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

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

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

b. Oral granules: a quantity limit of 2 packets per day or 56 packets per 28 days; and

12. For Trikafta® oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta® tablets cannot be used; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® or Symdeko® to Trikafta®; and
15. Subsequent approvals will be for the duration of 1 year.

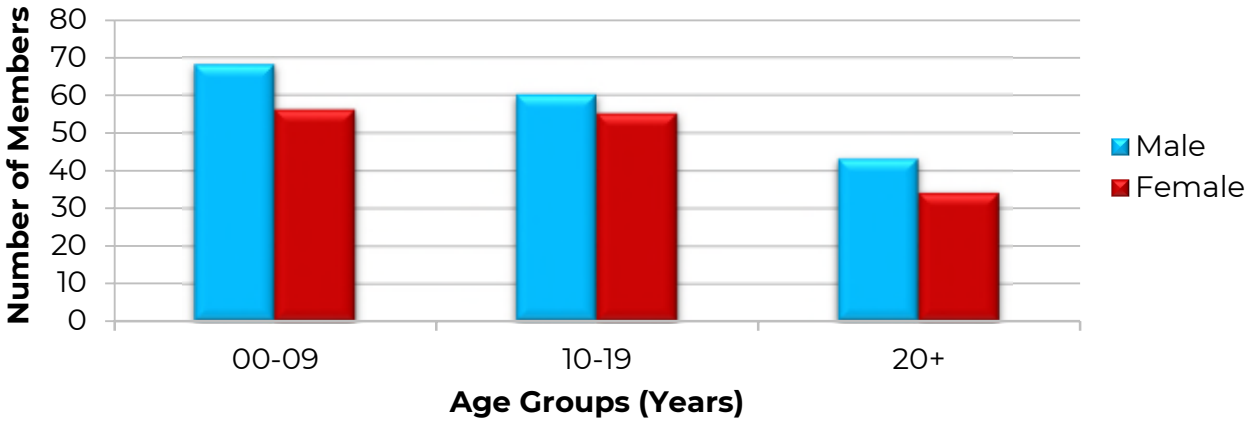
Utilization of CF Medications: Calendar Year 2023

Comparison of Calendar Years

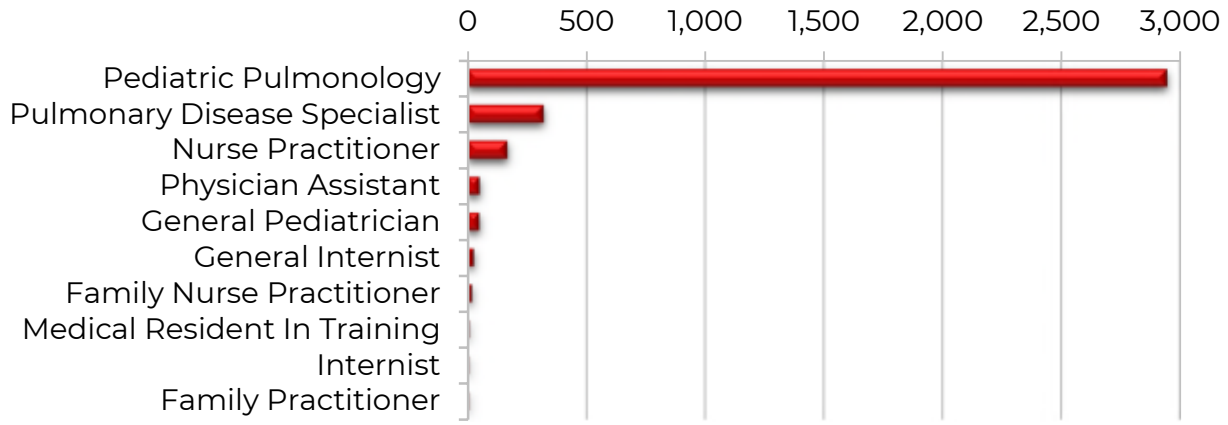
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	307	3,562	$45,075,239.41	$12,654.47	$373.36	389,216	120,729
2023	316	3,620	$49,068,384.60	$13,554.80	$412.82	378,922	118,861
% Change	**2.90%**	**1.60%**	**8.90%**	**7.10%**	**10.60%**	**-2.60%**	**-1.50%**
Change	**9**	**58**	**$3,993,145.19**	**$900.33**	**$39.46**	**-10,294**	**-1,868**

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

Demographics of Members Utilizing CF Medications



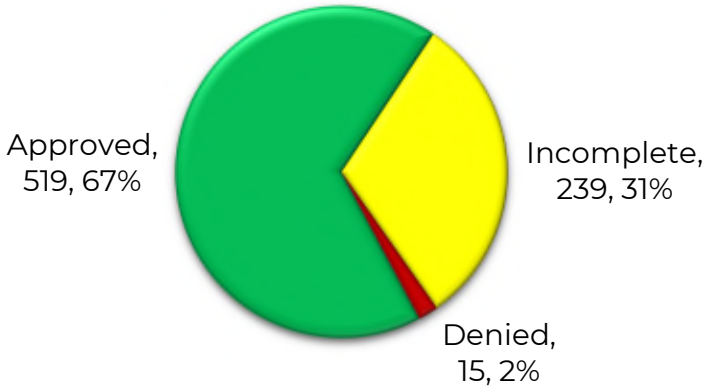
Top Prescriber Specialties of CF Medications by Number of Claims



Prior Authorization of CF Medications

There were 773 prior authorization requests submitted for CF medications during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Kalydeco® (ivacaftor tablets): August 2029
- Tobi® Podhaler® (tobramycin inhalation powder): November 2030
- Orkambi® (lumacaftor/ivacaftor tablets and granules): December 2030
- Kalydeco® (ivacaftor granules): February 2033
- Symdeko® (tezacaftor/ivacaftor and ivacaftor tablets): April 2035
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor tablets and granules): December 2037

Pipeline

- **SPL84:** SPL84 is an investigational short nucleotide that potentially could be used for CF patients with a specific splicing mutation. The short nucleotide ensures the ribonucleic acid (RNA) is cut and stitched correctly to allow a functional CF transmembrane conductance regulator (CFTR) protein to be made. A Phase 2 trial is currently enrolling patients with at least 1 copy of the splicing mutation, and a recent Phase 1a trial showed that SPL84 was safe and well tolerated.
- **Vanzacaftor/Tezacaftor/Deutivacaftor:** Vanzacaftor/tezacaftor/deutivacaftor is an investigational triple therapy that will be given once daily for patients with CF who have certain mutations in the *CFTR* gene. Two Phase 3 trials are currently underway in patients 12 years of age and older that compare vanzacaftor/tezacaftor/deutivacaftor to Trikafta®. Currently, there are also 2 open-label Phase 3 trials for patients down to 2 years of age. Vanzacaftor/tezacaftor/deutivacaftor was granted Fast Track and Orphan Drug designations, and the FDA accepted a New Drug Application (NDA) with a Prescription Drug User Fee Act (PDUFA) date of January 2, 2025.
- **VX-522:** VX-522 is an investigational inhaled messenger RNA (mRNA) therapy that delivers a full-length copy of *CFTR* mRNA to the lungs in order to create a functional CFTR protein. A Phase 2 trial for VX-522 is currently enrolling in patients 18 years of age or older who have mutations that are not responsive to CFTR modulators.

Recommendations

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

Utilization Details of CF Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ELEXACAFTOR/TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS						
TRIKAFTA TAB 100-50-75/150MG	1,128	130	$27,526,664.76	$24,403.07	8.68	56.10%
TRIKAFTA TAB 50-25-37.5/75MG	318	33	$7,974,947.10	$25,078.45	9.64	16.25%
TRIKAFTA PKT 100-50-75/75MG	73	16	$1,659,622.72	$22,734.56	4.56	3.38%
TRIKAFTA PKT 80-40-60/59.5MG	56	10	$1,385,592.92	$24,742.73	5.6	2.82%
SUBTOTAL	**1,575**	**189**	**$38,546,827.50**	**$24,474.18**	**8.33**	**78.56%**
DORNASE ALFA PRODUCTS						
PULMOZYME SOL 1MG/ML	1,385	185	$5,655,389.87	$4,083.31	7.49	11.53%
SUBTOTAL	**1,385**	**185**	**$5,655,389.87**	**$4,083.31**	**7.49**	**11.53%**
TOBRAMYCIN NEBULIZED PRODUCTS						
TOBRAMYCIN NEB 300MG/5ML	375	128	$546,787.38	$1,458.10	2.93	1.11%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TOBRAMYCIN NEB 300MG/4ML	30	12	$132,917.66	$4,430.59	2.5	0.27%
KITABIS PAK NEB 300MG/5ML	4	2	$18,045.64	$4,511.41	2	0.04%
SUBTOTAL	**409**	**142**	**$697,750.68**	**$1,705.99**	**2.88**	**1.42%**
LUMACAFTOR/IVACAFTOR COMBINATION PRODUCTS						
ORKAMBI GRA 100-125MG	65	11	$1,363,059.73	$20,970.15	5.91	2.78%
ORKAMBI GRA 150-188MG	39	6	$682,019.58	$17,487.68	6.5	1.39%
ORKAMBI TAB 100-125MG	5	3	$93,320.19	$18,664.04	1.67	0.19%
ORKAMBI GRA 75-94MG	3	3	$65,867.04	$21,955.68	1	0.13%
SUBTOTAL	**112**	**23**	**$2,204,266.54**	**$19,680.95**	**4.87**	**4.49%**
AZTREONAM PRODUCTS						
CAYSTON INH 75MG	57	16	$644,148.05	$11,300.84	3.56	1.31%
SUBTOTAL	**57**	**16**	**$644,148.05**	**$11,300.84**	**3.56**	**1.31%**
IVACAFTOR PRODUCTS						
KALYDECO PKT 50MG	21	2	$264,142.35	$12,578.21	10.5	0.54%
KALYDECO TAB 150MG	14	3	$351,082.30	$25,077.31	4.67	0.72%
KALYDECO PKT 75MG	6	1	$150,470.70	$25,078.45	6	0.31%
SUBTOTAL	**41**	**6**	**$765,695.35**	**$18,675.50**	**6.83**	**1.56%**
TOBRAMYCIN POWDER PRODUCTS						
TOBI PODHALER CAP 28MG	31	9	$353,045.76	$11,388.57	3.44	0.72%
SUBTOTAL	**31**	**9**	**$353,045.76**	**$11,388.57**	**3.44**	**0.72%**
TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS						
SYMDEKO TAB 100-150/150MG	10	2	$201,260.85	$20,126.09	5	0.41%
SUBTOTAL	**10**	**2**	**$201,260.85**	**$20,126.09**	**5**	**0.41%**
TOTAL	**3,620**	**316***	**$49,068,384.60**	**$13,554.80**	**11.46**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; GRA = granule; INH = inhalation; NEB = nebulized; PKT = packet; SOL = solution; TAB = tablet

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 08/2024. Last accessed 08/09/2024.
[2] Cystic Fibrosis Foundation. SPL84. Available online at: https://apps.cff.org/Trials/Pipeline/details/10208/SPL84. Last accessed 08/09/2024.
[3] Cystic Fibrosis Foundation. Vanzacaftor/Tezacaftor/Deutivacaftor. Available online at: https://apps.cff.org/Trials/Pipeline/details/10166/Vanzacaftor-tezacaftor-deutivacaftor. Last accessed 08/09/2024.
[4] Vertex Pharmaceuticals. Vertex Announces FDA Acceptance of New Drug Application for Vanzacaftor/Tezacaftor/Deutivacaftor, a Next-In-Class Triple Combination Treatment for Cystic Fibrosis. Available online at: https://news.vrtx.com/news-releases/news-release-details/vertex-announces-fda-acceptance-new-drug-application. Issued 07/02/2024. Last accessed 08/26/2024.
[5] Cystic Fibrosis Foundation. VX-522 mRNA. Available online at: https://apps.cff.org/Trials/Pipeline/details/10204/VX-522-mRNA. Last accessed 08/09/2024.

Appendix R

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

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

FDA NEWS RELEASE

For Immediate Release: August 30, 2024

FDA Authorizes Updated Novavax COVID-19 Vaccine to Better Protect Against Currently Circulating Variants

The FDA granted emergency use authorization (EUA) for an updated version of the Novavax COVID-19 vaccine that more closely targets currently circulating variants to provide better protection against serious consequences of COVID-19, including hospitalization and death. The updated vaccine is authorized for use in individuals 12 years of age and older. It includes a monovalent component that corresponds to the Omicron variant JN.1 strain of SARS-CoV-2.

This authorization follows the FDA's recent approvals and authorizations of updated mRNA COVID-19 vaccines for 2024-2025 manufactured by ModernaTX Inc. and Pfizer Inc.

What you need to know:

- Individuals 12 years of age and older who have never been vaccinated with any COVID-19 vaccine are eligible to receive 2 doses of this updated vaccine, 3 weeks apart.
- Individuals who have been vaccinated only with 1 dose of any Novavax COVID-19 vaccine are eligible to receive 1 dose of the updated Novavax COVID-19 vaccine at least 3 weeks after the previous dose.
- Those who have been vaccinated with a prior formula of a COVID-19 vaccine from another manufacturer or with 2 or more doses of a prior formula of the Novavax COVID-19 vaccine are eligible to receive a single dose of the updated Novavax COVID-19 vaccine at least 2 months after the last dose of a COVID-19 vaccine.

The FDA assessed manufacturing and nonclinical data to support the change to the 2024-2025 formula. The updated vaccine is manufactured using a similar process as previous formulas of this vaccine. Individuals who receive this vaccine may experience similar side effects as those reported by individuals who received previous formulas of this COVID-19 vaccine and as described in the fact sheets.

The FDA has determined that the updated Novavax COVID-19 vaccine has met the statutory criteria for issuance of an EUA, including that the known and potential benefits of the vaccine outweigh its known and potential risks in individuals 12 years of age and older.

As part of this action, the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is no longer authorized for use. The FDA granted the EUA of the Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) to Novavax Inc. of Gaithersburg, Maryland.

FDA NEWS RELEASE

For Immediate Release: August 26, 2024

FDA Clears First Device to Enable Automated Insulin Dosing for Individuals with Type 2 Diabetes

The FDA expanded the indications of the Insulet SmartAdjust technology, an interoperable automated glycemic controller previously indicated for the management

of type 1 diabetes in individuals 2 years of age and older, to also include management of type 2 diabetes in individuals 18 years of age and older. An interoperable automated glycemic controller is software that automatically adjusts insulin delivery to a person with diabetes by connecting to an alternate controller-enabled insulin pump (ACE pump) and integrated continuous glucose monitor (iCGM).

Previously, insulin therapy options for people with type 2 diabetes were limited to methods such as injection with a syringe, an insulin pen, or an insulin pump, all of which require patients to self-administer insulin 1 or more times a day and check blood glucose frequently to achieve the best results. Today's clearance provides a new option that can automate many of these manual tasks, potentially reducing the burden of living with this chronic disease.

The FDA reviewed data from a clinical study in which 289 individuals 18 years of age and older with type 2 diabetes on insulin used the Insulet SmartAdjust technology for 13 weeks. This study enrolled a diverse group of patients from different racial and ethnic backgrounds, with a wide range of ages, education, and income levels. Study participants had varying amounts of experience with diabetes and insulin use, and many subjects were also using common non-insulin diabetes medications like glucagon-like peptide 1 (GLP1) agonists. Overall, the study showed that patients' blood sugar control improved compared to before the study and these improvements were seen across all demographic groups. There were no complications or serious adverse events related to the use of the SmartAdjust technology. Adverse events reported during the study were generally mild to moderate, and included hyperglycemia, hypoglycemia, and skin irritation.

FDA NEWS RELEASE

For Immediate Release: August 22, 2024

FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants

The FDA approved and granted emergency use authorization (EUA) for updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2. The mRNA COVID-19 vaccines have been updated with this formula to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death. Today's actions relate to updated mRNA COVID-19 vaccines manufactured by ModernaTX Inc. and Pfizer Inc.

In early June, the FDA advised manufacturers of licensed and authorized COVID-19 vaccines that the COVID-19 vaccines (2024-2025 formula) should be monovalent JN.1 vaccines. Based on the further evolution of SARS-CoV-2 and a rise in cases of COVID-19, the FDA subsequently determined and advised manufacturers that the preferred JN.1-lineage for the COVID-19 vaccines (2024-2025 formula) is the KP.2 strain, if feasible.

The updated mRNA COVID-19 vaccines include Comirnaty® and Spikevax®, both of which are approved for individuals 12 years of age and older, and the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, both of which are authorized for emergency use for individuals 6 months through 11 years of age.

What you need to know:

- Unvaccinated individuals 6 months through 4 years of age are eligible to receive 3 doses of the updated, authorized Pfizer-BioNTech COVID-19 Vaccine or 2 doses of the updated, authorized Moderna COVID-19 Vaccine.

- Individuals 6 months through 4 years of age who have previously been vaccinated against COVID-19 are eligible to receive 1 or 2 doses of the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
- Individuals 5 years through 11 years of age regardless of previous vaccination are eligible to receive a single dose of the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines; if previously vaccinated, the dose is administered at least 2 months after the last dose of any COVID-19 vaccine.
- Individuals 12 years of age and older are eligible to receive a single dose of the updated, approved Comirnaty® or the updated, approved Spikevax®; if previously vaccinated, the dose is administered at least 2 months since the last dose of any COVID-19 vaccine.
- Additional doses are authorized for certain immunocompromised individuals ages 6 months through 11 years of age as described in the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine fact sheets.

Individuals who receive an updated mRNA COVID-19 vaccine may experience similar side effects as those reported by individuals who previously received mRNA COVID-19 vaccines and as described in the respective prescribing information or fact sheets. The updated vaccines are expected to provide protection against COVID-19 caused by the currently circulating variants. Barring the emergence of a markedly more infectious variant of SARS-CoV-2, the FDA anticipates that the composition of COVID-19 vaccines will need to be assessed annually, as occurs for seasonal influenza vaccines.

For today's approvals and authorizations of the mRNA COVID-19 vaccines, the FDA assessed manufacturing and nonclinical data to support the change to include the 2024-2025 formula in the mRNA COVID-19 vaccines. The updated mRNA vaccines are manufactured using a similar process as previous formulas of these vaccines. The mRNA COVID-19 vaccines have been administered to hundreds of millions of people in the United States, and the benefits of these vaccines continue to outweigh their risks.

On an ongoing basis, the FDA will review any additional COVID-19 vaccine applications submitted and take appropriate regulatory action.

The approval of Comirnaty® (COVID-19 Vaccine, mRNA) (2024-2025 Formula) was granted to BioNTech Manufacturing GmbH. The EUA amendment for the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) was issued to Pfizer Inc. The approval of Spikevax® (COVID-19 Vaccine, mRNA) (2024-2025 Formula) was granted to ModernaTX Inc. and the EUA amendment for the Moderna COVID-19 Vaccine (2024-2025 Formula) was issued to ModernaTX Inc.

FDA NEWS RELEASE

For Immediate Release: August 9, 2024

FDA Approves First Nasal Spray for Treatment of Anaphylaxis

The FDA approved neffy® (epinephrine nasal spray) for the emergency treatment of allergic reactions (Type I), including anaphylaxis, in adult and pediatric patients who weigh ≥30kg.

Allergic reactions happen when a person's immune system reacts abnormally to a substance that normally does not cause symptoms. Anaphylaxis is a severe, life-threatening allergic reaction that typically involves multiple parts of the body and is considered a medical emergency. Common allergens that can induce anaphylaxis include certain foods, medications, and insect stings. Symptoms usually occur within

minutes of exposure and include, but are not limited to, hives, swelling, itching, vomiting, difficulty breathing, and loss of consciousness. Epinephrine is the only life-saving treatment for anaphylaxis and has previously only been available for patients as an injection.

The approval of neffy® is based on 4 studies in 175 healthy adults, without anaphylaxis, that measured the epinephrine concentrations in the blood following administration of neffy® or approved epinephrine injection products. Results from these studies showed comparable epinephrine blood concentrations between neffy® and approved epinephrine injection products. Neffy® also demonstrated similar increases in blood pressure and heart rate as epinephrine injection products, 2 critical effects of epinephrine in the treatment of anaphylaxis. A study of neffy® in children weighing >66lbs showed that epinephrine concentrations in children were similar to adults who received neffy®.

Neffy® is a single-dose nasal spray administered into 1 nostril. As with epinephrine injection products, a second dose (using a new nasal spray to administer neffy® in the same nostril) may be given if there is no improvement in symptoms or symptoms worsen. Patients may need to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

Neffy® comes with a warning that certain nasal conditions, such as nasal polyps or a history of nasal surgery, may affect absorption of neffy®, and patients with these conditions should consult with a health care professional to consider use of an injectable epinephrine product. Neffy® also comes with warnings and precautions about use of epinephrine by people with certain coexisting conditions and allergic reactions associated with sulfite.

The most common side effects of neffy® include throat irritation, intranasal paresthesia, headache, nasal discomfort, feeling jittery, paresthesia, fatigue, tremor, rhinorrhea, nasal pruritus, sneezing, abdominal pain, gingival pain, oral hypoesthesia, nasal congestion, dizziness, nausea, and vomiting.

The FDA granted neffy® Fast Track designation for this application. The FDA granted the approval of neffy® to ARS Pharmaceuticals.

FDA NEWS RELEASE

For Immediate Release: August 7, 2024

FDA Approves First Nalmefene Hydrochloride Auto-Injector to Reverse Opioid Overdose

The FDA approved Zurnai™, the first nalmefene hydrochloride auto-injector for the emergency treatment of known or suspected opioid overdose in adults and pediatric patients 12 years of age and older. The FDA approved the first nasal spray formulation of nalmefene in May 2023.

Drug overdose persists as a major public health issue in the United States, with more than 107,000 reported fatal overdoses occurring in 2023, primarily driven by synthetic opioids like illicit fentanyl. Nalmefene and naloxone are 2 available options to reverse opioid overdose. The FDA has worked to increase availability and accessibility of both options to encourage harm reduction and reduce overdose death.

Nalmefene is an opioid receptor antagonist which is used to treat acute opioid overdose. If nalmefene is administered quickly, it can reverse the effects of opioid overdose, including respiratory depression, sedation, and hypotension. The newly approved product delivers 1.5mg of nalmefene through subcutaneous or intramuscular injection. Zurnai™ is a single-dose, pre-filled auto-injector and is available only by prescription.

The approval of Zurnai™ is supported by safety and pharmacokinetic studies, as well as a study in healthy individuals who use opioids recreationally, to assess how quickly the product works. The most common adverse reactions are feeling hot, dizziness, nausea, headache, chills, vomiting, allodynia, palpitations, tinnitus, ear discomfort, feeling abnormal, burning sensation, hot flush, and irritability.

The use of nalmefene hydrochloride in patients who are opioid-dependent may result in opioid withdrawal characterized by the following signs and symptoms: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

The FDA granted this application Fast Track and Priority Review designations. The FDA granted approval of Zurnai™ to Purdue Pharma L.P.

Current Drug Shortages Index (as of August 29, 2024):

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

Albuterol Sulfate Solution	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection, Syringes	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***

Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Indocyanine Green Injection	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Mefloquine Hydrochloride Tablet	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
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***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***
Vitamin A Palmitate Injection	***Currently in Shortage***