OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, August 14, 2024

No live meeting scheduled for August.
August 2024 will be a packet-only meeting.

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

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 – August 14, 2024

DATE: August 7, 2024

NOTE: **No live August meeting. August 2024 is a packet-only meeting.**

Enclosed are the following items related to the August packet meeting. Material is arranged in order of the agenda.

DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit/U.S. Food and Drug Administration (FDA) Safety Alerts – Appendix B

Annual Review of Wilson's Disease Medications and 30-Day Notice to Prior Authorize Penicillamine 250mg Tablet and Trientine 500mg Capsule – Appendix C

Annual Review of Corticosteroid Special Formulations and 30-Day Notice to Prior Authorize Eohilia™ (Budesonide Oral Suspension) – Appendix D

Annual Review of Iron Products and 30-Day Notice to Prior Authorize Accrufer® (Ferric Maltol) – Appendix E

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

Annual Review of Topical Corticosteroids – Appendix G

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) – Appendix H

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Packet Meeting – August 14, 2024

NOTE: ***No live August meeting. August 2024 is a packet-only meeting.***

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **DUR Board Meeting Minutes – See Appendix A**
   A. July 10, 2024 DUR Board Meeting Minutes
   B. July 10, 2024 DUR Board Recommendations Memorandum

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

2. **Update on Medication Coverage Authorization Unit/U.S. Food and Drug Administration (FDA) Safety Alerts – See Appendix B**
   A. Pharmacy Help Desk Activity for July 2024
   B. Medication Coverage Activity for July 2024
   C. FDA Safety Alerts

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

3. **Annual Review of Wilson's Disease Medications and 30-Day Notice to Prior Authorize Penicillamine 250mg Tablet and Trientine Hydrochloride 500mg Capsule – See Appendix C**
   A. Current Prior Authorization Criteria
   B. Utilization of Wilson's Disease Medications
   C. Prior Authorization of Wilson's Disease Medications
   D. Market News and Updates
   E. Cost Comparisons
   F. College of Pharmacy Recommendations

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

4. **Annual Review of Corticosteroid Special Formulations and 30-Day Notice to Prior Authorize Eohilia™ (Budesonide Oral Suspension) – See Appendix D**
   A. Current Prior Authorization Criteria
   B. Utilization of Corticosteroid Special Formulations
   C. Prior Authorization of Corticosteroid Special Formulations
   D. Market News and Updates
   E. Eohilia™ (Budesonide Oral Suspension) Product Summary
   F. Cost Comparison
   G. College of Pharmacy Recommendations
   H. Utilization Details of Corticosteroid Special Formulations

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

5. **Annual Review of Iron Products and 30-Day Notice to Prior Authorize Accrufer® (Ferric Maltol) – See Appendix E**
   A. Current Prior Authorization Criteria
   B. Utilization of Iron Products
   C. Prior Authorization of Iron Products
   D. Market News and Updates
   E. Accrufer® (Ferric Maltol) Product Summary
   F. Cost Comparison: Intravenous (IV) Iron Products
   G. College of Pharmacy Recommendations
   H. Utilization Details of Iron Products

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

6. **Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Tramadol 25mg Tablet – See Appendix F**
   A. Current Prior Authorization Criteria
   B. Utilization of Opioid Analgesics and MAT Medications
   C. Prior Authorization of Opioid Analgesics and MAT Medications
   D. Market News and Updates
   E. Cost Comparison: Tramadol
   F. College of Pharmacy Recommendations
   G. Utilization Details of Opioid Analgesics and MAT Medications

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

7. **Annual Review of Topical Corticosteroids – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Topical Corticosteroids
   C. Prior Authorization of Topical Corticosteroids
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of Topical Corticosteroids

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

8. **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) – See Appendix H**
   A. Current Prior Authorization Criteria
   B. Utilization of Various Systemic Antibiotics
   C. Prior Authorization of Various Systemic Antibiotics
   D. Market News and Updates

E. Product Summaries
F. Cost Comparisons
G. College of Pharmacy Recommendations
H. Utilization Details of Various Systemic Antibiotics

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

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

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

10. **Future Business* (Upcoming Product and Class Reviews)**
    A. Allergen Immunotherapies
    B. Amyloidosis Medications
    C. Breast Cancer Medications
    D. Cystic Fibrosis Medications
    *Future product and class reviews subject to change.

11. **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: July 11, 2024

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

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

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

Recommendation 1: Chronic Medication Adherence (CMA) Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Rezdiffra™ (Resmetirom)

MOTION CARRIED by unanimous approval.

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

Rezdiffra™ (Resmetirom) Approval Criteria:

1. An FDA approved indication of noncirrhotic nonalcoholic steatohepatitis (NASH); and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following (results of the selected test must be submitted with the request):
   a. FibroScan with vibration controlled transient elastography (VCTE) ≥8.5kPa and controlled attenuation parameter (CAP) ≥280dB/m; or
   b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
   c. Liver biopsy showing stage F2 or F3 fibrosis with NASH; and
4. Member must not have known liver cirrhosis (e.g., stage F4); and

5. Must be used in conjunction with diet and exercise [clinical documentation (e.g., office notes) of member's diet and exercise program must be included with the request]; and
6. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
   a. Type 2 diabetes; and
   b. Dyslipidemia; and
   c. Hypertension; and
7. Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra™; and
8. If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra™, prescriber must agree to reduce the dose as required in the package labeling; and
9. If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and
10. Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
11. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber documents the member is tolerating and responding well to the medication; and
12. A quantity limit of 30 tablets per 30 days will apply.

Recommendation 3: Vote to Prior Authorize Risvan® [Risperidone Intramuscular (IM) Injection] and Update the Approval Criteria for the Atypical Antipsychotic Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following Tier chart and criteria):

1. Prior authorization of Risvan® (risperidone IM injection), placement into Tier-3, and the current Long-Acting Injectable (LAI) Tier-3 criteria will apply; and
2. Updating the Tier-2, Tier-3, Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD), and LAI Products Tier-3 approval criteria to be consistent with clinical practice.

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	aripiprazole tablets with sensor (Abilify MyCite®)~

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

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

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

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. Clozapine does not count towards a Tier-1 trial; and
2. Members currently stable on a Tier-2 medication may be approved for continuation of therapy.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

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

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

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

2. Members currently stable on the requested medication may be approved for continuation of therapy; and
3. Tier structure rules still apply.

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

1. Use of LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower tiered LAI products available for the medication being requested, which are available without a prior authorization; and
2. Members currently stable on the requested medication may be approved for continuation of therapy.

Recommendation 4: 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

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of baclofen 15mg tablet, Ozobax® DS 10mg/5mL [baclofen double strength (DS) oral solution], and chlorzoxazone 250mg tablet with placement into the Special Prior Authorization (PA) Tier of the Muscle Relaxant Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone (Skelaxin®)	baclofen 5mg**, 15mg**
chlorzoxazone 500mg (Parafon Forte®)		baclofen oral granules (Lyvispah®)
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		**baclofen 10mg/5mL oral soln (Ozobax® DS)**
orphenadrine (Norflex®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
tizanidine tabs (Zanaflex®)		carisoprodol 250mg (Soma®)
		carisoprodol 350mg (Soma®)

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
		carisoprodol/ASA
		carisoprodol/ASA/codeine
		chlorzoxazone **250mg,** 375mg, 750mg
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		tizanidine caps (Zanaflex®)

*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).
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets

Baclofen 5mg Tablet and Baclofen 15mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a baclofen 10mg tablet to achieve a 5mg or 15mg dose must be provided.

Fleqsuvy® (Baclofen 25mg/5mL Oral Suspension), Lyvispah® (Baclofen Oral Granules), ~~and~~ Ozobax® (Baclofen 5mg/5mL Oral Solution), and Ozobax® DS [Baclofen Double Strength (DS) 10mg/5mL Oral Solution] Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Requests for Fleqsuvy®, ~~and~~ Ozobax®, or Ozobax® DS will require a patient-specific, clinically significant reason why the member cannot use Lyvispah®; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Chlorzoxazone 250mg Tablet Approval Criteria:

1. A patient-specific, clinically specific reason why the member cannot split a 500mg chlorzoxazone tablet to achieve the 250mg dose must be provided.

The College of Pharmacy recommends the prior authorization of Clindacin® ETZ Kit (clindamycin 1% swabs and cleanser) with the following criteria (shown in red):

Clindacin® ETZ Kit (Clindamycin 1% Swabs and Cleanser) Approval Criteria:

1. An FDA approved diagnosis; and

2. A patient specific, clinically significant reason the member cannot use the preferred topical clindamycin products including lotion, solution, swabs, or the preferred generic clindamycin gel (generic Cleocin T®) must be provided; and
3. Clindacin® ETZ kit will not be covered for members older than 20 years of age.

The College of Pharmacy recommends the prior authorization of Combogesic® IV (ibuprofen/acetaminophen injection) and Elyxyb™ (celecoxib oral solution) with placement into the Special PA Tier of the NSAIDs PBPA category with the following additional criteria (shown in red):

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) 50mg, 100mg, & 200mg caps	diclofenac ER (Voltaren® XR)	celecoxib (Celebrex®) 400mg caps
diclofenac epolamine (Flector® Patch) – **Brand Preferred**	diclofenac potassium (Cataflam®)	**celecoxib (Elyxyb™) oral soln**
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac (Zorvolex®)
diclofenac sodium 1% (Voltaren® Gel)	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac epolamine (Licart®) topical system
etodolac (Lodine®) 400mg & 500mg tabs	etodolac (Lodine®) 200mg & 300mg caps	diclofenac potassium (Cambia®) powder pack
flurbiprofen (Ansaid®)	etodolac ER (Lodine® XL)	diclofenac potassium (Lofena™) tabs
ibuprofen (Motrin®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	diclofenac potassium (Zipsor®) caps
meloxicam (Mobic®)	oxaprozin (Daypro®)	diclofenac sodium (Dyloject™) inj
nabumetone (Relafen®)	piroxicam (Feldene®)	diclofenac sodium (Pennsaid®) topical drops
naproxen* (Naprosyn®)	tolmetin (Tolectin®)	fenoprofen (Nalfon®)
naproxen EC (Naprosyn®)		ibuprofen (Caldolor®) inj
sulindac (Clinoril®)		**ibuprofen/APAP (Combogesic® IV) inj+**
		ibuprofen/famotidine (Duexis®)
		indomethacin (Indocin®) susp & ER caps
		indomethacin (Tivorbex®)
		ketoprofen (Orudis®) caps
		ketoprofen ER (Oruvail®)

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
		ketorolac tromethamine (Sprix®) nasal spray
		meclofenamate (Meclomen®)
		mefenamic acid (Ponstel®)
		meloxicam (Anjeso®) inj+
		meloxicam (Vivlodex®) caps
		meloxicam ODT (Qmiiz ODT™)
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
APAP = acetaminophen; caps = capsules; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets
+Unique criteria applies

Combogesic® IV (Ibuprofen/Acetaminophen Injection) Approval Criteria:

1. An FDA approved indication in members where an intravenous (IV) route of administration is considered clinically necessary for 1 of the following:
   a. Relief of mild-to-moderate pain; or
   b. Management of moderate-to-severe pain as an adjunct to opioid analgesics; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member requires IV administration and cannot use Tier-1 oral and/or topical alternatives must be provided; and
4. A quantity limit of 2,000mL (20 vials) per 5 days will apply; and
5. A maximum approval duration of 5 days will apply, as Combogesic® IV is only indicated for short-term use of 5 days or less.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and

4. Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose; and
5. Additionally, use of Elyxyb™ (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
6. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products; and
7. Additionally, use of Tivorbex® will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.

The College of Pharmacy recommends the prior authorization of Ingrezza® Sprinkle (valbenazine) with criteria similar to Ingrezza® (valbenazine) with the following additional criteria based on net cost and to be consistent with clinical practice (changes shown in red):

Ingrezza® (Valbenazine) and Ingrezza® Sprinkle (Valbenazine) Approval Criteria [Huntington's Disease Diagnosis]

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
5. Use of Ingrezza® Sprinkle will require a patient-specific, clinically significant reason why the member cannot use Ingrezza®; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting valbenazine therapy and throughout treatment; and
7. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
8. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
9. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
10. Member must not be taking monoamine oxidase inhibitors (MAOIs) in the last 14 days; and

11. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
12. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
13. Member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
14. Female members must not be pregnant or breastfeeding; and
15. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
16. Prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
17. A quantity limit of 1 capsule per day will apply; and
18. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased, and the member is not showing worsening signs of depression.

Ingrezza® (Valbenazine) and Ingrezza® Sprinkle (Valbenazine) Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
   a. Involuntary athetoid or choreiform movements; and
   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist, or a mid-level practitioner with a supervising physician that is a neurologist or psychiatrist; and
4. Use of Ingrezza® Sprinkle will require a patient-specific, clinically significant reason why the member cannot use Ingrezza®; and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
6. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
7. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
8. Member must not be taking monoamine oxidase inhibitors (MAOIs) in the last 14 days; and
9. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and

10. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
11. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
12. Female members must not be pregnant or breastfeeding; and
13. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
14. Prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
15. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
16. A quantity limit of 1 capsule per day will apply; and
17. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

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

Lodoco® (Colchicine) Approval Criteria:

1. An FDA approved indication to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death; and
2. Member must be 18 years of age or older; and
3. Member must have a diagnosis history of clinical atherosclerotic cardiovascular disease (ASCVD); and
    a. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD must be provided; and
4. Member must already be receiving guideline-directed therapy for atherosclerotic disease, as documented in the member's pharmacy claims history, unless contraindicated; and
5. Lodoco® must be prescribed by a cardiologist or other specialist with expertise in the treatment and management of ASCVD; and
6. Member must not have kidney failure, severe liver disease, or pre-existing blood dyscrasias; and
7. The member must not be taking any P-gp inhibitors (e.g., cyclosporine, ranolazine) or strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole) concurrently with Lodoco®; and
8. A patient-specific, clinically significant reason why the member cannot use the 0.6mg tablet, which is available without a prior authorization, must be provided; and
9. A quantity limit of 30 tablets per 30 days will apply.

Additionally, the College of Pharmacy recommends removing the prior authorization of Colcrys® (colchicine tablet) based on net cost (changes shown in red):

~~Colcrys® (Colchicine Tablet),~~ Gloperba® (Colchicine Oral Solution)~~,~~ and Mitigare® (Colchicine Capsule) Approval Criteria:

1. A quantity of 6 ~~tablets/~~capsules for a 3-day supply is available without prior authorization for treatment of acute gouty attacks; and
2. Failure of allopurinol after 6 months of treatment defined by persistent gouty attacks with serum urate levels greater than 6.0mg/dL; and
3. A patient-specific, clinically significant reason why colchicine tablets (generic Colcrys®) or colchicine/probenecid would not be a viable option for the member must be provided; and
4. For authorization of Gloperba, a patient-specific, clinically significant reason why the member cannot use colchicine tablets or capsules must be provided; and
5. A quantity limit of 60 ~~tablets/~~capsules per 30 days or 300mL per 30 days will apply for gout; and
6. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

The College of Pharmacy recommends the prior authorization of Millipred™ (prednisolone) tablet with the following criteria, which includes the addition of methylprednisolone and alternative corticosteroids available without a prior authorization per the DUR Board's recommendation (shown in red):

Millipred™ (Prednisolone 5mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use prednisone 5mg tablets, methylprednisolone 4mg tablets, or alternative oral corticosteroids that available without a prior authorization must be provided.

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

Motpoly XR™ [Lacosamide Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must weigh ≥50kg; and
3. A patient specific, clinically significant reason why the member cannot use the immediate-release tablets must be provided; and
4. The following quantity limits will apply:
    a. Motpoly XR™ 100mg: 30 capsules per 30 days; or
    b. Motpoly XR™ 150mg and 200mg: 60 capsules per 30 days.

The College of Pharmacy recommends the prior authorization of Neo-Synalar® (neomycin 0.5%/fluocinolone 0.025% cream) with placement into

Tier-2 of the Topical Antibiotic Products PBPA category with the following additional criteria (shown in red):

Topical Antibiotic Products*	
Tier-1	**Tier-2**
gentamicin 0.1% cream (Garamycin®)	mupirocin 2% cream (Bactroban®)
gentamicin 0.1% ointment (Garamycin®)	mupirocin 2% kit (Centany®)
gentamicin powder	mupirocin 2% nasal ointment (Bactroban®)
mupirocin 2% ointment (Bactroban®)	**neomycin 0.5%/fluocinolone 0.025% cream (Neo-Synalar®)†**
	ozenoxacin 1% cream (Xepi®)
	retapamulin ointment 2% (Altabax®)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†Unique criteria applies

Neo-Synalar® (Neomycin 0.5%/Fluocinolone 0.025% Cream) Approval Criteria:

1. An FDA approved diagnosis of corticosteroid-responsive dermatoses with secondary infection; and
2. A patient specific, clinically significant reason why the member cannot use a Tier-1 topical antibiotic in combination with a Tier-1 medium to very-high potency topical corticosteroid must be provided; and
3. Approvals will be for 1 tube for the duration of 7 days.

The College of Pharmacy recommends the prior authorization of PoKonza™ (potassium chloride 10mEq packet) with criteria similar to Klor-Con® (potassium chloride 20mEq packet) and updating the criteria as follows (changes shown in red):

Klor-Con® (Potassium Chloride 20mEq Packet) and PoKonza™ (Potassium Chloride 10mEq Packet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all of the following must be provided:
   a. Potassium chloride tablet; and
   b. Potassium chloride extended-release (ER) dispersible tablet; and
   c. Potassium chloride ER sprinkle capsule; and
   d. Potassium chloride oral solution.

The College of Pharmacy recommends the prior authorization of Suflave® (PEG-3350/sodium sulfate/potassium chloride/magnesium sulfate/sodium chloride) with criteria similar to the other bowel preparation medications (changes shown in red):

Clenpiq®, ColPrep™ Kit, OsmoPrep®, Plenvu®, Prepopik®, Suflave®, SUPREP®, and Sutab® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use other bowel preparation medications available without prior authorization must be provided; and
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, Moviprep® is available without prior authorization. Other medications currently available without a prior authorization include: Colyte®, Gavilyte®, Golytely®, and Trilyte®.

The College of Pharmacy recommends the prior authorization of valsartan 4mg/mL oral solution with placement into Tier-3 of the ARBs and ARB Combination Products PBPA category with the following additional criteria (shown in red):

Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**Special PA**
candesartan (Atacand®)+	candesartan 32mg (Atacand®)	azilsartan (Edarbi®)
irbesartan (Avapro®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	azilsartan/chlorthalidone (Edarbyclor®)
irbesartan/HCTZ (Avalide®)	telmisartan/HCTZ (Micardis® HCT)	candesartan/HCTZ (Atacand® HCT)
losartan (Cozaar®)		eprosartan (Teveten®)
losartan/HCTZ (Hyzaar®)		eprosartan/HCTZ (Teveten® HCT)
olmesartan (Benicar®)		telmisartan/amlodipine (Twynsta®)
olmesartan/amlodipine (Azor®)		**valsartan 4mg/mL oral solution**
olmesartan/HCTZ (Benicar HCT®)		
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
valsartan/amlodipine/HCTZ (Exforge® HCT)		
valsartan/HCTZ (Diovan HCT®)		

HCTZ = hydrochlorothiazide

Valsartan 4mg/mL Oral Solution Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Hypertension in adults and pediatric members 6 years of age and older; or

b. Heart failure; or
c. Post-myocardial infarction; and
2. A patient specific, clinically significant, reason why the member cannot use valsartan tablets must be provided; and
3. A quantity limit of 360mL per 36 days will apply.

The College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for RediTrex® due to product discontinuation and recommends updating the following criteria based on net cost (shown in red):

Otrexup®~~, and~~ Rasuvo®~~, and RediTrex®~~ (Methotrexate Injection Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Severe, active rheumatoid arthritis (RA) in adult members; or
   b. Active polyarticular juvenile idiopathic arthritis (pJIA) in pediatric members; or
   c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
2. A patient-specific, clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.~~; and~~
~~3. Authorization of Otrexup® will also require a patient-specific, clinically significant reason why the member cannot use Rasuvo® or RediTrex®.~~

Recommendation 5: Vote to Prior Authorize Qalsody® (Tofersen) and Rilutek® (Riluzole Oral Tablet) and Update the Approval Criteria for the Amyotrophic Lateral Sclerosis (ALS) Medications

MOTION CARRIED by unanimous approval.

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

Qalsody® (Tofersen) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must have a confirmed pathogenic mutation in the superoxide dismutase 1 (SOD1) gene (results of genetic testing must be submitted); and
3. Member must have weakness attributable to ALS; and
4. Member must be 18 years of age or older; and
5. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and
6. Must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and

a. Qalsody® must be shipped to the facility where the member is scheduled to receive treatment; and

7. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression.

Next, the College of Pharmacy recommends the prior authorization of Rilutek® (riluzole oral tablet) to ensure safe and appropriate use with the following criteria (shown in red):

Rilutek® (Riluzole Oral Tablet) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and
3. A quantity limit of 60 tablets per 30 days will apply.

Lastly, the College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for Relyvrio™ (sodium phenylbutyrate/taurursodiol) based on the planned withdrawal of the medication from the market (changes noted in red):

~~**Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Approval Criteria:**~~

~~1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and~~
~~2. Member must be 18 years of age or older; and~~
~~3. Disease duration of 18 months or less (for initial approval); or~~
~~a. A prior authorization request with patient-specific information may be submitted for consideration of Relyvrio™ for members with disease duration >18 months, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and~~
~~4. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and~~
~~5. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression; and~~
~~6. A quantity limit of 56 packets per 28 days will apply.~~

Recommendation 6: 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

MOTION CARRIED by unanimous approval.

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

Liqrev® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A patient-specific, clinically significant reason why the member cannot use generic sildenafil 20mg oral tablets, even when tablets are crushed, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension (generic Revatio®) must be provided.

The College of Pharmacy also recommends the prior authorization of Opsynvi® (macitentan/tadalafil) with criteria similar to Opsumit® (macitentan) and based on net costs (changes shown in red):

Opsumit® (Macitentan) and Opsynvi® (Macitentan/Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Requests for Opsynvi® will also require a patient-specific, clinically significant reason why the member cannot use Opsumit® in combination with generic sildenafil or tadalafil; and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program or the Macitentan-Containing Products REMS program; and
6. A quantity limit of 30 tablets per 30 days will apply.

Next, the College of Pharmacy recommends the prior authorization of Winrevair™ (sotatercept-csrk) with the following criteria (shown in red):

Winrevair™ (Sotatercept-csrk) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Member is currently taking PAH medications from at least 2 of the following categories for ≥90 days or has a contraindication to use of all alternatives:
    a. Phosphodiesterase-5 (PDE-5) inhibitor (e.g., sildenafil, tadalafil) or soluble guanylate cyclase stimulator (e.g., riociguat); or
    b. Endothelin-receptor antagonist (e.g., ambrisentan, bosentan); or
    c. Prostacyclin analogue or receptor agonist (e.g., epoprostenol, treprostinil); and
4. Prescriber must verify that Winrevair™ will be used concurrently with member's current PAH therapies; and
5. Medical supervision by a pulmonary specialist and/or cardiologist; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the preparation, subcutaneous (sub-Q) administration, and proper storage of Winrevair™; and
7. Prescriber must agree to monitor hemoglobin and platelet counts prior to each dose for the first 5 doses and periodically thereafter; and
8. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during therapy and for at least 4 months after the last dose; and
9. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. A quantity limit of 1 kit every 3 weeks will apply.
    a. Members requiring (2) 45mg or (2) 60mg vials based on their body weight will not be approved for multiple 1-vial kits but should use the 2-vial kits to achieve the dose required.

Finally, the College of Pharmacy recommends the following changes to the Adcirca® (tadalafil), Adempas® (riociguat), Orenitram® (treprostinil), Tadliq® (tadalafil oral suspension), Tyvaso DPI® (treprostinil powder for inhalation), and Uptravi® (selexipag) criteria to be consistent with clinical practice, which includes the removal of the Orenitram® trial from the Uptravi® approval criteria per the DUR Board's recommendation (changes shown in red):

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; or

4. A clinical exception for use as initial combination therapy with Letairis® (ambrisentan) applies; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 60 tablets per 30 days will apply.

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of pulmonary arterial hypertension must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
        i. Adcirca® (tadalafil) or Revatio® (sildenafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and
4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonia (PH-IIP); and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® Risk Evaluation and Mitigation Strategy (REMS) program; and
6. Members who are stabilized inpatient and who have a PAH or CTEPH diagnosis will be approved for continuation of therapy; and
7. A quantity limit of 90 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must have previous failed trials of at least 1 medication in each of the following categories or have a contraindication to use of all alternatives:
    a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
5. A quantity limit of 180 tablets per 30 days will apply.

Tadliq® (Tadalafil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Medical supervision by a pulmonary specialist or cardiologist; and

3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension must be provided; and
4. An age restriction will apply. The oral suspension formulation may be approvable for members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member cannot use generic tadalafil 20mg oral tablets, even when the tablets are crushed; and
5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 300mL per 30 days (2 bottles) will apply.

Tyvaso DPI® (Treprostinil Powder for Inhalation) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Pulmonary arterial hypertension (PAH); or
    b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and
        i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. For a diagnosis of PAH:
    a. Member must have previous failed trials of at least 1 of each of the following categories or have a contraindication to use of all alternatives:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. A patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and
4. For a diagnosis of PH-ILD, a patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension (PAH); and
2. Member must be 18 years of age or older; and
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination) or have a contraindication to use of all alternatives:
    a. Adcirca® (tadalafil), Adempas® (riociguat), or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    ~~c. Orenitram® (treprostinil); and~~
4. Medical supervision by a pulmonary specialist or cardiologist; and

5. Members who are stabilized inpatient and who have a PAH diagnosis will be approved for continuation of therapy; and
6. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

Recommendation 7: Vote to Prior Authorize Akeega® (Niraparib/ Abiraterone) and Anktiva® (Nogapendekin Alfa Inbakicept-pmln) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications

MOTION CARRIED by unanimous approval.

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

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

1. Diagnosis of metastatic CRPC; and
2. Presence of deleterious or suspected deleterious BRCA mutation based upon an FDA-approved test; and
3. Used in conjunction with prednisone; and
4. Used in conjunction with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

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

1. Diagnosis of NMIBC with carcinoma in situ (CIS); and
2. Cancer is unresponsive to initial Bacillus Calmette-Guerin (BCG) therapy; and
3. Will be used in conjunction with BCG; and
4. Initial approval will be for 6 induction doses; and
5. Subsequent requests must indicate if the member has had a complete response to induction dosing; and
    a. A second induction course (6 doses) may be approved if a complete response is not achieved at month 3; and
6. If complete response is achieved, maintenance dosing may be approved in 6-month intervals up to a maximum of 37 months of treatment.

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

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

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and

2. Tumor positive for ~~*FGFR2 or*~~ *FGFR3* genetic mutation; and
3. Disease has progressed on or after at least 1 line of systemic therapy; and
    a. Member has received prior treatment with a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor.

~~4. Use in second-line or greater treatments including:~~
    ~~a. Following at least 1 line of platinum-containing chemotherapy; and~~
    ~~b. Within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.~~

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

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

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

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

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

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

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

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

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

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

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

Recommendation 8: Annual Review of Testosterone Products

MOTION CARRIED by unanimous approval.

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

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

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

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

Recommendation 9: Annual Review of Colorectal Cancer (CRC) Medications and 30-Day Notice to Prior Authorize Avzivi® (Bevacizumab-tnjn) and Fruzaqla® (Fruquintinib)

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

Recommendation 10: 30-Day Notice to Prior Authorize Wegovy® (Semaglutide)

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

Recommendation 11: Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Filsuvez® (Birch Triterpenes 10% Topical Gel)

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

Recommendation 12: Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Kisunla™ (Donanemab-azbt)

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

Recommendation 13: 30-Day Notice to Prior Authorize Defencath® (Taurolidine/Heparin)

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

Recommendation 14: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

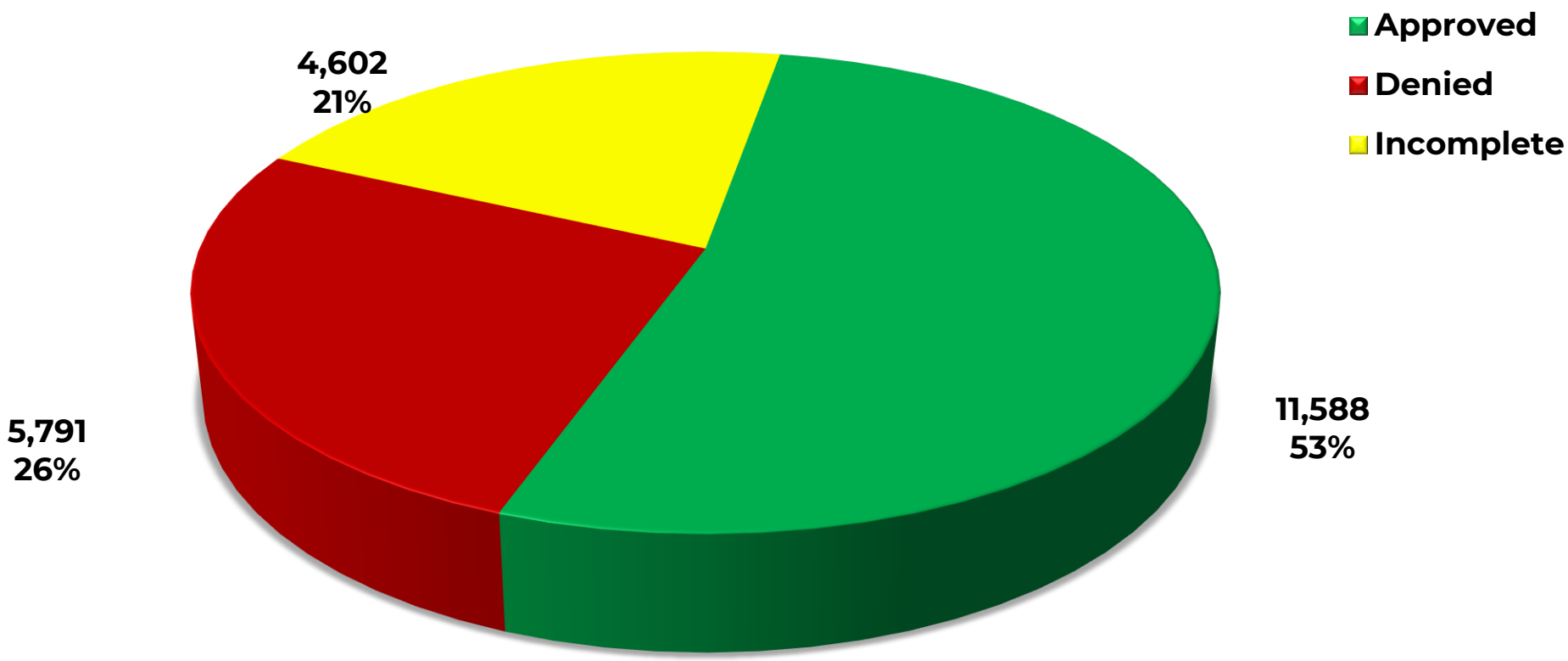
Recommendation 15: Future Business

No live DUR Board meeting scheduled for August 2024. August 2024 will be a packet-only meeting.

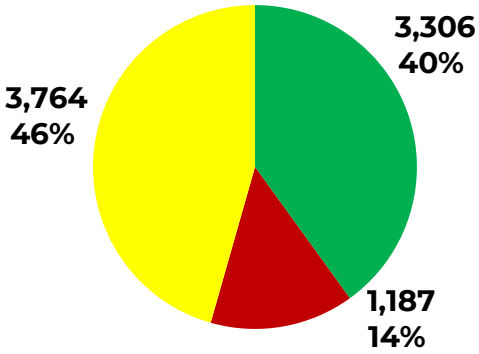
NO ACTION REQUIRED.

Appendix B

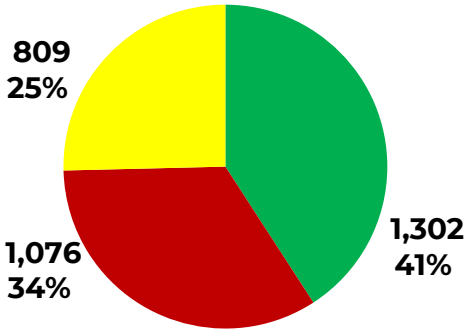
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JULY 2024



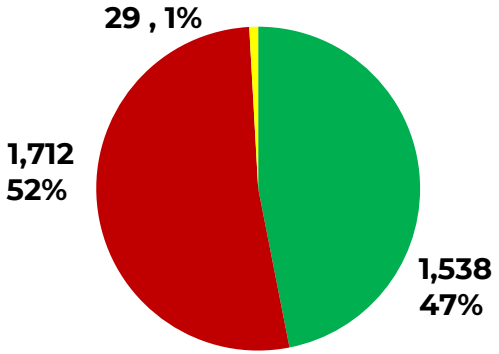
SoonerCare FFS



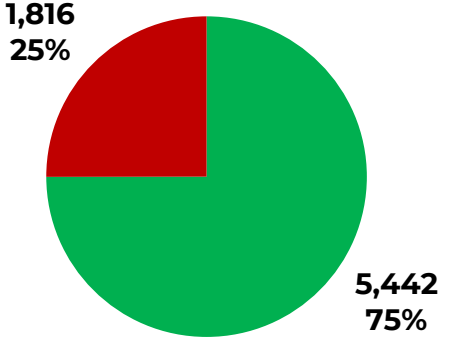
SoonerSelect Aetna



SoonerSelect Humana

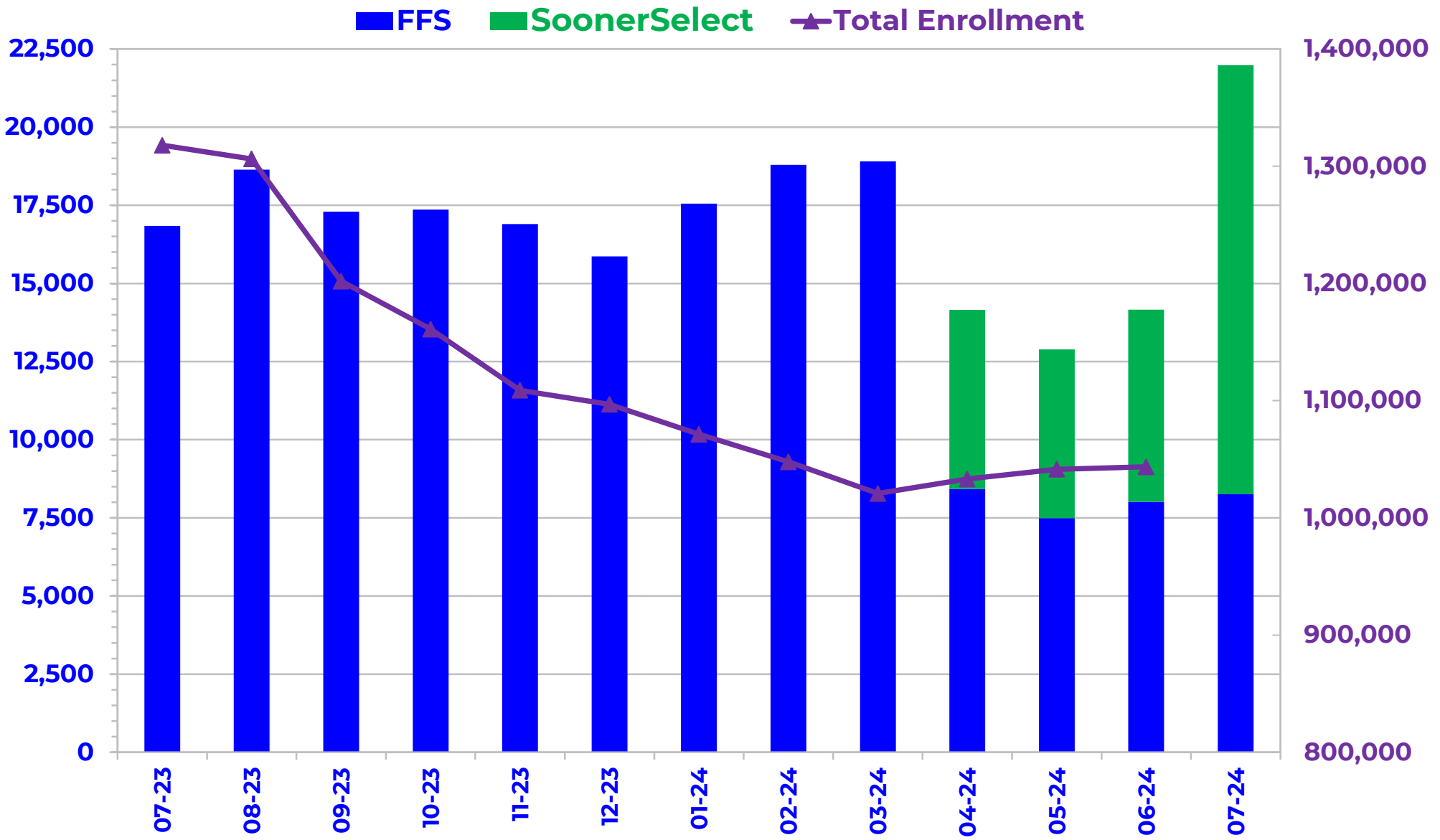


SoonerSelect OK Complete Health



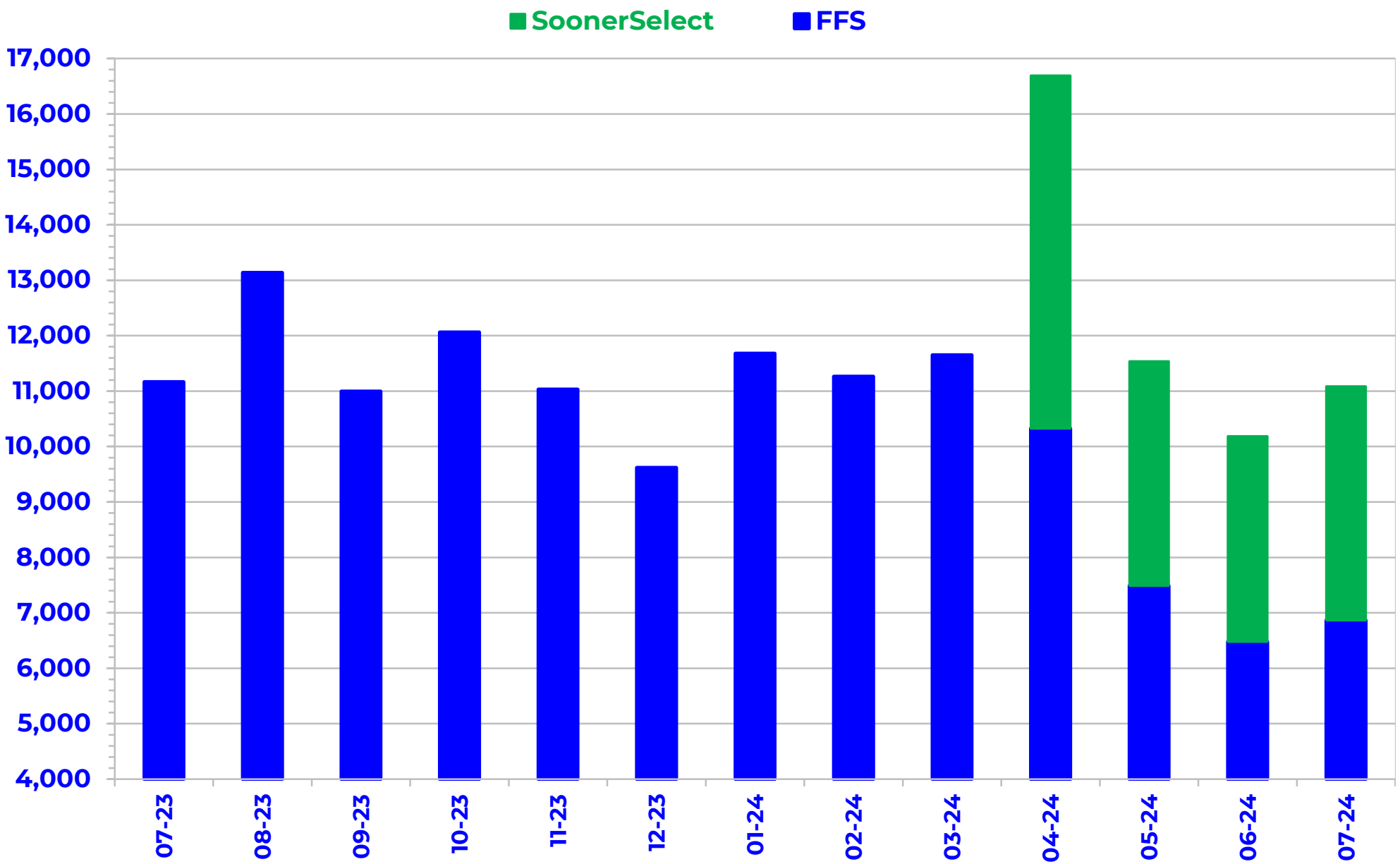
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JULY 2023 – JULY 2024



SoonerCare FFS Prior Authorization Activity

7/1/2024 Through 7/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	97	27	7	63	359
Analgesic - NonNarcotic	12	0	1	11	0
Analgesic, Narcotic	244	94	16	134	132
Antiasthma	46	21	7	18	286
Antibiotic	20	6	0	14	303
Anticonvulsant	186	94	5	87	334
Antidepressant	143	44	13	86	310
Antidiabetic	1,188	311	286	591	356
Antigout	13	4	1	8	267
Antihistamine	21	6	6	9	359
Antimigraine	270	67	76	127	292
Antineoplastic	180	117	8	55	181
Antiobesity	28	7	14	7	197
Antiparasitic	10	2	1	7	17
Antiulcers	42	5	9	28	140
Anxiolytic	20	3	4	13	288
Atypical Antipsychotics	304	119	18	167	359
Biologics	257	109	40	108	329
Bladder Control	105	16	32	57	359
Blood Thinners	16	1	0	15	358
Botox	26	17	5	4	321
Buprenorphine Medications	47	22	5	20	135
Calcium Channel Blockers	14	5	0	9	334
Cardiovascular	96	42	9	45	354
Chronic Obstructive Pulmonary	185	39	33	113	356
Constipation/Diarrhea	170	29	45	96	231
Contraceptive	31	13	3	15	359
Dermatological	368	99	119	150	236
Diabetic Supplies	275	108	41	126	218
Endocrine & Metabolic Drugs	66	28	4	34	278
Erythropoietin Stimulating Agents	22	10	9	3	120
Estrogen Derivative	16	2	2	12	300
Fibromyalgia	13	2	1	10	187
Gastrointestinal Agents	106	27	16	63	172
Glaucoma	14	1	1	12	360
Growth Hormones	56	32	6	18	161
Hematopoietic Agents	19	6	0	13	228

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hepatitis C	20	11	0	9	10
Insomnia	62	6	10	46	243
Insulin	215	90	14	111	300
Miscellaneous Antibiotics	19	2	4	13	13
Multiple Sclerosis	38	20	4	14	244
Muscle Relaxant	37	2	14	21	187
Nasal Allergy	15	1	3	11	360
Neurological Agents	158	51	25	82	196
Neuromuscular Agents	14	10	1	3	304
NSAIDs	30	1	10	19	360
Ophthalmic	23	4	5	14	359
Ophthalmic Anti-infectives	10	2	1	7	198
Osteoporosis	22	12	3	7	340
Other*	335	82	63	190	299
Otic Antibiotic	87	16	8	63	21
Respiratory Agents	33	17	1	15	315
Statins	37	9	13	15	157
Stimulant	923	533	30	360	347
Testosterone	64	14	12	38	359
Thyroid	10	4	2	4	358
Topical Antifungal	22	1	3	18	116
Topical Corticosteroids	20	0	6	14	0
Vitamin	79	14	54	11	131
Pharmacotherapy	138	134	0	4	323
Emergency PAs	0	0	0	0	
Total	**7,137**	**2,571**	**1,129**	**3,437**	
Overrides					
Brand	18	5	0	13	292
Compound	11	10	0	1	13
Cumulative Early Refill	1	1	0	0	7
Dosage Change	193	175	1	17	14
Ingredient Duplication	5	3	0	2	68
Lost/Broken Rx	60	56	0	4	21
MAT Override	16	11	0	5	84
NDC vs Age	175	107	20	48	298
NDC vs Sex	29	22	2	5	246
Nursing Home Issue	52	44	1	7	16
Opioid MME Limit	70	17	6	47	128
Opioid Quantity	15	9	1	5	186

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Other	18	12	0	6	13
Quantity vs. Days Supply	379	226	23	130	266
STBS/STBSM	15	11	1	3	130
Step Therapy Exception	8	3	1	4	279
Stolen	6	5	1	0	33
Temporary Unlock	1	1	0	0	5
Third Brand Request	48	17	1	30	17
Overrides Total	**1,120**	**735**	**58**	**327**	
Total Regular PAs + Overrides	**8,257**	**3,306**	**1,187**	**3,764**	

Denial Reasons	
Unable to verify required trials.	3,152
Does not meet established criteria.	1,218
Lack required information to process request.	606
Other PA Activity	
Duplicate Requests	1,108
Letters	35,374
No Process	0
Changes to existing PAs	506
Helpdesk Initiated Prior Authorizations	365
PAs Missing Information	474

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

SoonerSelect Aetna Prior Authorization Activity

7/1/2024 Through 7/31/2024

	Total	Approved	Denied	Void	Average Length of Approvals in Days
ACE Inhibitors	17	0	1	16	0
Advair/Symbicort/Dulera	52	13	11	28	70
Analgesic - NonNarcotic	8	2	6	0	66
Analgesic, Narcotic	118	59	35	24	148
Angiotensin Receptor Antagonist	6	4	1	1	219
Antiallergic	1	1	0	0	365
Antiasthma	53	16	18	19	145
Antibiotic	10	3	0	7	38
Anticonvulsant	35	17	13	5	190
Antidepressant	210	52	69	89	106
Antidiabetic	533	209	241	83	181
Antifungal	1	1	0	0	62
Antigout	6	1	1	4	61
Antihemophilic Factor	3	2	0	1	365
Antihistamine	14	7	7	0	261
Antimigraine	140	41	80	19	123
Antineoplastic	31	12	1	18	146
Antiobesity	8	1	2	5	73
Antiparasitic	13	6	6	1	4
Antiparkinsons	9	2	1	6	91
Antipsychotic	2	0	0	2	0
Antiulcers	47	3	7	37	71
Antiviral	2	1	1	0	92
Anxiolytic	32	15	9	8	164
Atypical Antipsychotics	162	60	59	43	158
Benign Prostatic Hypertrophy	5	0	5	0	0
Biologics	82	64	8	10	298
Bladder Control	10	2	7	1	81
Blood Thinners	7	4	1	2	183
Botox	3	0	0	3	0
Buprenorphine Medications	48	24	20	4	63
Calcium Channel Blockers	14	2	1	11	91
Cardiovascular	56	22	4	30	127
Cephalosporins	1	1	0	0	30
Chronic Obstructive Pulmonary Disease	63	30	32	1	225

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

	Total	Approved	Denied	Void	Average Length of Approvals in Days
Constipation/Diarrhea Medications	48	24	24	0	88
Contraceptive	16	5	7	4	146
Corticosteroid	4	0	1	3	0
Cough/Cold/Allergy	1	0	0	1	0
Dermatological	186	78	75	33	97
Diabetic Supplies	163	89	40	34	234
Diuretic	7	0	0	7	0
Endocrine & Metabolic Drugs	17	8	7	2	152
Erythropoietin Stimulating Agents	2	1	1	0	112
Estrogen Derivative	7	5	1	1	292
Fibric Acid Derivatives	3	0	1	2	0
Fibromyalgia	17	4	0	13	79
Fish Oils	2	0	2	0	0
Gastrointestinal Agents	41	10	17	14	39
Genitourinary Agents	6	1	4	1	73
Glaucoma	8	4	1	3	122
Gonadotropin-releasing Hormone Agonist	3	1	1	1	135
Growth Hormones	6	3	1	2	153
Hematopoietic Agents	7	2	4	1	75
Hepatitis C	3	0	2	1	0
HFA Rescue Inhalers	29	0	2	27	0
Insomnia	21	2	10	9	25
Insulin	70	31	18	21	219
Miscellaneous Antibiotics	10	3	2	5	8
Multiple Sclerosis	14	5	5	4	122
Muscle Relaxant	14	2	9	3	46
Nasal Allergy	14	3	6	5	137
Neurological Agents	25	9	10	6	98
Non-Classified	44	15	19	10	159
NSAIDs	27	7	5	15	92
Ocular Allergy	4	1	3	0	122
Ophthalmic	10	1	4	5	52
Ophthalmic Anti-infectives	8	3	1	4	79
Ophthalmic NSAIDs	1	0	1	0	0
Osteoporosis	3	1	2	0	183
Otic Antibiotic	37	5	29	3	22
Pediculicide	1	0	1	0	0
Prenatal Vitamins	2	0	2	0	0

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

	Total	Approved	Denied	Void	Average Length of Approvals in Days
Respiratory Agents	3	1	2	0	122
Statins	38	4	8	26	14
Stimulant	327	242	43	42	286
Testosterone	48	19	27	2	164
Thyroid	7	3	2	2	156
Topical Antibiotic	5	0	1	4	0
Topical Antifungal	11	4	6	1	56
Topical Corticosteroids	23	4	10	9	48
Toradol	1	0	0	1	0
Vitamin	41	25	12	4	190
****Total**	**3,187**	**1,302**	**1,076**	**809**	

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

	Total	Approved	Denied	Void	Average Length of Approvals in Days
Overrides					
Brand	1	1	0	0	
Quantity Limit	28	28	0	0	
Step Therapy Exception	4	4	0	0	
Other	809	0	0	809	
Overrides Total	**842**	**33**	**0**	**809**	

Denial Reasons	
Benefit	33
Experimental/Investigational	138
Lack required information to process request	103
Medical Necessity	802
Other PA Activity	
Duplicate Requests	11
Letters	3,495
No Process	261
Changes to existing PAs	38
Helpdesk Initiated PAs	4
PAs missing information	9

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

SoonerSelect Humana Prior Authorization Activity

7/1/2024 Through 7/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	52	0	51	1	0
Allergen Immunotherapy	3	1	2	0	365
Analgesic - NonNarcotic	5	1	4	0	122
Analgesic, Narcotic	100	54	45	1	202
Anti-inflammatory	2	0	2	0	0
Antiasthma	27	14	13	0	232
Antibiotic	5	2	3	0	183
Anticonvulsant	18	9	9	0	183
Antidepressant	60	24	36	0	223
Antidiabetic	450	243	202	5	289
Antifungal	2	0	2	0	0
Antigout	12	4	8	0	183
Antihistamine	2	2	0	0	365
Antimigraine	170	95	71	4	323
Antineoplastic	29	25	4	0	167
Antiobesity	1	0	1	0	0
Antiparasitic	2	1	1	0	183
Antiplatelet	1	1	0	0	30
Antiulcers	5	2	3	0	55
Antiviral	2	2	0	0	93
Anxiolytic	5	3	2	0	365
Biologics	115	86	28	1	253
Bladder Control	25	4	19	2	112
Blood Thinners	2	0	2	0	0
Botox	16	11	5	0	365
Buprenorphine Medications	100	67	32	1	128
Calcium Channel Blockers	3	1	2	0	183
Cardiovascular	36	21	15	0	232
Chronic Obstructive Pulmonary Disease	95	30	65	0	297
Constipation/Diarrhea Medications	78	37	40	1	118
Contraceptive	12	4	8	0	365
Corticosteroid	1	0	1	0	0
Dermatological	131	95	36	0	238
Endocrine & Metabolic Drugs	26	6	20	0	188
Erythropoietin Stimulating Agents	4	3	1	0	82
Estrogen Derivative	3	1	2	0	365
Fibromyalgia	1	1	0	0	365
Fish Oils	2	0	2	0	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents	28	9	18	1	123
Glaucoma	2	0	2	0	0
Gonadotropin-releasing Hormone Agonist	2	2	0	0	365
Growth Hormones	22	16	6	0	265
Hematopoietic Agents	4	1	3	0	183
Hepatitis C	4	2	2	0	84
HFA Rescue Inhalers	6	0	6	0	0
Insomnia	11	3	8	0	71
Insulin	63	16	47	0	195
Miscellaneous Antibiotics	3	0	3	0	0
Multiple Sclerosis	18	6	12	0	56
Muscle Relaxant	34	14	19	1	138
Nasal Allergy	5	2	3	0	365
Neurological Agents	34	16	18	0	160
Non-Classified	47	36	9	2	308
NSAIDs	4	0	4	0	0
Ophthalmic	12	5	7	0	129
Ophthalmic Anti-infectives	10	5	5	0	129
Ophthalmic Corticosteroid	1	0	1	0	0
Ophthalmic NSAIDs	3	0	3	0	0
Osteoporosis	13	3	10	0	85
Otic Antibiotic	3	2	1	0	183
Passive Immunizing Agents	1	1	0	0	31
Respiratory Agents	11	7	4	0	228
Statins	21	9	11	1	111
Stimulant	68	34	33	1	210
Testosterone	80	24	56	0	237
Thyroid	8	3	5	0	183
Topical Antifungal	9	2	7	0	183
Topical Corticosteroids	13	3	9	1	110
Vitamin	48	23	25	0	181
Total	**2,191**	**1,094**	**1,074**	**23**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Ingredient Duplication	48	13	35	0	380
MAT Override	10	5	5	0	584
NDC vs. Age	171	123	46	2	361
Opioid MME Limit	3	2	1	0	365
Opioid Quantity	4	4	0	0	366
Other	237	24	213	0	373
Quantity vs. Days Supply	265	143	121	1	365
STBS/STBSM	55	23	32	0	338
Step Therapy Exception	295	107	185	3	363
Overrides Total	**1,088**	**444**	**638**	**6**	
Total Regular PAs + Overrides	**3,279**	**1,538**	**1,712**	**29**	

Denial Reasons	
Benefit	486
Medical Necessity	1,226

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

SoonerSelect OK Complete Health Prior Authorization Activity

7/1/2024 Through 7/31/2024

	Total	Approved	Denied	Average Length of Approvals in Days
ACE Inhibitors	46	45	1	187
Advair/Symbicort/Dulera	163	116	47	214
Allergen Immunotherapy	3	0	3	0
Analgesic - NonNarcotic	8	0	8	0
Analgesic, Narcotic	195	108	87	264
Angiotensin Receptor Antagonist	31	31	0	174
Anorectal	1	0	1	0
Antiallergic	1	0	1	0
Antiasthma	50	32	18	255
Antibiotic	6	1	5	367
Anticoagulant	1	1	0	155
Anticonvulsant	321	295	26	194
Antidepressant	564	491	73	208
Antidiabetic	1,040	689	351	371
Antifungal	3	1	2	176
Antigout	4	2	2	365
Antihemophilic Factor	2	1	1	365
Antihistamine	32	15	17	365
Anti-inflammatory	1	1	0	365
Antimigraine	159	38	121	294
Antineoplastic	16	14	2	302
Antiobesity	41	0	41	0
Antiparasitic	2	1	1	365
Antiparkinsons	13	11	2	221
Antiulcers	120	112	8	180
Anxiolytic	135	120	15	189
Atypical Antipsychotics	329	241	88	243
Benign Prostatic Hypertrophy	13	11	2	188
Biologics	113	77	36	360
Bladder Control	37	19	18	233
Blood Thinners	4	4	0	167
Botox	2	0	2	0
Buprenorphine Medications	19	6	13	319
Calcium Channel Blockers	36	35	1	196
Cardiovascular	175	153	22	206
Chronic Obstructive Pulmonary Disease	73	18	55	310
Constipation/Diarrhea Medications	80	30	50	307
Contraceptive	17	7	10	336
Corticosteroid	6	5	1	183

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

	Total	Approved	Denied	Average Length of Approvals in Days
Cough/Cold/Allergy	2	1	1	169
Dermatological	168	95	73	278
Diabetic Supplies	170	106	64	364
Diuretic	59	58	1	175
Endocrine & Metabolic Drugs	19	4	15	365
Erythropoietin Stimulating Agents	3	2	1	238
Estrogen Derivative	11	3	8	416
Fibric Acid Derivatives	6	3	3	365
Fibromyalgia	87	82	5	179
Fish Oils	9	5	4	279
Gastrointestinal Agents	28	10	18	299
Genitourinary Agents	3	2	1	365
Glaucoma	13	11	2	205
Gonadotropin-releasing Hormone Agonist	8	7	1	299
Growth Hormones	36	23	13	264
Hematopoietic Agents	8	4	4	365
Hepatitis C	6	2	4	70
HFA Rescue Inhalers	9	8	1	193
Insomnia	37	16	21	236
Insulin	198	168	30	227
Miscellaneous Antibiotics	3	3	0	365
Multiple Sclerosis	8	1	7	180
Muscle Relaxant	14	3	11	365
Nasal Allergy	11	1	10	365
Neurological Agents	23	10	13	347
Non-Classified	135	80	55	342
NSAIDs	15	7	8	311
Ophthalmic	4	0	4	0
Ophthalmic Anti-infectives	7	5	2	243
Ophthalmic Corticosteroid	4	2	2	163
Osteoporosis	7	7	0	254
Otic Antibiotic	70	31	39	350
Passive Immunizing Agents	1	1	0	365
Pediculicide	2	2	0	365
Prenatal Vitamins	4	4	0	314
Respiratory Agents	8	5	3	291
Statins	58	48	10	184
Stimulant	1,852	1,713	139	233
Testosterone	94	24	70	349
Thyroid	65	59	6	191
Topical Antibiotic	1	0	1	0
Topical Antifungal	23	8	15	342

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

	Total	Approved	Denied	Average Length of Approvals in Days
Topical Corticosteroids	16	8	8	290
Vitamin	91	79	12	355
Total	**7,258**	**5,442**	**1,816**	

Denial Reasons	
Benefit	112
Medical Necessity	1704

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

U.S. Food and Drug Administration (FDA) Safety Alerts*

***Additional information, including the full news release, on the following FDA Safety Communications can be found on the FDA website at: https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications.**

Oklahoma Health Care Authority
August 2024

Introduction[1,2,3,4]

The following are recent FDA safety alerts included for the Drug Utilization Review (DUR) Board's consideration. SoonerCare specific data may be presented where applicable. The College of Pharmacy will make recommendations as well as take recommendations from the DUR Board.

Date	Drug	Issue
11/28/2023	**Levetiracetam and clobazam**	**Serious drug reaction to levetiracetam and clobazam**

Issue Details: The FDA is warning that antiseizure medications levetiracetam (Keppra®, Keppra® XR, Elepsia™ XR, Spritam®) and clobazam (Onfi®, Sympazan®) can cause a rare, but serious reaction that can be life-threatening if not diagnosed and treated quickly. The reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death.

FDA Recommendation(s): The FDA is requiring manufacturers of these medications to add new warnings about DRESS to the *Prescribing Information* and the *Medication Guide* for patients and caregivers.

- The warnings for both products will include information that early symptoms of DRESS such as fever or swollen lymph nodes can be present even when a rash cannot be seen. This is different from other serious skin-related reactions that can happen with these medications where a rash is present early on, including Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN).

Pharmacy Claims Evaluation: During calendar year (CY) 2023, a total of 8,811 unique SoonerCare members had paid claims for levetiracetam or clobazam, accounting for 48,175 paid claims and an average of 5.47 claims per member.

SoonerCare Action: Currently, Keppra® (levetiracetam), Keppra® XR [levetiracetam extended-release (ER)], and Onfi® (clobazam) do not require a prior authorization (PA) through SoonerCare; however, Elepsia™ XR (levetiracetam ER), Sympazan® (clobazam oral films), and Spritam® (levetiracetam tablets for oral suspension) do require a PA for coverage consideration. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
01/11/2024	**Glucagon-like peptide-1 receptor agonists (GLP-1 RAs)**	**Ongoing evaluation of reports of suicidal thoughts or actions in patients taking GLP-1 RAs**

Issue Details: The FDA has been evaluating reports of suicidal thoughts or actions in patients treated with GLP-1 RAs. The FDA's preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions. Over the last several months, the FDA has conducted detailed reviews of reports of suicidal thoughts or actions received in the FDA Adverse Event Reporting System (FAERS). Because the information provided was often limited and because these events can be influenced by other potential factors, the FDA determined that the information in these reports did not demonstrate a clear relationship with the use of GLP-1 RAs. Similarly, their reviews of the clinical trials, including large outcome studies and observational studies, did not find an association between use of GLP-1 RAs and the occurrence of suicidal thoughts or actions. However, because of the small number of suicidal thoughts or actions observed in both people using GLP-1 RAs and in the comparative control groups, the FDA states they cannot definitively rule out that a small risk may exist; therefore, the FDA is continuing to look into this issue. Additional evaluations include a meta-analysis of clinical trials across all GLP-1 RA products and an analysis of postmarketing data in the Sentinel System. The FDA will communicate their final conclusions and recommendations after they complete the review or have more information to share.

FDA Recommendation(s):

- Patients should not stop taking GLP-1 RAs without first consulting with their health care provider. Patients should talk to their health care provider if they have questions, concerns, or if they experience any new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior.
- The current *Prescribing Information* for GLP-1 RAs approved to treat patients with obesity or overweight contains information about the risk of suicidal thoughts and actions. This information is also included in the labels of other types of weight loss medications and is based on reports of such events observed with a variety of older medications used or tested for weight loss.
- Consistent with the *Prescribing Information* for these medications, health care professionals should monitor and advise patients using GLP-1 RAs to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Health care providers should consult the *Prescribing Information* when treating patients with these medications.

- Additionally, health care providers should report side effects involving GLP-1 RAs or any other medications to the FDA MedWatch program.

Pharmacy Claims Evaluation: During CY 2023, a total of 11,076 unique SoonerCare members had paid claims for GLP-1 RAs, accounting for 60,355 paid claims and an average of 5.45 claims per member.
SoonerCare Action: Currently, GLP-1 RAs indicated for type 2 diabetes are covered through SoonerCare with a PA. GLP-1 RAs that are FDA approved to treat obesity or overweight only are not covered by SoonerCare. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
01/19/2024	**Prolia® (denosumab)**	**Risk of severe hypocalcemia in patients with advanced chronic kidney disease (CKD) receiving Prolia®**

Issue Details: Based on a completed FDA review of available information, it was concluded that the osteoporosis medicine Prolia® increases the risk of severe hypocalcemia in patients with advanced CKD, particularly patients on dialysis. Severe hypocalcemia appears to be more common in patients with CKD who also have a condition known as mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia®, severe hypocalcemia resulted in serious harm, including hospitalization, life-threatening events, and death.
FDA Recommendation(s): The FDA is adding a *Boxed Warning* to the Prolia® *Prescribing Information* about the significant risk of developing severe hypocalcemia in patients with advanced CKD. This warning and new labeling contains information to help reduce this risk, including appropriate patient selection for Prolia® treatment, increased monitoring of blood calcium levels, and other strategies. The FDA is also adding this updated information to the patient *Medication Guide* and the Prolia® Risk Evaluation and Mitigation Strategy (REMS) program.
Pharmacy Claims Evaluation: During CY 2023, a total of 53 SoonerCare members had paid claims for Prolia®, accounting for 76 paid claims and an average of 1.43 claims per member.
Medical Claims Evaluation: During fiscal year (FY) 2023, a total of 64 SoonerCare members had paid claims for Prolia®, accounting for 95 paid claims and an average of 1.48 claims per member.
SoonerCare Action: Currently, the use of Prolia® requires prior authorization for all SoonerCare members. The College of Pharmacy will continue to monitor the FDA recommendations.

[1] U.S. Food and Drug Administration (FDA). Drug Safety Communications. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications. Last revised 01/19/2024. Last accessed 07/17/2024.
[2] U.S. FDA. FDA Warns of Rare but Serious Drug Reaction to the Antiseizure Medicines Levetiracetam (Keppra® XR, Elepsia™ XR, Spritam®) and Clobazam (Onfi®, Sympazan®). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-rare-serious-drug-reaction-antiseizure-medicines-levetiracetam-keppra-keppra-xr-elepsia-xr. Issued 11/28/2023. Last accessed 07/17/2024.
[3] U.S. FDA. Update on FDA's Ongoing Evaluation of Reports of Suicidal Thoughts or Actions in Patients Taking a Certain Type of Medicines Approved for Type 2 Diabetes and Obesity. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/update-fdas-ongoing-evaluation-reports-suicidal-thoughts-or-actions-patients-taking-certain-type. Issued 01/11/2024. Last accessed 07/18/2024.
[4] U.S. FDA. FDA Adds Boxed Warning for Increased Risk of Severe Hypocalcemia in Patients with Advanced Chronic Kidney Disease (CKD) Taking Osteoporosis Medicine Prolia® (Denosumab). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-severe-hypocalcemia-patients-advanced-chronic-kidney-disease. Issued 01/19/2024. Last accessed 07/18/2024.

Appendix C

Calendar Year 2023 Annual Review of Wilson's Disease Medications and 30-Day Notice to Prior Authorize Penicillamine 250mg Tablet and Trientine Hydrochloride 500mg Capsule

Oklahoma Health Care Authority
August 2024

Current Prior Authorization Criteria

Cuvrior® (Trientine Tetrahydrochloride) Approval Criteria:

1. An FDA approved diagnosis of Wilson's disease; and
   a. Diagnosis must be confirmed by a Leipzig score ≥4; and
2. Member must be 18 years of age or older; and
3. Cuvrior® must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of Wilson's disease (or an advanced care practitioner with a supervising physician who is 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 penicillamine, generic trientine hydrocholoride, 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.

Utilization of Wilson's Disease Medications: Calendar Year 2023

There was no SoonerCare utilization of Wilson's disease medications during calendar year 2023.

Prior Authorization of Wilson's Disease Medications

There were no prior authorization requests submitted for Wilson's disease medications during calendar year 2023.

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Cuvrior® (trientine tetrahydrochloride): May 2039

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).

Pipeline:

- **UX701:** UX701 is an investigational adeno-associated virus 9 (AAV9) gene therapy that delivers a modified form of the *ATP7B* gene, a protein-coding gene that provides instructions for making the copper-transporting ATPase 2 protein which is important for the elimination of excess copper from the body. Wilson's disease is caused by mutations in the *ATP7B* gene, leading to a buildup of copper in the liver and other tissues. UX701 was granted Orphan Drug and Fast Track designations by the FDA for Wilson's disease. Ultragenyx has initiated the Cyprus2+ Phase 1/2/3 trial and interim data from all 3 Stage 1 patients is expected in the second half of 2024.

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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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 07/2024. Last accessed 07/05/2024.

[2] U.S. FDA. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Product Details for Abbreviated New Drug Application (ANDA) 212238. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=212238#43437. Last revised 07/2024. Last accessed 07/15/2024.

[3] Ultragenyx Pharmaceuticals. Ultragenyx Announces Completion of Dosing Across Stage 1 Cohorts in Pivotal Phase 1/2/3 Cyprus2+ Study Evaluating UX701 Gene Therapy for the Treatment of Wilson Disease. Available online at: https://ir.ultragenyx.com/news-releases/news-release-details/ultragenyx-announces-completion-dosing-across-stage-1-cohorts. Issued 01/25/2024. Last accessed 07/05/2024.

Appendix D

Calendar Year 2023 Annual Review of Corticosteroid Special Formulations and 30-Day Notice to Prior Authorize Eohilia™ (Budesonide Oral Suspension)

Oklahoma Health Care Authority
August 2024

Current Prior Authorization Criteria

Alkindi Sprinkle® (Hydrocortisone Oral Granule) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed, must be provided.

Millipred™ (Prednisolone 5mg Tablet) Approval Criteria:

1. 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.

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.

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; 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.

TaperDex™ (Dexamethasone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use dexamethasone 1.5mg individual tablets, which are available without a prior authorization, must be provided.

Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy; and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of rapid disease progression as demonstrated by ≥1 of the following, despite maximal supportive care:
    a. Urine protein-to-creatinine ratio (UPCR) ≥1.5g/g; or
    b. Proteinuria >0.75g/day; and
6. Member must be on a stable dose of a maximally-tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. A patient-specific, clinically significant reason why a 6-month trial of an alternative formulation of budesonide DR oral capsules (e.g., Entocort® EC) or alternative oral corticosteroids is not appropriate for the member must be provided; and
8. Approval duration will be for 9 months; and
9. A quantity limit of 120 capsules per 30 days will apply.

Zilretta® [Triamcinolone Acetonide Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of osteoarthritis (OA) pain of the knee; and
2. Zilretta® will only be approvable for use in the knee(s) for OA pain; and
3. A patient-specific, clinically significant reason why the member cannot use Kenalog-40® (triamcinolone acetonide 40mg injection) and Depo-Medrol® (methylprednisolone injection) must be provided; and
4. A quantity limit of 1 injection per knee per 12 weeks will apply.

Utilization of Corticosteroid Special Formulations: Calendar Year 2023

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	787	1,057	$114,062.58	$107.91	$22.18	5,833	5,143
2023	634	888	$246,328.98	$277.40	$52.43	5,978	4,698
% Change	**-19.40%**	**-16.00%**	**116.00%**	**157.10%**	**136.40%**	**2.50%**	**-8.70%**
Change	**-153**	**-169**	**$132,266.40**	**$169.49**	**$30.25**	**145**	**-445**

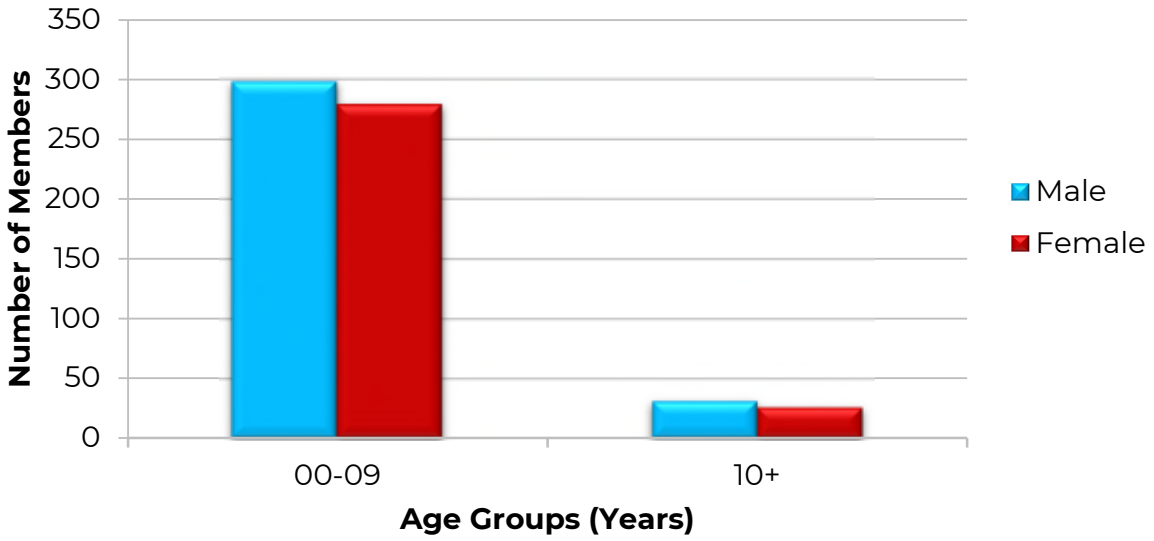
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

Comparison of Calendar Years: Medical Claims

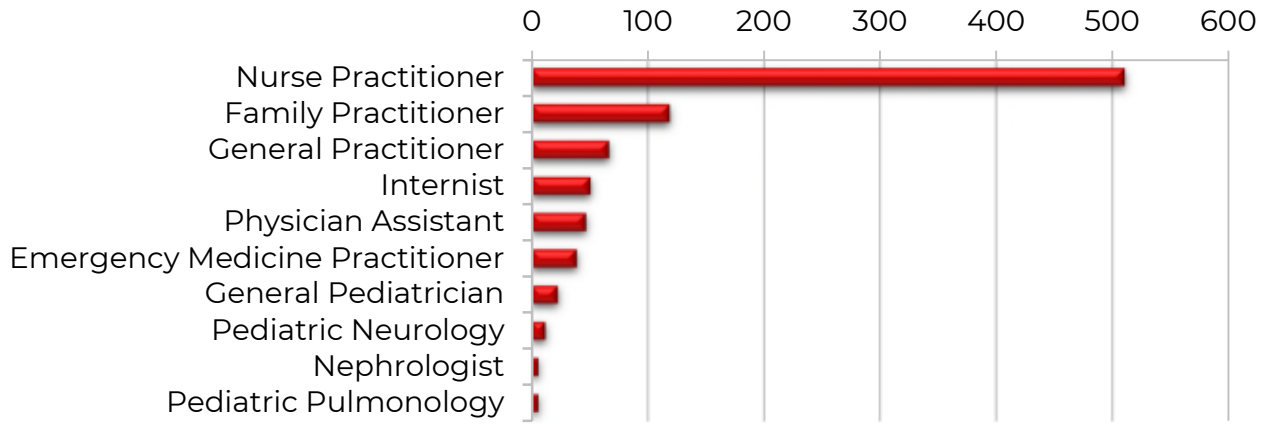
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	6	7	$4,916.16	$702.31	1.17
2023	24	19	$16,322.24	$680.09	1.26
% Change	**300%**	**171.43%**	**232.01%**	**-3.16%**	**7.69%**
Change	**18**	**12**	**$11,406.08**	**-$22.22**	**0.09**

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

Demographics of Members Utilizing Corticosteroid Special Formulations



Top Prescriber Specialties of Corticosteroid Special Formulations by Number of Claims



Prior Authorization of Corticosteroid Special Formulations

There were 137 prior authorization requests submitted for corticosteroid special formulations 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]

Anticipated Patent Expiration(s):

- Zilretta® [triamcinolone acetonide extended-release (ER) injection]: August 2031
- Alkindi® Sprinkle (hydrocortisone oral granule): May 2034
- Eohilia™ (budesonide oral suspension): January 2039
- Tarpeyo® [budesonide delayed-release (DR) capsule]: January 2043

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

- **December 2023:** The FDA granted full approval to Tarpeyo® (budesonide DR capsule) to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease

progression. It was previously approved under an accelerated approval, based on the surrogate marker of proteinuria. The confirmatory trial showed a statistically significant benefit over placebo in estimated glomerular filtration rate (eGFR) over the 2-year trial period. At 2 years, there was a 6.11mL/min/1.73m^2 decline in eGFR in the Tarpeyo® group compared with a 12mL/min/1.73m^2 decline in the placebo group (P<0.0001).
- **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).

Pipeline:
- **APT-1011 (Fluticasone Propionate):** APT-1011 is a once daily, orally disintegrating tablet being studied for the treatment of EoE that is designed to deliver fluticasone propionate directly to the esophageal mucosa with low systemic absorption. APT-1011 had successful results in FLUTE 1 (Phase 2b trial) and FLUTE 2 (Phase 3 trial). A second Phase 3 trial, FLUTE 3, is ongoing.

Eohilia™ (Budesonide Oral Suspension) Product Summary[5,6]

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.
- Key Inclusion Criteria:
  - 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[7]

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]	$21.46	$1,545.12[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 FDA approved diagnosis of eosinophilic esophagitis (EoE); 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 ≥2 episodes of dysphagia per week; and
5. Member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf); and
6. Member must have a documented trial for a minimum of 8 weeks that resulted in failure with 1 high-dose proton pump inhibitor (or have a contraindication or documented intolerance); and
7. A patient specific, clinically significant reason why the member cannot use a swallowed respiratory corticosteroid (e.g., budesonide, Flovent®) must be provided; and
8. Approvals will be for (1) 3-month treatment course; and
9. A quantity limit of 600mL per 30 days will apply; and
10. 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.

Utilization Details of Corticosteroid Special Formulations: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREDNISOLONE PRODUCTS						
PREDNISOLONE 15MG ODT	482	364	$48,073.58	$99.74	1.32	19.52%
PREDNISOLONE 10MG ODT	278	224	$16,708.21	$60.10	1.24	6.78%
PREDNISOLONE 30MG ODT	116	88	$14,923.02	$128.65	1.32	6.06%
PREDNISOLONE 5MG TAB	1	1	$1,123.61	$1,123.61	1	0.46%
SUBTOTAL	**877**	**677**	**$80,828.42**	**$92.16**	**1.3**	**32.81%**
BUDESONIDE PRODUCTS						
TARPEYO CAP 4MG	11	2	$165,500.56	$15,045.51	5.5	67.19%
SUBTOTAL	**11**	**2**	**$165,500.56**	**$15,045.51**	**5.5**	**67.19%**
TOTAL	**888**	**634***	**$246,328.98**	**$277.40**	**1.4**	**100%**

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

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZILRETTA INJ 32MG J3304	24	19	$16,322.24	$680.09	1.26
TOTAL	**24**	**19**	**$16,322.24**	**$680.09**	**1.26**

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 07/2024. Last accessed 07/01/2024.
[2] 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: 07/01/2024.
[3] Calliditas Therapeutics. Calliditas Therapeutics Announces Full FDA Approval of Tarpeyo®, the Only FDA-Approved Treatment for IgA Nephropathy to Significantly Reduce the Loss of Kidney Function. Available online at: https://www.calliditas.se/en/calliditas-therapeutics-announces-full-fda-approval-of-tarpeyo-the-only-fda-approved-treatment-for-iga-nephropathy-to-significantly-reduce-the-loss-of-kidney-function/. Issued 12/20/2023. Last accessed 07/01/2024.
[4] Ellodi Pharmaceuticals. Ellodi Pharmaceuticals Announces FLUTE-2 Data to be Presented at Digestive Disease Week (DDW) 2024 with APT-1011 in Patients with Eosinophilic Esophagitis. Available online at: https://ellodipharma.com/ellodi-pharmaceuticals-announces-flute-2-data-to-be-presented-at-ddw-2024-with-apt-1011-in-patients-with-eosinophilic-esophagitis/. Issued 05/21/2024. Last accessed 07/17/2024.
[5] 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 07/01/2024.
[6] Hirano I, Collins M, Katzka D, et al. Budesonide Oral Suspension Improves Outcomes in Patients with Eosinophilic Esophagitis: Results from a Phase 3 Trial. *Clinical Gastroenterology and Hepatology* 2022; 20:525-534. doi: 10.1016/j.cgh.2021.04.022.
[7] Papadopoulou A, Koletzko S, Heuschkel R, et al. Management Guidelines of Eosinophilic Esophagitis in Children. *J Pediatric Gastroenterol Nutr* 2014; 58(1): 107-118. doi: 10.1097/MPG.0b013e3182a80be1.

Appendix E

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

Oklahoma Health Care Authority
August 2024

Current Prior Authorization Criteria

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 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 Diagnosis]:

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

5. Member must have left ventricular ejection fraction (LVEF) <45%; and
6. Member's current weight (kg) and hemoglobin (Hb) (g/dL) must be provided to ensure appropriate dosing according to package labeling; and
7. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided; and
8. Initial approvals will be for 1 or 2 doses only (depending on member's weight and Hb) according to package labeling; and
9. Subsequent requests for maintenance doses at weeks 12, 24, and 36 will require submission of updated lab results verifying continued iron deficiency for each dose and will be approved for (1) 500mg dose at a time.

Monoferric® (Ferric Derisomaltose) Approval Criteria:

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

Utilization of Iron Products: Medical Claims

Comparison of Calendar Years

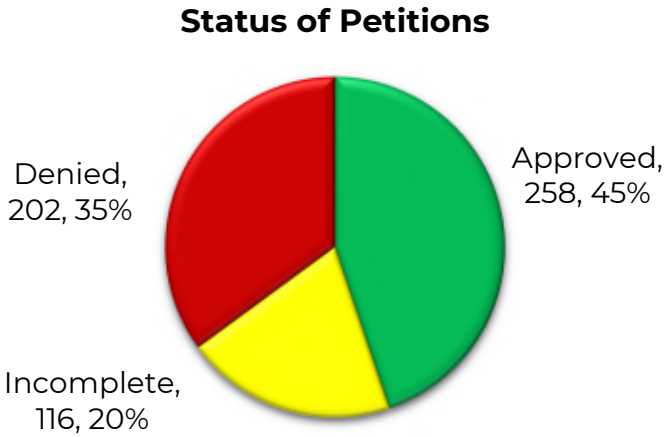
Calendar Year	Total Members*	Total Claims+	Total Cost	Cost/ Claim	Claims/ Member
2022	1,349	3,916	$482,251.84	$123.15	2.9
2023	1,928	6,466	$757,764.69	$117.19	3.35
% Change	**42.92%**	**65.12%**	**57.13%**	**-4.84%**	**15.52%**
Change	**579**	**2,550**	**$275,512.85**	**-$5.96**	**0.45**

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 iron products totaled $319,544.75.[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.

Prior Authorization of Iron Products

There were 576 prior authorization requests submitted for iron products during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Injectafer® (ferric carboxymaltose injection): February 2028
- Accrufer® (ferric maltol): October 2035
- Monoferric® (ferric derisomaltose injection): June 2036

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[3,4,5]

Therapeutic Class: Iron replacement product

Indication(s): Treatment of iron deficiency in adults

How Supplied: 30mg oral capsules

[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.

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.

Utilization Details of Iron Products: Calendar Year 2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
J1756 IRON SUC INJ (VENOFER)	5,713	1,390	$213,060.78	$37.29	4.11	28.12%
J1750 IRON DEX INJ (INFED)	518	413	$148,469.61	$286.62	1.25	19.59%
J1437 FER DERIS INJ (MONOFERRIC)	161	145	$350,346.00	$2,176.06	1.11	46.23%
J1439 FER CARB INJ (INJECTAFER)	48	24	$38,707.50	$806.41	2	5.11%
Q0138 FERUMOXYTOL INJ (FERAHEME)	26	16	$7,180.80	$276.18	1.63	0.95%
TOTAL	**6,466**	**1,928**	**$757,764.69**	**$117.19**	**3.35**	**100%**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
CARB = carboxymaltose; DERIS = derisomaltose; DEX = dextran; FER = ferric; INJ = injection; SUC = sucrose
Please note: Reimbursement of IV iron products for members with end stage renal disease (ESRD) receiving dialysis is included in the bundled dialysis payment and cannot be reimbursed separately. Utilization data for IV iron products reimbursed in the bundled dialysis payment is not included in the above table or in this report.

[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 07/2024. Last accessed 07/15/2024.
[2] 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 07/19/2024.
[3] 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 07/15/2024.
[4] 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.
[5] 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 F

Calendar Year 2023 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Tramadol 25mg Tablet

Oklahoma Health Care Authority
August 2024

Current Prior Authorization Criteria: Opioid Analgesics

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®)	oxymorphone ER tab
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	Morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	tramadol ER cap (ConZip®)
tapentadol ER tab 50mg (Nucynta® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	
	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®)	levorphanol tab
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)		oxycodone tab (Oxaydo®)	tramadol 100mg tab
hydromorphone tab & soln (Dilaudid®)		oxycodone tab (RoxyBond™)	tramadol soln (Qdolo™)
meperidine tab & soln (Demerol®)			
morphine IR tab & soln (MSIR®)			
oxycodone/APAP tab & soln (Percocet®)			
oxycodone/ASA tab (Percodan®)			
oxycodone IR cap (Oxy IR®)			***Oncology Only:***
oxycodone IR tab & soln (Roxicodone®)			fentanyl buccal film (Onsolis®)
tapentadol IR (Nucynta®)			fentanyl buccal tab (Fentora®)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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

- Tier-1 products are covered with no prior authorization necessary.
- Members with an oncology-related diagnosis are exempt from the prior authorization process and do not require a pain contract.
- Only 1 long-acting and 1 short-acting medication can be used concurrently.
- Short-acting, solid dosage formulation products are limited to a quantity of 4 units per day or a quantity of 120 units per 30 days. An exception applies to members with a current oncology-related diagnosis, sickle cell disease diagnosis, or hemophilia diagnosis.
- An age restriction applies on oral liquid narcotic analgesic products for all members older than 12 years of age and oral solid dosage forms for all members younger than 10 years of age.
- An age restriction applies for all tramadol and codeine products (both liquid and solid dosage formulations) for members younger than 12 years of age. 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.

Opioid Analgesics Tier-2 Approval Criteria:

1. A documented 30-day trial/titration period with at least 1 Tier-1 medication within the last 90 days is required for a Tier-2 long-acting medication; and
2. A chronic pain diagnosis requiring time-released medication (for long-acting medications); or
3. A documented 30-day trial with at least 2 Tier-1 short-acting medications within the last 90 days is required for a Tier-2 short-acting medication; or
4. A documented allergy or contraindication(s) to all available Tier-1 medications.

Opioid Analgesics Tier-3 Approval Criteria:

1. A documented 30-day trial with at least 2 Tier-2 long-acting medications within the last 90 days is required for approval of a Tier-3 long-acting medication; or
2. A documented 30-day trial with at least 2 Tier-2 short-acting medications within the last 90 days is required for approval of a Tier-3 short-acting medication; or
3. A documented allergy or contraindication(s) to all available Tier-2 medications.

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Abstral®, Actiq®, 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. 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
    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
    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. 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.
8. 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.
9. 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.
10. Tramadol 100mg Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

Approval Criteria for Greater than 12 Claims Per Year of Hydrocodone Products:

1. Members may be approved for greater than 12 claims per year of hydrocodone products if the member has a pain contract with a single prescriber. A copy of the pain contract must be submitted with the prior authorization request. Requests outside of the plan outlined in the contract will not be approved.
2. Members with a current oncology-related diagnosis, hemophilia diagnosis, or sickle cell disease diagnosis do not require a pain contract for additional approvals.
3. Members in long-term care facilities do not require a pain contract for additional approvals.

Approval Criteria for Greater than the Opioid Morphine Milligram Equivalent (MME) Limit:

1. SoonerCare has an opioid MME limitation of 90 MME per day. Members with a daily MME >90 will require prior authorization. Each request for >90 MME per day will be evaluated on a case-by-case basis; and
2. Patient-specific, clinically significant reasoning for daily doses >90 MME must be provided; and
3. Reasoning why tapering to below the SoonerCare MME limit is not appropriate for the member must be provided; and
    a. 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
4. For members unable to taper to below the SoonerCare MME limit or for whom tapering to below the SoonerCare MME limit is not appropriate, the prescriber must attest to all of the following:
    a. Other non-pharmacologic therapies have been ineffective (i.e., physical therapy); and
    b. Other non-opioid pharmacologic therapies have been ineffective [i.e., non-steroidal anti-inflammatory drugs (NSAIDs)]; and
    c. Risk factors for respiratory depression have been reviewed (i.e., concurrent benzodiazepine use, asthma); and
    d. Counseling on opioid overdose has been provided and a prescription for naloxone has been offered to the member; and
    e. Member has been evaluated for opioid use disorder; and
    f. Pain treatment plan has been established and includes realistic goals for pain and function; and
    g. Monitoring plan is established including random urine drug screens and review of the Oklahoma Prescription Monitoring Program (PMP); and

h. Dose reduction has resulted in loss of pain control and/or function; and
i. Further escalation in dose will not be allowed by provider. Authorization will only be granted at current MME; and
j. The benefits of high-dose opioid therapy for both pain and function in the member outweigh the risks to member safety; and

5. Requests for members exceeding the 90 MME limit per day can be approved when there is documentation of pain associated with end-of-life care, palliative care, or hospice; and
6. Members with oncology, sickle cell disease, or hemophilia diagnoses are excluded from the MME limit.

Current Prior Authorization Criteria: MAT Medications

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 SL units per 30 days will apply.
   c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
   d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
   e. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
   f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.

g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
h. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

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

1. Each request for >16mg 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.

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

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder; and
2. For Sublocade®, member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; or
3. For Brixadi™, member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
4. Concomitant treatment with opioids (including tramadol) will be denied; and

5. Medication should only be prepared and administered by a health care provider; and
6. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual tablets) must be provided; and
7. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
8. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
9. A quantity limit of 1 monthly dose per 28 days or 4 weekly doses per 28 days will apply.

Lucemyra® (Lofexidine) Approval Criteria:

1. An FDA approved indication for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults; and
2. Date of opioid discontinuation must be listed on the prior authorization request; and
3. Prescriber must verify member has been screened for hepatic and renal impairment and that dosing is appropriate for the member's degree of hepatic and renal function; and
4. Prescriber must verify member's vital signs have been monitored and that the member is capable of and has been instructed on self-monitoring for hypotension, orthostasis, bradycardia, and associated symptoms; and
5. Member must not have severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia; and
6. Member must not have congenital long QT syndrome; and
7. Prescriber must verify Lucemyra® will be used in conjunction with a comprehensive management program for the treatment of opioid use disorder; and
8. A patient-specific, clinically significant reason why clonidine tablets or patches cannot be used in place of Lucemyra® to mitigate opioid withdrawal symptoms must be provided; and
9. Approvals will be for a maximum duration of 14 days; and
10. A quantity limit of 12 tablets per day will apply.

Utilization of Opioid Analgesics and MAT Medications: Calendar Year 2023

Comparison of Calendar Years: Opioid Analgesics (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	104,606	305,717	$10,256,360.64	$33.55	$1.91	18,945,471	5,371,368
2023	110,949	318,174	$11,167,646.46	$35.10	$1.99	19,867,336	5,620,553
% Change	**6.10%**	**4.10%**	**8.90%**	**4.60%**	**4.20%**	**4.90%**	**4.60%**
Change	**6,343**	**12,457**	**$911,285.82**	**$1.55**	**$0.08**	**921,865**	**249,185**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: Butrans® and Belbuca® are included in the above opioid analgesics data as they are only indicated for chronic pain and are not indicated for the treatment of opioid dependence.

- Aggregate drug rebates collected during calendar year 2023 for opioid analgesics totaled $6,134,838.79.[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.

Comparison of Calendar Years: MAT Medications (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	8,435	57,470	$5,694,802.18	$99.09	$4.01	2,517,094	1,421,880
2023	10,559	65,522	$8,353,173.53	$127.49	$5.05	2,824,132	1,654,312
% Change	**25.20%**	**14.00%**	**46.70%**	**28.70%**	**25.90%**	**12.20%**	**16.30%**
Change	**2,124**	**8,052**	**$2,658,371.35**	**$28.40**	**$1.04**	**307,038**	**232,432**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: The above MAT medications data does not include Butrans® or Belbuca® claims.

Comparison of Calendar Years: MAT Medications (Medical Claims)

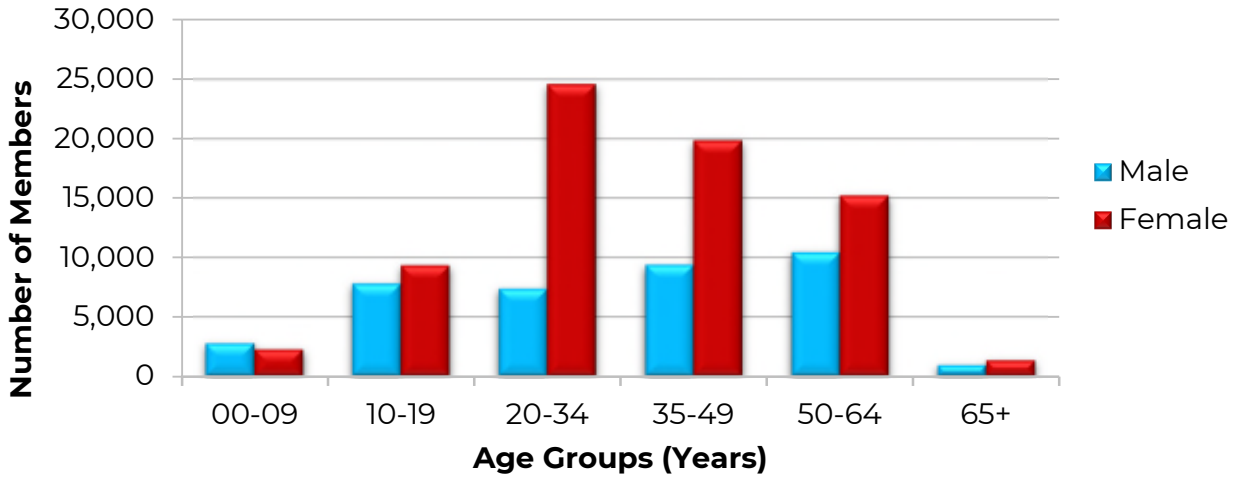
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	4	7	$8,318.58	$1,188.37	1.75
2023	11	33	$24,110.96	$730.64	3
% Change	**175.00%**	**371.43%**	**189.84%**	**-38.52%**	**71.43%**
Change	**7**	**26**	**$15,792.38**	**-$457.73**	**1.25**

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

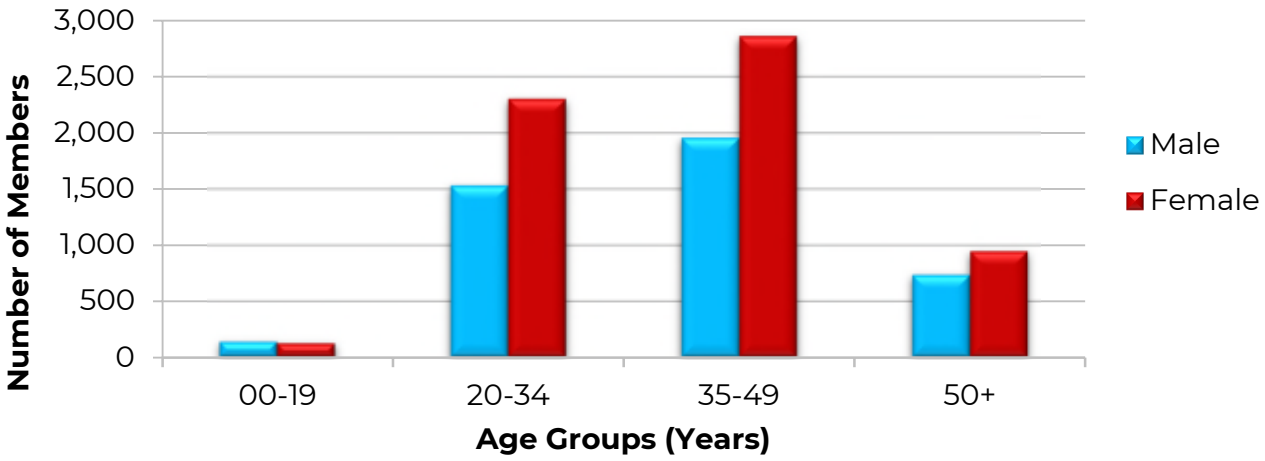
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

- Aggregate drug rebates collected during calendar year 2023 for MAT medications totaled $1,781,996.38.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Opioid Analgesics

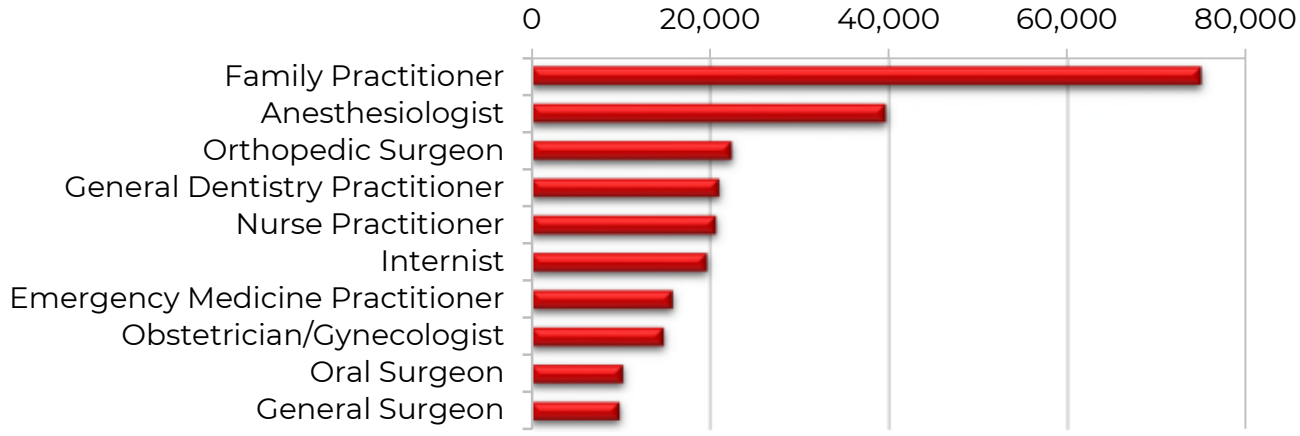


Demographics of Members Utilizing MAT Medications

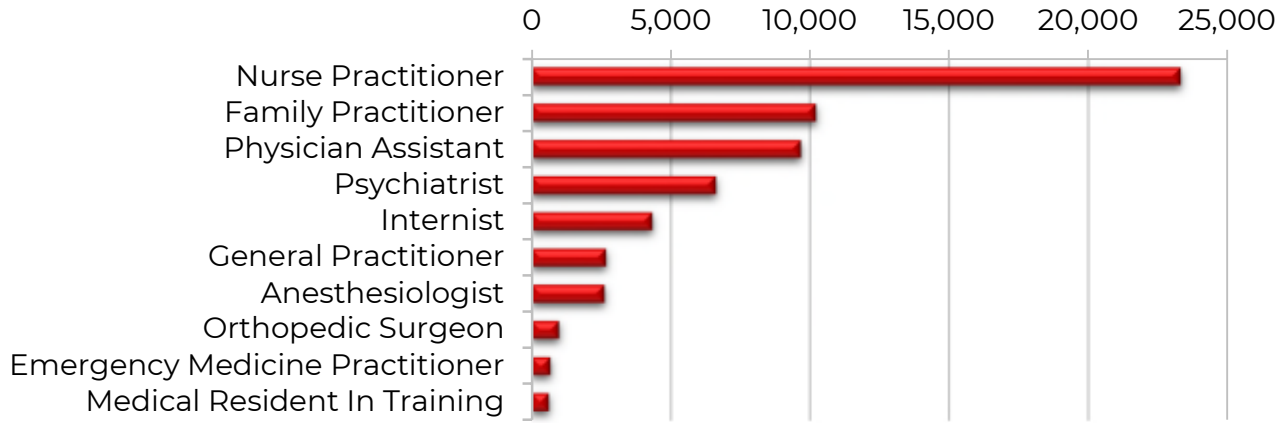


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Top Prescriber Specialties of Opioid Analgesics by Number of Claims



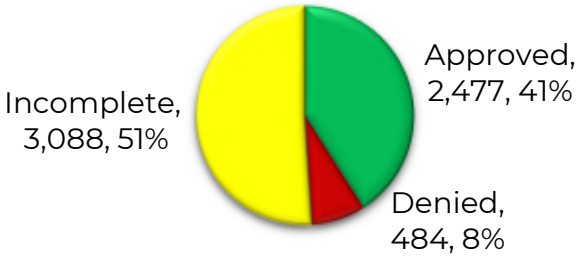
Top Prescriber Specialties of MAT Medications by Number of Claims



Prior Authorization of Opioid Analgesics and MAT Medications

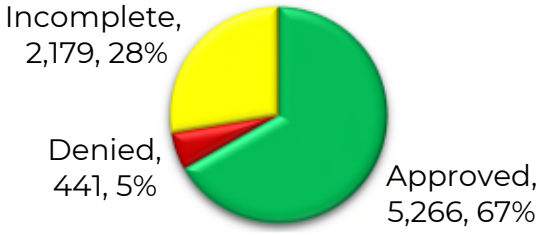
There were 6,049 prior authorization requests submitted for opioid analgesics during calendar year 2023. Computer edits are in place to detect diagnosis, quantity/day supply, and lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions: Opioid Analgesics



There were 7,886 prior authorizations submitted for MAT medications during calendar year 2023. Computer edits are in place to detect diagnosis, concomitant opioid claims, and quantity/day supply and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2023.

Status of Petitions: MAT Medications



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

Anticipated Patent Expiration(s):

- Nucynta® (tapentadol IR tablet): June 2025
- Fentora® (fentanyl buccal tablet): June 2028
- Nucynta® ER [tapentadol extended-release (ER) tablet]: September 2028
- Seglentis (celecoxib/tramadol tablet): June 2031
- Hysingla® ER (hydrocodone ER tablet): December 2031
- Brixadi™ (buprenorphine ER injection): July 2032
- Zubsolv® [buprenorphine/naloxone sublingual (SL) tablet]: September 2032
- Belbuca® (buprenorphine ER buccal film): December 2032
- Zohydro® ER (hydrocodone ER capsule): September 2034
- Sublocade® (buprenorphine ER injection): November 2035
- Xtampza® ER (oxycodone ER capsule): September 2036
- Qdolo™ (tramadol oral solution): September 2040

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.

News:

- **February 2024:** The Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Health and Human Services (HHS) published the final rule for Part 8 of Title 42 of the Code of Federal Regulation (CFR), which updated the regulations for Opioid Treatment Programs (OTPs). The revisions are the first changes made in 20 years and permanently implemented changes made during the COVID-19 pandemic to improve access to care for patients seeking treatment for substance use disorder (SUD). Some notable changes include:
  - The elimination of the 1-year opioid addiction history requirement, promotion of priority treatment for pregnant individuals, and removal of the requirement that patients under the age of 18 years have 2 unsuccessful attempts at treatment before entering treatment at the OTP
  - The addition of "shared decision making" to all care plans
  - Consideration of take-home doses of methadone and buprenorphine under certain conditions
  - Screening patients via telehealth is now allowed

- The expansion of the scope of practice for nurse practitioners and physician assistants to prescribe medication for OUD if consistent with state law

Cost Comparison: Tramadol[6]

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®)

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

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

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

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

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

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

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

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

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

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

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

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

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

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

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

Utilization Details of Opioid Analgesics: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SHORT-ACTING OPIOID ANALGESICS					
IMMEDIATE-RELEASE HYDROCODONE PRODUCTS					
HYDROCOD/APAP TAB 5-325MG	55,493	39,135	$692,047.00	$12.47	1.42
HYDROCOD/APAP TAB 10-325MG	48,596	9,311	$986,371.38	$20.30	5.22
HYDROCOD/APAP TAB 7.5-325MG	46,290	21,937	$730,295.98	$15.78	2.11
HYDROCOD/APAP SOL 7.5-325MG	5,081	4,729	$106,256.18	$20.91	1.07
HYDROCOD/IBU TAB 7.5-200MG	104	40	$2,691.46	$25.88	2.6
HYDROCOD/IBU TAB 10-200MG	47	10	$14,822.98	$315.38	4.7
HYDROCOD/IBU TAB 5-200MG	10	6	$1,268.56	$126.86	1.67
HYRDOCOD/APAP TAB 10-300MG	6	4	$219.76	$36.63	1.5
SUBTOTAL	**155,627**	**75,172**	**$2,533,973.30**	**$16.28**	**2.07**
IMMEDIATE-RELEASE OXYCODONE PRODUCTS					
OXYCOD/APAP TAB 5-325MG	21,089	14,718	$263,065.44	$12.47	1.43
OXYCOD/APAP TAB 10-325MG	21,059	4,333	$515,048.79	$24.46	4.86
OXYCOD/APAP TAB 7.5-325MG	12,268	4,813	$212,581.23	$17.33	2.55
OXYCODONE TAB 5MG	10,496	7,716	$124,193.44	$11.83	1.36
OXYCODONE TAB 10MG	7,520	2,022	$142,072.72	$18.89	3.72
OXYCODONE TAB 15MG	6,076	963	$126,804.30	$20.87	6.31
OXYCODONE SOL 5MG/5ML	2,293	2,089	$38,975.59	$17.00	1.1

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OXYCODONE TAB 20MG	1,518	321	$41,198.98	$27.14	4.73
OXYCODONE TAB 30MG	637	133	$19,896.21	$31.23	4.79
OXYCODONE CAP HCL 5MG	184	147	$4,165.54	$22.64	1.25
OXYCODONE CAP 5MG	136	119	$2,815.61	$20.70	1.14
ENDOCET TAB 5-325MG	130	122	$1,627.98	$12.52	1.07
ENDOCET TAB 10-325MG	102	56	$2,578.64	$25.28	1.82
ENDOCET TAB 7.5-325MG	28	22	$448.88	$16.03	1.27
OXYCODONE CONC 100MG/5ML	10	9	$783.14	$78.31	1.11
OXYCOD/APAP TAB 2.5-325MG	7	6	$205.60	$29.37	1.17
OXYCOD/APAP SOL 5-325MG/5ML	3	2	$600.43	$200.14	1.5
SUBTOTAL	**83,556**	**37,591**	**$1,497,062.52**	**$17.92**	**2.22**
IMMEDIATE-RELEASE TRAMADOL PRODUCTS					
TRAMADOL HCL TAB 50MG	37,210	14,661	$414,965.34	$11.15	2.54
TRAMADOL/APAP TAB 37.5-325MG	285	190	$3,798.23	$13.33	1.5
TRAMADOL HCL TAB 100MG	1	1	$117.08	$117.08	1
SEGLENTIS TAB 56-44MG	1	1	$98.44	$98.44	1
SUBTOTAL	**37,497**	**14,853**	**$418,979.09**	**$11.17**	**2.52**
CODEINE PRODUCTS					
APAP/CODEINE TAB 300-30MG	12,262	7,769	$156,379.24	$12.75	1.58
APAP/CODEINE TAB 300-60MG	7,574	2,099	$182,581.11	$24.11	3.61
BUT/APAP/CAF/COD CAP 50/325/40/30MG	355	101	$20,831.95	$58.68	3.51
APAP/CODEINE TAB 300-15MG	343	260	$4,250.77	$12.39	1.32
BUT/ASA/CAF/COD CAP 50/325/40/30MG	88	22	$7,338.13	$83.39	4
CODEINE SULF TAB 30MG	32	8	$1,333.10	$41.66	4
ASCOMP/COD CAP 30MG	18	7	$2,055.19	$114.18	2.57
APAP/CODEINE SOL 120-12MG/5ML	16	3	$353.20	$22.08	5.33
CODEINE SULF TAB 60MG	8	3	$988.05	$123.51	2.67
CODEINE SULF TAB 15MG	3	2	$187.16	$62.39	1.5
BUT/ASA/CAF/COD CAP 50/325/40/30MG	1	1	$74.26	$74.26	1
SUBTOTAL	**20,700**	**10,275**	**$376,372.16**	**$18.18**	**2.01**
IMMEDIATE-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG	1,302	357	$36,359.45	$27.93	3.65
MORPHINE SULF TAB 30MG	200	44	$8,405.09	$42.03	4.55
MORPHINE SULF SOL 100MG/5ML	85	53	$2,580.73	$30.36	1.6
MORPHINE SULF SOL 10MG/5ML	33	16	$909.46	$27.56	2.06
MORPHINE SULF SOL 20MG/5ML	20	8	$246.63	$12.33	2.5
MORPHINE SUL SOL 20MG/ML	2	2	$53.18	$26.59	1
SUBTOTAL	**1,642**	**480**	**$48,554.54**	**$29.57**	**3.42**
IMMEDIATE-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 4MG	820	206	$13,275.60	$16.19	3.98
HYDROMORPHONE TAB 2MG	615	327	$8,089.78	$13.15	1.88
HYDROMORPHONE TAB 8MG	94	20	$2,839.46	$30.21	4.7
HYDROMORPHONE LIQ 1MG/ML	21	7	$6,038.15	$287.53	3

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**1,550**	**560**	**$30,242.99**	**$19.51**	**2.77**
MEPERIDINE PRODUCTS					
MEPERIDINE SOL 50MG/5ML	220	175	$1,882.00	$8.55	1.26
MEPERIDINE TAB 50MG	3	2	$124.93	$41.64	1.5
SUBTOTAL	**223**	**177**	**$2,006.93**	**$9.00**	**1.26**
PENTAZOCINE PRODUCTS					
PENTAZ/NALOX TAB 50-0.5MG	83	21	$14,241.04	$171.58	3.95
SUBTOTAL	**83**	**21**	**$14,241.04**	**$171.58**	**3.95**
IMMEDIATE-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA TAB 50MG	44	12	$32,355.22	$735.35	3.67
NUCYNTA TAB 75MG	1	1	$461.16	$461.16	1
SUBTOTAL	**45**	**13**	**$32,816.38**	**$729.25**	**3.46**
IMMEDIATE-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG	22	5	$833.89	$37.90	4.4
OXYMORPHONE TAB 5MG	2	2	$46.63	$23.32	1
SUBTOTAL	**24**	**7**	**$880.52**	**$36.69**	**3.43**
SHORT-ACTING SUBTOTAL	**300,947**	**139,149**	**$4,955,129.47**	**$16.47**	**2.16**
LONG-ACTING OPIOID ANALGESICS					
BUPRENORPHINE PAIN PRODUCTS					
BUTRANS DIS 10MCG/HR	1,556	671	$813,794.90	$523.00	2.32
BUTRANS DIS 20MCG/HR	1,542	321	$1,410,562.38	$914.76	4.8
BUTRANS DIS 15MCG/HR	1,290	373	$961,896.24	$745.66	3.46
BUTRANS DIS 5MCG/HR	635	339	$221,703.51	$349.14	1.87
BUTRANS DIS 7.5MCG/HR	415	186	$199,726.67	$481.27	2.23
BELBUCA MIS 450MCG	173	43	$141,964.47	$820.60	4.02
BELBUCA MIS 900MCG	144	17	$137,348.64	$953.81	8.47
BELBUCA MIS 600MCG	128	31	$107,936.89	$843.26	4.13
BELBUCA MIS 300MCG	125	44	$76,234.38	$609.88	2.84
BELBUCA MIS 150MCG	118	43	$44,763.55	$379.35	2.74
BELBUCA MIS 750MCG	91	15	$84,068.30	$923.83	6.07
BELBUCA MIS 75MCG	29	15	$11,482.16	$395.94	1.93
BUPRENORPHINE DIS 10MCG/HR	6	4	$916.14	$152.69	1.5
BUPRENORPHINE DIS 20MCG/HR	2	2	$675.04	$337.52	1
BUPRENORPHINE DIS 15MCG/HR	1	1	$279.26	$279.26	1
SUBTOTAL	**6,255**	**2,105**	**$4,213,352.53**	**$673.60**	**2.97**
EXTENDED-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG ER	2,706	505	$53,509.28	$19.77	5.36
MORPHINE SULF TAB 30MG ER	1,349	255	$37,299.13	$27.65	5.29
MORPHINE SULF TAB 60MG ER	195	50	$8,040.50	$41.23	3.9
MORPHINE SULF TAB 100MG ER	45	9	$3,142.72	$69.84	5
MORPHINE SULF CAP 10MG ER	42	12	$5,291.32	$125.98	3.5
MORPHINE SULF CAP 30MG ER	17	4	$2,791.62	$164.21	4.25
MORPHINE SULF CAP 20MG ER	12	3	$2,068.06	$172.34	4

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
MORPHINE SULF CAP 50MG ER	7	1	$704.02	$100.57	7
MORPHINE SULF CAP 60MG ER	5	1	$1,327.75	$265.55	5
SUBTOTAL	**4,378**	**840**	**$114,174.40**	**$26.08**	**5.21**
EXTENDED-RELEASE OXYCODONE PRODUCTS					
OXYCONTIN TAB 10MG ER	1,643	299	$379,014.36	$230.68	5.49
OXYCONTIN TAB 15MG ER	680	119	$254,864.17	$374.80	5.71
OXYCONTIN TAB 20MG ER	661	148	$312,887.54	$473.35	4.47
OXYCONTIN TAB 30MG ER	305	54	$218,313.56	$715.78	5.65
OXYCONTIN TAB 40MG ER	150	22	$135,294.81	$901.97	6.82
XTAMPZA ER CAP 9MG	113	22	$35,305.99	$312.44	5.14
XTAMPZA ER CAP 18MG	71	11	$39,376.30	$554.60	6.45
OXYCONTIN TAB 80MG ER	50	10	$86,283.17	$1,725.66	5
XTAMPZA ER CAP 13.5MG	48	11	$20,687.98	$431.00	4.36
OXYCONTIN TAB 60MG ER	41	10	$50,396.08	$1,229.17	4.1
XTAMPZA ER CAP 36MG	34	7	$42,734.95	$1,256.91	4.86
XTAMPZA ER CAP 27MG	26	6	$17,579.01	$676.12	4.33
SUBTOTAL	**3,822**	**719**	**$1,592,737.92**	**$416.73**	**5.32**
EXTENDED-RELEASE TRAMADOL PRODUCTS					
TRAMADOL TAB 200MG ER 24HR	509	105	$25,549.22	$50.19	4.85
TRAMADOL TAB 100MG ER 24HR	509	126	$18,132.71	$35.62	4.04
TRAMADOL TAB 300MG ER 24HR	203	40	$13,540.30	$66.70	5.08
TRAMADOL TAB 200MG BIPHASIC	5	4	$430.69	$86.14	1.25
TRAMADOL TAB 100MG BIPHASIC	5	3	$277.35	$55.47	1.67
SUBTOTAL	**1,231**	**278**	**$57,930.27**	**$47.06**	**4.43**
EXTENDED-RELEASE FENTANYL PRODUCTS					
FENTANYL DIS 25MCG/HR	358	108	$13,095.28	$36.58	3.31
FENTANYL DIS 12MCG/HR	250	60	$19,416.12	$77.66	4.17
FENTANYL DIS 50MCG/HR	149	60	$9,538.31	$64.02	2.48
FENTANYL DIS 75MCG/HR	97	27	$7,928.40	$81.74	3.59
FENTANYL DIS 37.5MCG/HR	69	15	$27,945.08	$405.00	4.6
FENTANYL DIS 100MCG/HR	49	21	$4,385.07	$89.49	2.33
SUBTOTAL	**972**	**291**	**$82,308.26**	**$84.68**	**3.34**
METHADONE PRODUCTS					
METHADONE TAB 10MG	168	26	$3,360.57	$20.00	6.46
METHADONE TAB 5MG	75	18	$1,187.69	$15.84	4.17
METHADONE SOL 10MG/5ML	59	40	$793.51	$13.45	1.48
SUBTOTAL	**302**	**84**	**$5,341.77**	**$17.69**	**3.6**
EXTENDED-RELEASE HYDROCODONE PRODUCTS					
HYSINGLA ER TAB 40MG	82	8	$52,722.45	$642.96	10.25
HYSINGLA ER TAB 20MG	52	6	$17,107.00	$328.98	8.67
HYSINGLA ER TAB 60MG	27	3	$24,356.25	$902.08	9
HYSINGLA ER TAB 30MG	25	5	$11,098.35	$443.93	5
HYSINGLA ER TAB 80MG	13	1	$15,761.97	$1,212.46	13

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
HYDROCODONE TAB 30MG ER	13	2	$3,386.36	$260.49	6.5
HYDROCODONE CAP 10MG ER	9	1	$3,352.77	$372.53	9
HYDROCODONE TAB 40MG ER	6	2	$1,995.66	$332.61	3
HYDROCODONE TAB 20MG ER	5	2	$1,015.33	$203.07	2.5
HYDROCODONE CAP 30MG ER	5	3	$1,496.29	$299.26	1.67
SUBTOTAL	**237**	**33**	**$132,292.43**	**$558.20**	**7.18**
EXTENDED-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 20MG ER	9	1	$6,576.88	$730.76	9
OXYMORPHONE TAB 10MG ER	6	1	$2,060.08	$343.35	6
SUBTOTAL	**15**	**2**	**$8,636.96**	**$575.80**	**7.5**
EXTENDED-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA ER TAB 50MG	8	3	$3,590.09	$448.76	2.67
NUCYNTA ER TAB 100MG	2	2	$1,297.91	$648.96	1
SUBTOTAL	**10**	**5**	**$4,888.00**	**$488.80**	**2**
EXTENDED-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 16MG ER	2	1	$219.50	$109.75	2
HYDROMORPHONE TAB 12MG ER	2	1	$541.86	$270.93	2
HYDROMORPHONE TAB 8MG ER	1	1	$93.09	$93.09	1
SUBTOTAL	**5**	**3**	**$854.45**	**$170.89**	**1.67**
LONG-ACTING SUBTOTAL	**17,227**	**4,360**	**$6,212,516.99**	**$360.63**	**3.95**
OPIOID TOTAL	**318,174**	**110,949***	**$11,167,646.46**	**$35.10**	**2.87**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
APAP = acetaminophen; ASA = aspirin; BUT = butalbital; CAF = caffeine; CAP = capsule; COD = codeine; CONC = concentrate; DIS = patch; ER = extended-release; HCL = hydrochloride; HYDROCOD = hydrocodone; IBU = ibuprofen; LIQ = liquid; MIS = film; NALOX = naloxone; OXYCOD = oxycodone; PENTAZ = pentazocine; SOL = solution; SULF = sulfate; TAB = tablet

Utilization Details of MAT Medications: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUPRENORPHINE MAT PRODUCTS					
BUPREN/NALOX SUB 8-2MG	40,371	5,585	$2,174,332.26	$53.86	7.23
BUPRENORPHIN SUB 8MG	6,769	940	$339,261.87	$50.12	7.2
BUPREN/NALOX SUB 2-0.5MG	3,000	658	$103,554.31	$34.52	4.56
BUPREN/NALOX MIS 8-2MG	1,735	235	$325,713.71	$187.73	7.38
SUBLOCADE INJ 300MG/1.5ML	1,027	345	$1,982,611.58	$1,930.49	2.98
BUPRENORPHIN SUB 2MG	937	245	$27,394.22	$29.24	3.82
SUBLOCADE INJ 100MG/0.5ML	671	176	$1,290,522.44	$1,923.28	3.81
ZUBSOLV SUB 5.7-1.4MG	179	19	$73,105.53	$408.41	9.42
SUBOXONE MIS 8-2MG	119	14	$98,440.66	$827.23	8.5
BUPREN/NALOX MIS 12-3MG	46	6	$18,421.02	$400.46	7.67
BUPREN/NALOX MIS 2-0.5MG	45	12	$3,311.42	$73.59	3.75

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZUBSOLV SUB 8.6-2.1MG	43	5	$41,514.05	$965.44	8.6
BUPREN/NALOX MIS 4-1MG	19	3	$2,239.15	$117.85	6.33
ZUBSOLV SUB 2.9-0.71MG	5	1	$1,906.27	$381.25	5
BRIXADI SOL 8MG/0.16ML	5	1	$2,132.05	$426.41	5
BRIXADI SOL 96MG/0.27ML	2	1	$3,212.82	$1,606.41	2
BRIXADI SOL 128MG/0.36ML	1	1	$1,606.41	$1,606.41	1
SUBTOTAL	**54,974**	**8,247**	**$6,489,279.77**	**$118.04**	**6.67**
NALTREXONE PRODUCTS					
NALTREXONE TAB 50MG	9,534	3,383	$319,301.22	$33.49	2.82
VIVITROL INJ 380MG	1,014	309	$1,544,592.54	$1,523.27	3.28
SUBTOTAL	**10,548**	**3,692**	**$1,863,893.76**	**$176.71**	**2.86**
MAT TOTAL	**65,522**	**10,559***	**$8,353,173.53**	**$127.49**	**6.21**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BUPREN = buprenorphine; INJ = injection; MAT = medication-assisted treatment; MIS = film; NALOX = naloxone; SOL = solution; SUB = sublingual tablet; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J2315 NALTREXONE INJ 1MG (VIVITROL)	26	7	$11,906.60	$457.95	3.71
Q9991 BUPRENORPHINE INJ 100MG (SUBLOCADE)	4	2	$6,973.92	$1,743.48	2
Q9992 BUPRENORPHINE INJ 300MG (SUBLOCADE)	3	2	$5,230.44	$1,743.48	1.5
MAT TOTAL	**33**	**11**	**$24,110.96**	**$730.64**	**3**

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 07/2024. Last accessed 07/12/2024.
[2] 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 07/2024. Last accessed 07/15/2024.
[3] 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.
[4] Substance Abuse and Mental Health Services Administration (SAMHSA). 42 CFR Part 8 Final Rule. Available online at: https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8. Last Updated 01/31/2024. Last accessed 07/16/2024.
[5] SAMHSA. The 42 CFR Part 8 Final Rule Table of Changes. Available online at: https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/final-rule-table-changes. Last Updated 01/31/2024. Last accessed 07/16/2024.
[6] 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 07/18/2024.

Appendix G

Calendar Year 2023 Annual Review of Topical Corticosteroids

Oklahoma Health Care Authority
August 2024

Current Prior Authorization Criteria

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	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	halobetasol propionate 0.01% (Bryhali®)	L
halobetasol propionate 0.05% (Ultravate®)	C,O	halcinonide 0.1% (Halog®)	C,O,So	halobetasol propionate 0.05%	F
		halobetasol propionate 0.05% (Ultravate®)	L		
		halobetasol propionate/lactic acid 0.05%/10% (Ultravate X®)	C		

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

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C	alclometasone dipropionate 0.05% (Aclovate®)	O
fluocinolone acetonide 0.01% (Capex®)	Sh	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	hydrocortisone/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

Topical Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 topical corticosteroids of similar potency in the past 30 days that did not yield adequate relief; and
2. If Tier-1 trials are completed and do not yield adequate relief, the member must also provide a patient-specific, clinically significant reason for requesting a Tier-2 medication in the same potency instead of trying a higher potency; and
3. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage formulation of that medication in Tier-2 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over standard formulations.

Topical Corticosteroids Tier-3 Approval Criteria:

1. Documented trials of all Tier-1 and Tier-2 topical corticosteroids of similar potency in the past 90 days that did not yield adequate relief; and
2. If Tier-1 and Tier-2 trials are completed and do not yield adequate relief, the member must also provide a patient-specific, clinically significant reason for requesting a Tier-3 medication in the same potency instead of trying a higher potency; and
3. When the same medication is available in Tier-1 or Tier-2, a patient-specific, clinically significant reason must be provided for using a special dosage form of that medication in Tier-3 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

Utilization of Topical Corticosteroids: Calendar Year 2023

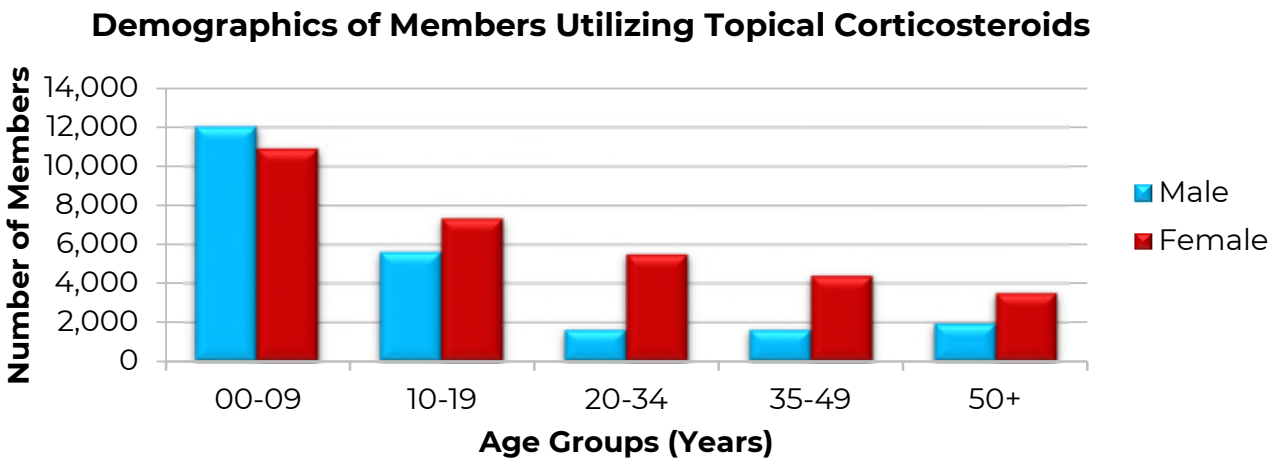
Comparison of Calendar Years

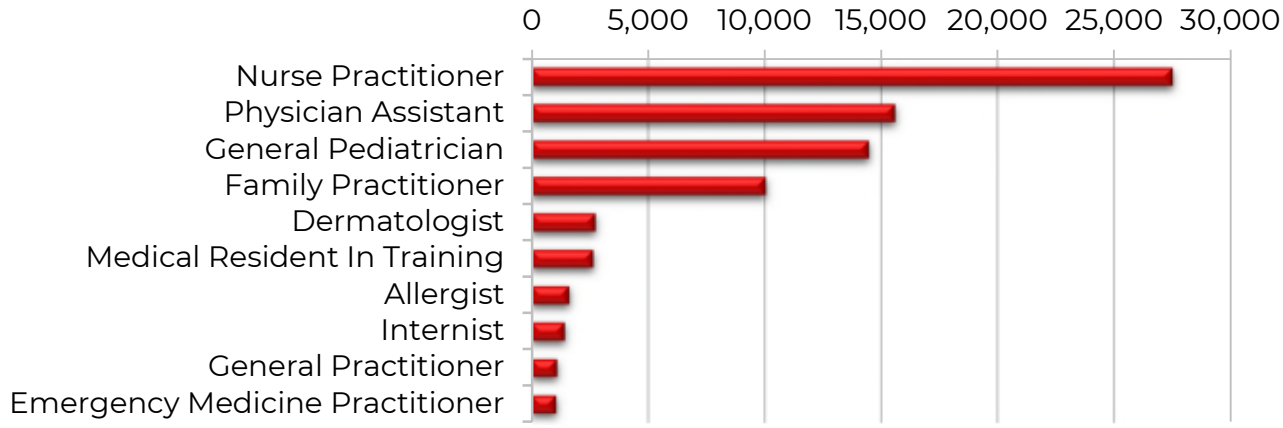
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	48,090	73,517	$1,217,084.53	$16.56	$0.88	5,597,195	1,384,151
2023	54,274	82,135	$1,322,064.88	$16.10	$0.84	6,083,763	1,566,475
% Change	**12.90%**	**11.70%**	**8.60%**	**-2.80%**	**-4.50%**	**8.70%**	**13.20%**
Change	**6,184**	**8,618**	**$104,980.35**	**-$0.46**	**-$0.04**	**486,568**	**182,324**

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

- Aggregate drug rebates collected during calendar year 2023 for topical corticosteroids totaled $44,017.29.[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.

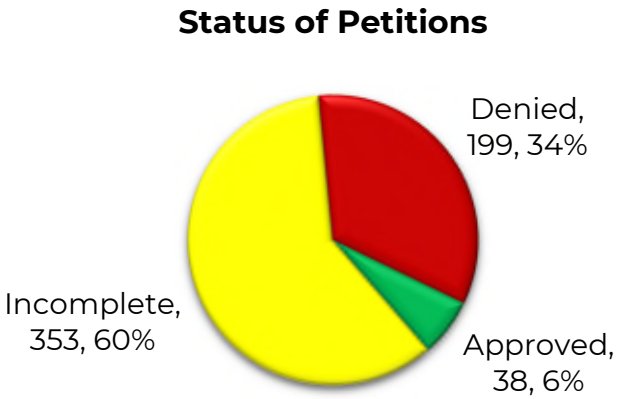
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.





Prior Authorization of Topical Corticosteroids

There were 590 prior authorization requests submitted for topical corticosteroids during calendar year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Topicort® (desoximetasone 0.25% spray): September 2028
- Bryhali® (halobetasol propionate 0.01% lotion): November 2031
- Enstilar® (calcipotriene/betamethasone dipropionate 0.064%/0.005% foam): December 2031
- Ultravate® (halobetasol 0.05% lotion): June 2033

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	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**
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.12% (Luxiq®)	F	**clocortolone pivalate 0.1% (Cloderm®)**	**C**

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

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

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

Utilization Details of Topical Corticosteroids: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
LOW POTENCY PRODUCTS						
HYDROCORTISONE CRE 2.5%	6,061	4,827	$75,864.36	$12.52	1.26	5.74%
TRIAMCINOLONE CRE 0.025%	4,320	3,519	$55,839.96	$12.93	1.23	4.22%
HYDROCORTISONE OINT 2.5%	4,131	2,874	$67,232.45	$16.28	1.44	5.09%
HYDROCORTISONE CRE 1%	1,033	903	$10,498.73	$10.16	1.14	0.79%
HYDROCORTISONE OINT 1%	702	618	$9,168.75	$13.06	1.14	0.69%
HYDROCORTISONE LOT 2.5%	408	325	$11,615.49	$28.47	1.26	0.88%
DESONIDE CRE 0.05%	324	259	$8,329.26	$25.71	1.25	0.63%
DESONIDE OINT 0.05%	176	130	$5,448.38	$30.96	1.35	0.41%
TRIAMCINOLONE LOT 0.025%	144	124	$5,040.60	$35.00	1.16	0.38%
FLUOCINOLONE ACT SOL 0.01%	144	94	$3,731.38	$25.91	1.53	0.28%
HYDROCORTISONE POW	95	76	$1,445.92	$15.22	1.25	0.11%
TRIAMCINOLONE ACT POW	19	19	$493.62	$25.98	1	0.04%
HYDROCORTISONE MICRO POW	2	2	$60.50	$30.25	1	0.00%
SUBTOTAL	**17,559**	**13,770**	**$254,769.40**	**$14.51**	**1.28**	**19.27%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE CRE 0.1%	26,875	21,039	$364,612.75	$13.57	1.28	27.58%
TRIAMCINOLONE OINT 0.1%	16,047	12,191	$247,617.29	$15.43	1.32	18.73%
TRIAMCINOLONE CRE 0.5%	3,229	2,457	$49,257.61	$15.25	1.31	3.73%
TRIAMCINOLONE OINT 0.025%	2,766	2,260	$41,279.11	$14.92	1.22	3.12%
TRIAMCINOLONE OINT 0.5%	1,341	1,082	$25,193.52	$18.79	1.24	1.91%
MOMETASONE CRE 0.1%	903	650	$20,572.12	$22.78	1.39	1.56%
BETAMETH VAL CRE 0.1%	500	375	$14,362.48	$28.72	1.33	1.09%
FLUTICASONE CRE 0.05%	437	327	$10,263.97	$23.49	1.34	0.78%
TRIAMCINOLONE LOT 0.1%	399	335	$11,687.03	$29.29	1.19	0.88%
BETAMETH VAL OINT 0.1%	316	239	$9,321.17	$29.50	1.32	0.71%
MOMETASONE OINT 0.1%	277	184	$5,114.51	$18.46	1.51	0.39%
MOMETASONE SOL 0.1%	165	112	$4,543.53	$27.54	1.47	0.34%
BETAMETH DIP LOT 0.05%	149	99	$4,586.21	$30.78	1.51	0.35%
FLUTICASONE OIN 0.005%	76	51	$2,231.99	$29.37	1.49	0.17%
SUBTOTAL	**53,480**	**41,401**	**$810,643.29**	**$15.16**	**1.29**	**61.32%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL CRE 0.05%	2,596	1,725	$48,600.76	$18.72	1.5	3.68%
CLOBETASOL SOL 0.05%	2,523	1,481	$56,385.53	$22.35	1.7	4.26%
CLOBETASOL OINT 0.05%	2,108	1,386	$39,062.52	$18.53	1.52	2.95%
BETAMETH DIP CRE 0.05%	1,012	805	$31,902.78	$31.52	1.26	2.41%
FLUOCINONIDE SOL 0.05%	774	482	$19,369.35	$25.03	1.61	1.47%
AUG BETAMETH DIP CRE 0.05%	660	491	$10,953.78	$16.60	1.34	0.83%
BETAMETH DIP OINT 0.05%	401	293	$16,494.35	$41.13	1.37	1.25%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FLUOCINONIDE OINT 0.05%	301	188	$7,880.63	$26.18	1.6	0.60%
FLUOCINONIDE CRE 0.05%	218	129	$8,057.31	$36.96	1.69	0.61%
AUG BETAMETH DIP OINT 0.05%	129	96	$4,327.55	$33.55	1.34	0.33%
CLOBETASOL EMOL CRE 0.05%	120	81	$5,129.70	$42.75	1.48	0.39%
HALOBETASOL OINT 0.05%	73	51	$2,346.91	$32.15	1.43	0.18%
HALOBETASOL CRE 0.05%	67	41	$2,048.78	$30.58	1.63	0.15%
FLUOCINONIDE CRE 0.1%	23	15	$533.48	$23.19	1.53	0.04%
DESOXIMETASONE CRE 0.25%	22	19	$581.42	$26.43	1.16	0.04%
CLOBETASOL FOAM 0.05%	19	18	$714.49	$37.60	1.06	0.05%
DESOXIMETASONE OINT 0.25%	12	10	$273.37	$22.78	1.2	0.02%
SUBTOTAL	**11,058**	**7,311**	**$254,662.71**	**$23.03**	**1.51**	**19.26%**
TIER-1 TOTAL	**82,097**	**62,482**	**$1,320,075.40**	**$16.08**	**1.31**	**99.85%**
TIER-2 UTILIZATION						
LOW POTENCY PRODUCTS						
FLUOCINOLONE ACT SCALP OIL 0.01%	7	2	$235.92	$33.70	3.5	0.02%
FLUOCINOLONE ACT BODY OIL 0.01%	2	2	$69.90	$34.95	1	0.01%
DERMA-SMOOTH FS BODY OIL 0.01%	1	1	$46.27	$46.27	1	0.00%
SUBTOTAL	**10**	**5**	**$352.09**	**$35.21**	**2**	**0.03%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE OINT 0.05%	2	2	$457.61	$228.81	1	0.03%
SUBTOTAL	**2**	**2**	**$457.61**	**$228.81**	**1**	**0.03%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL LOT 0.05%	12	2	$662.91	$55.24	6	0.05%
CLOBETASOL SHA 0.05%	10	2	$209.42	$20.94	5	0.02%
FLUOCINONIDE GEL 0.05%	2	2	$64.63	$32.32	1	0.00%
SUBTOTAL	**24**	**6**	**$936.96**	**$39.04**	**4**	**0.07%**
TIER-2 TOTAL	**36**	**13**	**$1,746.66**	**$48.52**	**2.77**	**0.13%**
TIER-3 UTILIZATION						
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
DESOXIMETASONE CRE 0.05%	2	1	$242.82	$121.41	2	0.02%
TIER-3 TOTAL	**2**	**1**	**$242.82**	**$121.41**	**2**	**0.02%**
TOTAL	**82,135**	**54,274***	**$1,322,064.88**	**$16.10**	**1.51**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = acetonide; AUG = augmented; BETAMETH = betamethasone; CRE = cream; DIP = dipropionate; EMOL = emollient; LOT = lotion; MICRO = micronized; OINT = ointment; POW = powder; SOL = solution; SHA = shampoo; VAL = valerate

[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 07/2024. Last accessed 07/17/2024.

Appendix H

Calendar Year 2023 Annual Review of Various Systemic Antibiotics and 30-Day Notice 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)

Oklahoma Health Care Authority
August 2024

Current Prior Authorization Criteria

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®)
   - 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®)

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or

    c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 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, 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).

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible bacteria; and
2. 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
3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible bacteria; and
2. 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, monotherapy with a respiratory fluoroquinolone (e.g., levofloxacin, moxifloxacin, gemifloxacin), 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); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-

specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

Cedax® (Ceftibuten) and Suprax® (Cefixime) Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent; and
2. A patient-specific, clinically significant reason why member cannot use cephalexin, cefdinir, or other cost effective therapeutic equivalent medication(s) must be provided.

Ciprofloxacin 100mg Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use alternative strengths of ciprofloxacin tablets, levofloxacin tablets, moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

Ciprofloxacin 500mg and 1,000mg Extended-Release (ER) Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use the immediate-release formulation of ciprofloxacin tablets, levofloxacin tablets, moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

Ciprofloxacin 250mg/mL and 500mg/mL Oral Suspension and Levofloxacin 25mg/mL Oral Solution Approval Criteria:

1. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations cannot be used.

Dalvance® (Dalbavancin) Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent and resistant to the cephalosporin-class of antibiotics and other antibiotics commonly used for diagnosis or infection; and
2. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, or other cost effective therapeutic equivalent medication(s) must be provided; and
3. A quantity limit of 3 vials per 7 days will apply.

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
    a. Complicated urinary tract infection (cUTI), including pyelonephritis; or
    b. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and

3. 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).

Kimyrsa™ (Oritavancin) Approval Criteria:

1. An FDA approved indication for the treatment of acute bacterial skin and skin structure infection (ABSSSI) caused or suspected to be caused by susceptible isolates of designated gram-positive microorganisms; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use Orbactiv® (oritavancin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Minocycline (50, 75, 100mg) Immediate-Release (IR) Tablet:

1. Approval requires a patient-specific, clinically significant reason why the member requires the IR tablet formulation and cannot use the IR capsule formulation and/or other cost effective therapeutic equivalent medication(s).

Nuzyra® (Omadacycline) Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible microorganisms; 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. Use of Nuzyra® vials will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Nuzyra® (Omadacycline) Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible microorganisms; 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 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. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).
    a. For Nuzyra® vials, an initial quantity limit of 4 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablet formulation for the remainder of therapy.

Ofloxacin 300mg and 400mg Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use ciprofloxacin tablets, levofloxacin tablets, moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

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

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

Seysara® (Sarecycline) Approval Criteria:

1. An FDA approved diagnosis of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Seysara® is not covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use minocycline, doxycycline, tetracycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and

5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate strength according to package labeling; and
6. A quantity limit of 30 tablets per 30 days will apply.

Sivextro® (Tedizolid) Tablet and Vial Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent and resistant to the cephalosporin class of antibiotics and other antibiotics commonly used for diagnosis or infection; and
2. A patient-specific, clinically significant reason why the member cannot use linezolid or other cost effective therapeutic equivalent medication(s) must be provided; and
3. A quantity limit of 6 tablets or vials per 6 days will apply.

Solosec® (Secnidazole Oral Granules) Approval Criteria:

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

Tetracycline 250mg and 500mg Capsule 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).

Vabomere® (Meropenem/Vaborbactam Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI) or pyelonephritis; 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; 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
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).

Xenleta® (Lefamulin) Approval Criteria:

1. An FDA approved diagnosis of community-acquired bacterial pneumonia (CABP) caused by designated susceptible microorganisms; 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 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. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Xerava™ (Eravacycline) Approval Criteria:

1. An FDA approved diagnosis of complicated intra-abdominal infection (cIAI) caused by designated susceptible microorganisms; 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, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Zemdri® (Plazomicin) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including pyelonephritis, caused by designated susceptible microorganisms; and

2. A patient-specific, clinically significant reason why the member cannot use an appropriate alternative aminoglycoside (e.g., gentamicin, tobramycin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

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

Utilization of Various Systemic Antibiotics: Calendar Year 2023

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	323	472	$745,866.12	$1,580.22	$118.22	50,089	6,309
2023	302	440	$554,797.26	$1,260.90	$99.05	45,376	5,601
% Change	**-6.50%**	**-6.80%**	**-25.60%**	**-20.20%**	**-16.20%**	**-9.40%**	**-11.20%**
Change	**-21**	**-32**	**-$191,068.86**	**-$319.32**	**-$19.17**	**-4,713**	**-708**

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

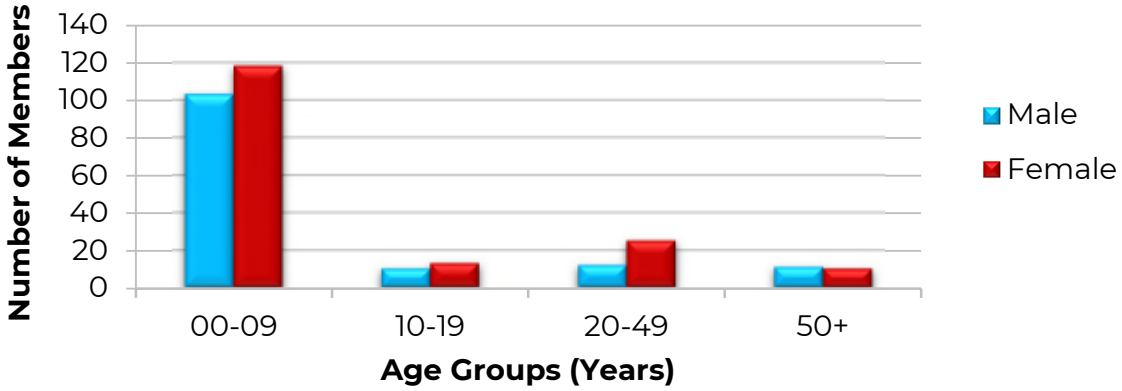
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	19	28	$126,388.80	$4,513.87	1.47
2023	18	101	$141,831.20	$1,404.27	5.61
% Change	**-5.26%**	**260.71%**	**12.22%**	**-68.89%**	**281.63%**
Change	**-1**	**73**	**$15,442.40**	**-$3,109.60**	**4.14**

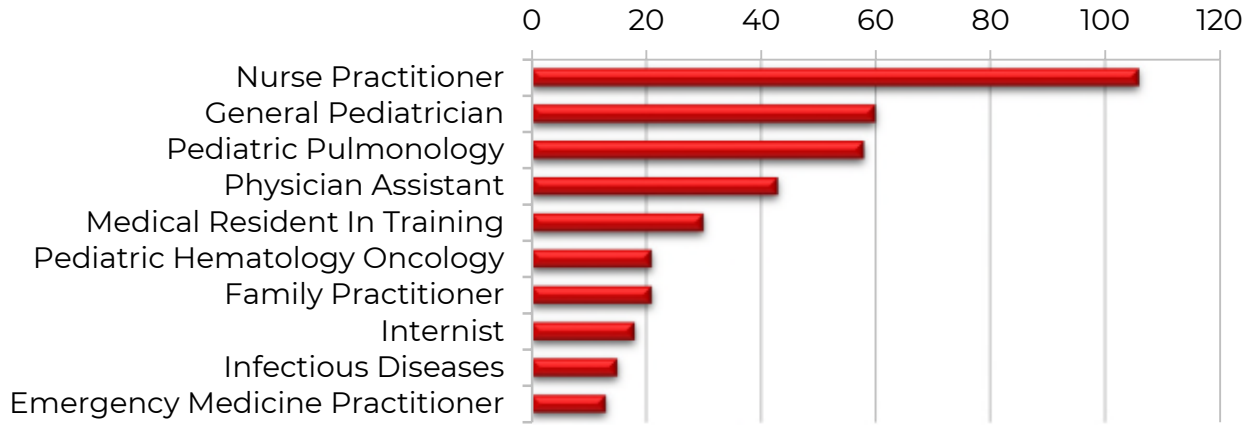
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

- Aggregate drug rebates collected during calendar year 2023 for the various systemic antibiotics totaled $101,897.57.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Various Systemic Antibiotics



Top Prescriber Specialties of Various Systemic Antibiotics by Number of Claims

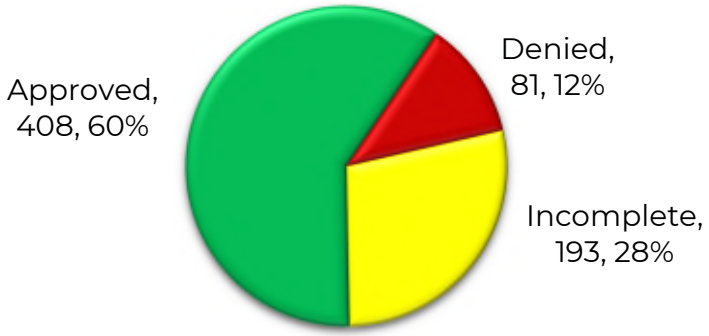


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Prior Authorization of Various Systemic Antibiotics

There were 682 prior authorization requests submitted for various systemic antibiotics 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]

Anticipated Patent Expiration(s):

- Ximino® [minocycline extended-release (ER) capsule]: April 2027
- Doryx® [doxycycline hyclate delayed-release (DR) tablet]: February 2028
- Dalvance® [dalbavancin vial for intravenous (IV) infusion]: May 2028
- Suprax® (cefixime 500mg/5mL oral suspension): December 2028
- Xenleta® (lefamulin vial for IV infusion): January 2029
- Exblifep® (cefepime/enmetazobactam vial for IV infusion): February 2029
- Recarbrio™ (imipenem/cilastatin/relebactam vial for IV infusion): November 2029
- Sivextro® (tedizolid tablet and vial for IV infusion): December 2030
- Xenleta® (lefamulin tablet): May 2031
- Baxdela® (delafloxacin tablet): June 2031
- Zemdri® (plazomicin vial for IV infusion): June 2031
- Solodyn® (minocycline ER tablet): November 2031
- Avycaz® (ceftazidime/avibactam vial for IV infusion): June 2032
- Baxdela® (delafloxacin vial for IV infusion): February 2033
- Seysara® (sarecycline tablet): February 2033
- Zevtera® (ceftobiprole medocaril sodium vial for IV infusion): April 2034
- Doryx® MPC (doxycycline hyclate DR tablet): October 2034
- Orbactiv® (oritavancin vial for IV infusion): July 2035
- Kimyrsa™ (oritavancin vial for IV infusion): July 2035
- Zerbaxa® (ceftolozane/tazobactam vial for IV infusion): August 2035
- Fetroja® (cefiderocol vial for IV infusion): September 2035
- Solosec® (secnidazole 2g oral granules): September 2035
- Xacduro® (sulbactam/durlobactam vial for IV infusion): November 2035

- Nuzyra® (omadacycline tablet and vial for IV infusion): October 2037
- Xerava™ (eravacycline vial for IV infusion): October 2037
- Vabomere® (meropenem/vaborbactam vial for IV infusion): April 2039

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 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.

Pipeline:

- **Zoliflodacin:** In April 2024, Innoviva Specialty Therapeutics announced positive results from a Phase 3 trial for zoliflodacin, a first-in-class antibiotic. Zoliflodacin 3 gram oral suspension was evaluated as a single dose for the treatment of uncomplicated gonorrhea and was found to be non-inferior to 500mg of intramuscular ceftriaxone in combination with 1 gram of oral azithromycin. Zoliflodacin demonstrated efficacy at urogenital and extragenital sites of infection. The manufacturer plans to file an application for approval with the FDA in early 2025.

Exblifep® (Cefepime/Enmetazobactam) Product Summary[15,16]

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[17]

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 *Prescribing Information* 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[18,19,20,21]

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)	$0.24	$0.48⁺
doxycycline monohydrate 100mg cap (generic)	$0.21	$0.42⁺

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)	$5.93	$11.86	$35.58
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).

Utilization Details of Various Systemic Antibiotics: Calendar Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEVOFLOXACIN PRODUCTS					
LEVOFLOXACIN SOL 25MG/ML	179	117	$22,970.16	$128.32	1.53
SUBTOTAL	**179**	**117**	**$22,970.16**	**$128.32**	**1.53**
CIPROFLOXACIN PRODUCTS					
CIPRO 10% SUS 500MG/5ML	88	65	$16,174.92	$183.81	1.35
CIPRO 5% SUS 250MG/5ML	75	69	$12,454.45	$166.06	1.09
CIPROFLOXACIN 5% SUS 250MG/5ML	1	1	$108.93	$108.93	1
SUBTOTAL	**164**	**135**	**$28,738.30**	**$175.23**	**1.21**
TETRACYCLINE PRODUCTS					
TETRACYCLINE CAP 500MG	28	27	$1,550.28	$55.37	1.04
TETRACYCLINE CAP 250MG	2	1	$103.32	$51.66	2
SUBTOTAL	**30**	**28**	**$1,653.60**	**$55.12**	**1.07**
OMADACYCLINE PRODUCTS					
NUZYRA TAB 150MG	27	15	$294,804.11	$10,918.67	1.8
SUBTOTAL	**27**	**15**	**$294,804.11**	**$10,918.67**	**1.8**
CEFIXIME PRODUCTS					
CEFIXIME CAP 400MG	6	3	$839.07	$139.85	2
CEFIXIME SUS 200MG/5ML	4	4	$554.10	$138.53	1
CEFIXIME SUS 100MG/5ML	3	2	$320.52	$106.84	1.5
SUBTOTAL	**13**	**9**	**$1,713.69**	**$131.82**	**1.44**
TEDIZOLID PRODUCTS					
SIVEXTRO TAB 200MG	9	4	$131,591.33	$14,621.26	2.25

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**9**	**4**	**$131,591.33**	**$14,621.26**	**2.25**
CEFTOLOZANE/TAZOBACTAM PRODUCTS					
ZERBAXA INJ 1.5GM	9	5	$39,071.89	$4,341.32	1.8
SUBTOTAL	**9**	**5**	**$39,071.89**	**$4,341.32**	**1.8**
CEFTAZIDIME/AVIBACTAM PRODUCTS					
AVYCAZ INJ 2-0.5GM	5	3	$31,703.97	$6,340.79	1.67
SUBTOTAL	**5**	**3**	**$31,703.97**	**$6,340.79**	**1.67**
DOXYCYCLINE PRODUCTS					
DOXYCYCLINE HYC TAB 200MG DR	1	1	$761.59	$761.59	1
DOXYCYCLINE HYC TAB 75MG	1	1	$66.00	$66.00	1
SUBTOTAL	**2**	**2**	**$827.59**	**$413.80**	**1**
DELAFLOXACIN PRODUCTS					
BAXDELA TAB 450MG	1	1	$1,605.41	$1,605.41	1
SUBTOTAL	**1**	**1**	**$1,605.41**	**$1,605.41**	**1**
AMOXICILLIN PRODUCTS					
AMOX-POT CLA TAB ER 1000-62.5MG	1	1	$117.21	$117.21	1
SUBTOTAL	**1**	**1**	**$117.21**	**$117.21**	**1**
TOTAL	**440**	**302***	**$554,797.26**	**$1,260.90**	**1.46**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMOX-POT CLA = amoxicillin/clavulanate potassium; CAP = capsule; DR = delayed release; ER = extended-release; HYC = hyclate; INJ = injection; SOL = solution; SUS = suspension; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
CEFTOLOZANE-TAZO INJ (J0695)	76	2	$34,260.00	$450.79	38
DALBAVANCIN INJ (J0875)	24	15	$102,602.00	$4,275.00	1.6
ORITAVANCIN (KIMYRSA) INJ (J2406)	1	1	$4,969.20	$4,969.20	1
TOTAL	**101†**	**18***	**$141,831.20**	**$1,404.27**	**4.8**

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

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Appendix I

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 2, 2024

FDA Approves First Gene Therapy to Treat Adults with Metastatic Synovial Sarcoma

The FDA approved Tecelra® (afamitresgene autoleucel), a gene therapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA antigen(s) A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive, and whose tumor expresses the MAGE-A4 antigen as determined by FDA authorized companion diagnostic devices.

Synovial sarcoma is a rare form of cancer in which malignant cells develop and form a tumor in soft tissues of the body. This type of cancer can occur in many parts of the body, most commonly developing in the extremities. The cancerous cells may also spread to other parts of the body. Each year, synovial sarcoma impacts about 1,000 people in the United States and most often occurs in adult males in their 30s or younger. Treatment typically involves surgery to remove the tumor and may also include radiotherapy and/or chemotherapy if the tumor is larger, returns after being removed, or has spread beyond its original location.

Tecelra® is also the first FDA-approved T cell receptor (TCR) gene therapy. The product is an autologous T cell immunotherapy composed of a patient's own T cells. T cells in Tecelra® are modified to express a TCR that targets MAGE-A4, an antigen expressed by cancer cells in synovial sarcoma. The product is administered as a single intravenous (IV) dose.

The safety and effectiveness of Tecelra® were evaluated in a multicenter, open-label clinical trial including patients with inoperable and metastatic synovial sarcoma who had received prior systemic therapy and whose tumor expressed the MAGE-A4 tumor antigen. Effectiveness was evaluated based on overall response rate and the duration of response to treatment with Tecelra®. Among the 44 patients in the trial who received Tecelra®, the overall response rate was 43.2% and the median duration of response was 6 months.

The most common adverse reactions associated with Tecelra® included nausea, vomiting, fatigue, infections, fever, constipation, dyspnea, abdominal pain, non-cardiac chest pain, decreased appetite, tachycardia, back pain, hypotension, diarrhea, and edema.

Patients treated with Tecelra® may experience cytokine release syndrome (CRS), which is a dangerous type of aggressive immune system response, including potentially life-threatening reactions. CRS was observed following administration of Tecelra® during clinical trials. A *Boxed Warning* is included in the label containing information about this risk.

Patients may also exhibit Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), an immune system-related syndrome that can occur following some immunotherapies, infections, secondary malignancies, or hypersensitivity reactions, and severe cytopenia for several weeks following lymphodepleting chemotherapy and Tecelra® infusion. Patients receiving this product should be monitored for signs and symptoms of infection and are advised not to drive or engage in hazardous occupations or activities for at least 4 weeks after receiving Tecelra®.

The FDA granted Tecelra® Orphan Drug, Regenerative Medicine Advanced Therapy, and Priority Review designations for this indication. This application was reviewed using a coordinated, cross-agency approach, including CBER, the FDA's Oncology Center of Excellence, and the Center for Devices and Radiological Health. The FDA granted the approval of Tecelra® to Adaptimmune, LLC.

FDA NEWS RELEASE

For Immediate Release: July 8, 2024

FDA Updates Guidance to Further Empower Companies to Address the Spread of Misinformation

The FDA is advancing its mission of ensuring the public has access to accurate, up-to-date science-based information to inform decisions about FDA-regulated medical products to maintain and improve their health. The FDA is providing updated recommendations to empower industry seeking to voluntarily address misinformation about or related to their approved/cleared medical products.

In today's health care system, health care providers and consumers often turn to the internet to obtain health and medical-related information. However, not all information found online about medical products is reliable. There are many false statements and conclusions shared online and the structure and popularity of social media platforms have meant that false, inaccurate, and/or misleading information about medical products can spread rapidly to a broad audience. Basing medical decisions on inaccurate information can have adverse consequences as it can lead patients and health care providers to choose treatments that are not safe and effective, or to forgo treatments that are. The FDA believes it is critically important to promptly address misinformation about medical products. The revised draft guidance issued today supports the efforts of medical product companies that share this interest in helping the public get factual, accurate, and scientifically sound information about medical products.

Specifically, the revised draft guidance, *Addressing Misinformation About Medical Devices and Prescription Drugs Questions and Answers*, sets out a policy that supports companies that issue certain kinds of internet-based communications to address internet-based misinformation about or related to their approved/cleared medical products when that misinformation is created or disseminated by an independent third party. For example, a company might choose to use this type of communication when a celebrity, health care provider, or influencer, not acting on behalf of the company, posts false, inaccurate, and/or misleading representations of fact about the company's approved/cleared medical product on social media. Additionally, this revised draft guidance provides companies with many examples that illustrate the types of misinformation found online that a company might choose to address with a tailored responsive communication, along with some considerations relevant to the current digital information environment.

The revised draft guidance also describes existing avenues that companies might also choose to use to address misinformation about their medical products wherever that misinformation may appear. This draft guidance revises and replaces the draft guidance for industry, *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices*, issued in June 2014. The revised draft guidance is open for public comment for 60 days.

In addition to providing these updated draft recommendations, the FDA has taken and will continue to take steps to communicate accurate, up-to-date, science-based information to the public. Some examples of such efforts include:

- Providing timely, digestible, factual information to news media and other organizations;
- Creating resources on the FDA's website and social media to address common questions about the products the agency regulates;
- Participating in speaking engagements to draw attention to the dangers of misinformation and to provide factual information about FDA-regulated medical products and public health issues;
- Providing interested parties with toolkits of resources; and
- Posting memos and other regulatory documents that outline the agency's decision-making, consistent with applicable law(s).

The FDA will continue to proactively offer resources about medical products to provide factual and scientifically sound information to the public. The FDA remains committed to helping address misinformation and continues to support other interested parties that choose to engage on this critical issue.

Current Drug Shortages Index (as of July 31, 2024):

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

Albuterol Sulfate Solution	***Currently in Shortage***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***

Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
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***
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***
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sucralfate Tablet	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***
Vitamin A Palmitate Injection	***Currently in Shortage***