OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, August 10, 2022

No live meeting scheduled for August.
August 2022 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 10, 2022

DATE: August 3, 2022

NOTE: No live August meeting. August 2022 is a packet-only meeting.

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

DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit/Use of Statins in Members with Diabetes Mellitus (DM) – Appendix B

30-Day Notice to Prior Authorize Camzyos™ (Mavacamten) – Appendix C

Annual Review of Intravenous (IV) Iron Products – Appendix D

Annual Review of Ophthalmic Anti-Inflammatory Products – Appendix E

Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – Appendix F

Annual Review of Topical Corticosteroids – Appendix G

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

Future Business

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Packet – August 10, 2022

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

NOTE: ***No live August meeting. August 2022 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 13, 2022 DUR Board Meeting Minutes
   B. July 13, 2022 DUR Board Recommendations Memorandum

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

2. **Update on Medication Coverage Authorization Unit/Use of Statins in Members with Diabetes Mellitus (DM) – See Appendix B**
   A. Pharmacy Helpdesk Activity for July 2022
   B. Medication Coverage Activity for July 2022
   C. Use of Statins in Members with DM

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

3. **30-Day Notice to Prior Authorize Camzyos™ (Mavacamten) – See Appendix C**
   A. Introduction
   B. Camzyos™ (Mavacamten) Product Summary
   C. College of Pharmacy Recommendations

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

4. **Annual Review of Intravenous (IV) Iron Products – See Appendix D**
   A. Current Prior Authorization Criteria
   B. Utilization of IV Iron Products
   C. Prior Authorization of IV Iron Products
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of IV Iron Products

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

5. **Annual Review of Ophthalmic Anti-Inflammatory Products – See Appendix E**
   A. Current Prior Authorization Criteria

B. Utilization of Ophthalmic Anti-Inflammatory Products
C. Prior Authorization of Ophthalmic Anti-Inflammatory Products
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Ophthalmic Anti-Inflammatory Products

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

6. **Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – See Appendix F**

A. Current Prior Authorization Criteria: Opioid Analgesics
B. Current Prior Authorization Criteria: MAT Medications
C. Utilization of Opioid Analgesics and MAT Medications
D. Prior Authorization of Opioid Analgesics and MAT Medications
E. Market News and Updates
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. Ha, Dr. Muchmore, Chairman:

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

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

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

A. Amyloidosis Medications
B. Breast Cancer Medications
C. Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators
D. Synagis® (Palivizumab)

*Future product and class reviews subject to change.

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 13, 2022

DUR BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.		X
Jennifer de los Angeles, Pharm.D., BCOP	X	
Jennifer Boyett, MHS; PA-C	X	
Megan A. Hanner, D.O.	X	
Lynn Mitchell, M.D.; Vice Chairwoman		X
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.	X	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Wendi Chandler, Pharm.D.; Clinical Pharmacist	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Thomas Ha, Pharm.D.; Clinical Pharmacist	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Thara Kottoor, Pharm.D.; Pharmacy Resident	X	
Morgan Masterson, Pharm.D; 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	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor		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: Allison Baxley, Pharm.D., BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.	X	
Laura Tidmore, Pharm.D.	X	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony; Chief Operating Officer		X
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief of Staff		X
Kevin Corbett, C.P.A.; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Josh Holloway, J.D.; Deputy General Counsel	X	

Debra Montgomery, D.O.; Medical Director		X
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim 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:	
Kenneth Berry, Alkermes	Audrey Rattan, Alkermes
Robert Greely, Biogen	Christopher Ngai, Calliditas
Ed Eldridge, Gilead	Frank Alvarado, Johnson & Johnson
Ed Clasby, Medtronic	Christy Olson, Medtronic
Shellie Keast, Mercer	Brent Parker, Merck
Mark Kaiser, Otsuka	Marc Parker, Sunovion
Bob Atkins, Biogen	Heather Higgins, Jazz
Sheri Jepsen, Seagen	Steven Angelcyk, Embecta
Tom Seignious, Azurity	Robin Selsor, Aimmune
Evie Knisely, Novartis	Bettina Buob, Neurelis
Maggie Shaffer, Alzheimer's Association	Burl Beasley, OMES
Aaron Austin, Takeda	Rhonda Clark, Indivior
Gina Heinen, Novo Nordisk	Himanshu Patel, McDermott, Will, & Emery
Jeff Knappen, Spark	Craig Irwin, Acadia
Raquel Jordan, Takeda	Tracey Maravilla, Ascendis
Chrystal Mayes, Sanofi	

PRESENT FOR PUBLIC COMMENT:	
Kenneth Berry, Alkermes	Christopher Ngai, Calliditas Therapeutics
Robert Greely, Biogen	

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:01pm. 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. 8 KENNETH BERRY
2B: AGENDA ITEM NO. 10 CHRISTOPHER NGAI
2C: AGENDA ITEM NO. 14 ROBERT GREELY
ACTION: NONE REQUIRED

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

3A: JUNE 8, 2022 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore
Dr. Muñoz moved to approve; seconded by Ms. Boyett

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 2022
4B: MEDICATION COVERAGE ACTIVITY FOR JUNE 2022
4C: CMA PROGRAM UPDATE

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

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE XELSTRYM™ (DEXTROAMPHETAMINE TRANSDERMAL SYSTEM) AND UPDATE THE APPROVAL CRITERIA FOR THE ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS**

5A: MARKET NEWS AND UPDATES
5B: XELSTRYM™ (DEXTROAMPHETAMINE TRANDSERMAL SYSTEM) PRODUCT SUMMARY
5C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Travers
Dr. Muñoz moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE LIVTENCITY™ (MARIBAVIR)**

6A: MARKET NEWS AND UPDATES
6B: LIVTENCITY™ (MARIBAVIR) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Ha
Dr. Muñoz moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE QUVIVIQ™ (DARIDOREXANT) AND UPDATE THE APPROVAL CRITERIA FOR THE INSOMNIA MEDICATIONS**

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

Materials included in agenda packet; presented by Dr. Ha
Dr. Muñoz moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE INVEGA HAFYERA™ (PALIPERIDONE PALMITATE INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS**

8A: MARKET NEWS AND UPDATES
8B: INVEGA HAFYERA™ (PALIPERIDONE PALMITATE) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH)**

9A: MARKET NEWS AND UPDATE
9B: RYPLAZIM® (PLASMINOGEN, HUMAN-TVMH) PRODUCT SUMMARY

9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE CITALOPRAM CAPSULE, DARTISLA ODT™ (GLYCOPYRROLATE ORALLY DISINTEGRATING TABLET), FLEQSUVY™ (BACLOFEN ORAL SUSPENSION), LOFENA™ (DICLOFENAC POTASSIUM TABLET), LOREEV XR™ (LORAZEPAM EXTENDED-RELEASE CAPSULE), NORLIQVA® (AMLODIPINE BESYLATE ORAL SOLUTION), SEGLENTIS® (CELECOXIB/TRAMADOL TABLET), SUTAB® (SODIUM SULFATE/MAGNESIUM SULFATE/POTASSIUM CHLORIDE TABLET), TARPEYO™ (BUDESONIDE DELAYED-RELEASE CAPSULE), VUITY™ (PILOCARPINE 1.25% OPHTHALMIC SOLUTION), AND XIPERE™ (TRIAMCINOLONE ACETONIDE INJECTION)
10A: INTRODUCTION
10B: PRODUCT SUMMARIES AND COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
Dr. Muñoz moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE CAMCEVI™ (LEUPROLIDE), PLUVICTO® (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN), TIVDAK® (TISOTUMAB VEDOTIN-TFTV), AND WELIREG™ (BELZUTIFAN) AND UPDATE THE APPROVAL CRITERIA FOR THE GENITOURINARY AND CERVICAL/ENDOMETRIAL CANCER MEDICATIONS
11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Muñoz moved to approve; seconded by Ms. Boyett
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF COLORECTAL CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALYMSYS® (BEVACIZUMAB-MALY), LONSURF® (TRIFLURIDINE/TIPIRACIL), AND STIVARGA® (REGORAFENIB)
12A: INTRODUCTION
12B: CURRENT PRIOR AUTHORIZATION CRITERIA
12C: UTILIZATION OF COLORECTAL CANCER MEDICATIONS
12D: PRIOR AUTHORIZATION OF COLORECTAL CANCER MEDICATIONS
12E: MARKET NEWS AND UPDATES
12F: PRODUCT SUMMARIES
12G: COLLEGE OF PHARMACY RECOMMENDATIONS
12H: UTILIZATION DETAILS OF COLORECTAL CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 13: ANNUAL REVIEW OF DANYELZA® (NAXITAMAB-GQGK), KOSELUGO® (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), QINLOCK™ (RIPRETINIB), AND TRUSELTIQ™ (INFIGRATINIB)
13A: INTRODUCTION
13B: CURRENT PRIOR AUTHORIZATION CRITERIA

13C: UTILIZATION OF DANYELZA® (NAXITAMAB-GQGK), KOSELUGO® (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), QINLOCK™ (RIPRETINIB), AND TRUSELTIQ™ (INFIGRATINIB)
13D: PRIOR AUTHORIZATION OF DANYELZA® (NAXITAMAB-GQGK), KOSELUGO® (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), QINLOCK™ (RIPRETINIB), AND TRUSELTIQ™ (INFIGRATINIB)
13E: MARKET NEWS AND UPDATES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF DANYELZA® (NAXITAMAB-GQGK), KOSELUGO® (SELUMETINIB), PEMAZYRE® (PEMIGATINIB), QINLOCK™ (RIPRETINIB), AND TRUSELTIQ™ (INFIGRATINIB)
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ALZHEIMER'S DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ADLARITY® (DONEPEZIL TRANSDERMAL SYSTEM) AND ADUHELM™ (ADUCANUMAB-AVWA)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
14C: PRIOR AUTHORIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: ADUHELM™ (ADUCANUMAB-AVWA) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: 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. 15: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE TLANDO® (TESTOSTERONE UNDECANOATE)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF TESTOSTERONE PRODUCTS
15C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
15D: MARKET NEWS AND UPDATES
15E: COST COMPARISON
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS
Materials included in agenda packet; presented by Dr. Chandler
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 16: ANNUAL REVIEW OF VARIOUS SYSTEMIC ANTIBIOTICS
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF VARIOUS SYSTEMIC ANTIBIOTICS
16C: PRIOR AUTHORIZATION OF VARIOUS SYSTEMIC ANTIBIOTICS
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS
16F: UTILIZATION DETAILS OF VARIOUS SYSTEMIC ANTIBIOTICS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: ANNUAL REVIEW OF ISTURISA® (OSILODROSTAT) AND 30-DAY NOTICE TO PRIOR AUTHORIZE RECORLEV® (LEVOKETOCONAZOLE)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA

17B: UTILIZATION OF ISTURISA® (OSILODROSTAT)
17C: PRIOR AUTHORIZATION OF ISTURISA® (OSILODROSTAT)
17D: MARKET NEWS AND UPDATES
17E: RECORLEV® (LEVOKETOCONAZOLE) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ha
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 18: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
No live DUR Board meeting scheduled for August 2022. August 2022 will be a packet-only meeting.
19A: INTRAVENOUS (IV) IRON PRODUCTS
19B: OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
19C: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
19D: TOPICAL CORTICOSTEROIDS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: ADJOURNMENT
The meeting was adjourned at 5:40pm.

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

Memorandum

Date: July 15, 2022

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 13, 2022

Recommendation 1: Chronic Medication Adherence (CMA) Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Xelstrym™ (Dextroamphetamine Transdermal System) and Update the Approval Criteria for Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications

MOTION CARRIED by unanimous approval.

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

1. Updating the approval criteria for Qelbree® (viloxazine) based on the recent FDA approved age expansion
2. Updating the approval criteria for Xywav® (calcium/magnesium/ potassium/sodium oxybates) based on the recent FDA approval for idiopathic hypersomnia
3. The prior authorization of Dyanavel XR® [amphetamine extended-release (ER) tablets] and placement into Tier-2 of the Long-Acting Stimulants category of the ADHD Medications PBPA Tier chart

4. The prior authorization of Xelstrym™ (dextroamphetamine transdermal system) and placement into the Special PA Tier of the ADHD Medications PBPA Tier chart with the following additional criteria

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

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

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.

+Unique criteria applies for the diagnosis of binge eating disorder (BED).

ΔUnique criteria applies in addition to tier trial requirements.

ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

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

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 365 days; and

b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, Vyvanse® Chewable Tablets, and Xelstrym™ Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, Dexedrine Spansules®, Evekeo®, ProCentra®, and Zenzedi® Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Mydayis® Approval Criteria:
   a. A covered diagnosis; and
   b. Member must be 13 years of age or older; and
   c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 ~~to 17~~ years of age or older; and
   c. Previously failed trials (within the last 180 days) with any 2 Tier-1 or Tier-2 ADHD medications, unless contraindicated, that did not yield adequate results; and

i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for 2 Tier-1 or Tier-2 ADHD medications within the past 180 days of claims history; and

d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and
e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
f. A quantity limit of 30 capsules per 30 days will apply for the 100mg strengths and 60 capsules per 30 days will apply for the 150mg and 200mg strength.

ADHD Medications Additional Criteria:

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

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and

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

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
   a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
   b. Absence of cataplexy; and
   c. Multiple sleep latency test (MSLT) results showing 1 of the following:
      i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
      ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
   d. At least 1 of the following:
      i. MSLT showing mean sleep latency ≤8 minutes; or
      ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
   e. Insufficient sleep syndrome has been ruled out; and

    f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and
2. Diagnosis must be confirmed by a sleep specialist; and
3. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
5. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
    a. Tier-1 stimulant; or
    b. Tier-2 stimulant; or
    c. Nuvigil®; or
    d. Provigil®; or
    e. Clarithromycin; and
6. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Recommendation 3: Vote to Prior Authorize Livtencity™ (Maribavir)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Livtencity™ (maribavir) with the following criteria:

Livtencity™ (Maribavir) Approval Criteria:

1. An FDA approved indication of the treatment of post-transplant cytomegalovirus (CMV) infection and disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric members (12 years of age and older weighing ≥35kg); and

2. A previously failed trial at least 14 days in duration with ganciclovir, valganciclovir, cidofovir, or foscarnet; and
3. Prescriber must verify the member does not have CMV disease involving the central nervous system including the retina (CMV retinitis); and
4. Prescriber must verify member will not receive concurrent treatment with ganciclovir and/or valganciclovir while taking Livtencity™; and
5. Prescriber must verify the member will be monitored for virologic failure during and after treatment with Livtencity™; and
6. Livtencity™ must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify Livtencity™ will not be used concomitantly with strong inducers of CYP3A4 (e.g., rifampin, rifabutin, St. John's wort) except carbamazepine, phenobarbital, or phenytoin. Use of carbamazepine, phenobarbital, or phenytoin concomitantly with Livtencity™ will require dose adjustment according to package labeling; and
8. Prescriber must agree to monitor drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-glycoprotein (P-gp) substrates (e.g., tacrolimus, cyclosporine, sirolimus, everolimus) throughout treatment with Livtencity™ and adjust the dose of immunosuppressant drug(s) as needed; and
9. Approvals will be for a maximum duration of 8 weeks, and a quantity limit of 112 tablets per 28 days will apply.

Recommendation 4: Vote to Prior Authorize Quviviq™ (Daridorexant) and Update the Approval Criteria for the Insomnia Medications

MOTION CARRIED by unanimous approval.

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

1. Updating the approval criteria for Hetlioz® (tasimelteon capsules) based on the new FDA approved indication
2. The prior authorization of Hetlioz LQ™ (tasimelteon oral suspension) and placement into the Special Prior Authorization (PA) Tier of the Insomnia Medications PBPA Tier chart with the following additional criteria
3. The prior authorization of Quviviq™ (daridorexant) and placement into the Special PA category of the Insomnia Medications PBPA category

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	**daridorexant (Quviviq™)**
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)
flurazepam (Dalmane®)			tasimelteon (Hetlioz®, **Hetlioz LQ™**)+
ramelteon (Rozerem®) – **Brand Preferred**			temazepam (Restoril®) 7.5mg and 22.5mg
temazepam (Restoril®) 15mg and 30mg			zolpidem SL tablets (Edluar®)
triazolam (Halcion®)			zolpidem SL tablets (Intermezzo®)
zaleplon (Sonata®)			zolpidem oral spray (Zolpimist®)
zolpidem (Ambien®)			

CR = controlled release; PA = prior authorization; SL = sublingual
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).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of ~~Tier-1 formulations~~ lower-tiered medications.
+Individual criteria specific to tasimelteon applies.

Hetlioz® (Tasimelteon Capsule) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. ~~An FDA approved diagnosis of~~ Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; ~~and~~ or
   b. Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older for a diagnosis of Non-24 or 16 years of age or older for a diagnosis of SMS; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
5. A quantity limit of 30 capsules for 30 days will apply.

Hetlioz LQ™ (Tasimelteon Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) confirmed by a sleep specialist; and
2. Member must be 3 to 15 years of age; and
3. Member must have a failed trial of appropriately timed doses of melatonin; 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 the Hetlioz LQ™ *Prescribing Information*; and
5. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication.

Recommendation 5: Vote to Prior Authorize Invega Hafyera™ (Paliperidone Palmitate Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the placement of Invega Hafyera™ (paliperidone palmitate IM injection) into Tier-1 of the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red):

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

Atypical Antipsychotic Medications*		
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; ODT = orally disintegrating tablet; susp = suspension; sub-Q = subcutaneous
¥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 Invega Hafyera™ requires members to have been adequately treated with the 1-month paliperidone palmitate injection (Invega Sustenna®) for at least 4 months or the 3-month paliperidone palmitate injection (Invega Trinza®) for at least one 3-month cycle.
**Use of Invega Trinza® requires members to have been adequately treated with the 1-month paliperidone palmitate injection (Invega Sustenna®) for at least 4 months.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.

Additionally, the College of Pharmacy recommends adding the following criteria to Lybalvi™ (olanzapine/samidorphan):

Lybalvi™ (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must be stable on olanzapine for at least 14 days and be experiencing significant weight gain (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and has had no excessive weight gain while on therapy must be provided.

Recommendation 6: Vote to Prior Authorize Ryplazim® (Plasminogen, Human-tvmh)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Ryplazim® (plasminogen, human-tvmh) with the following criteria:

Ryplazim® (Plasminogen, Human-tvmh) Approval Criteria:

1. An FDA approved indication of plasminogen deficiency type 1 (hypoplasminogenemia) as confirmed by at least 2 of the following:

a. Genetic testing confirming biallelic mutations in the plasminogen (*PLG*) gene; or
b. Plasminogen activity level ≤45%; or
c. Documentation of clinical symptoms and lesions consistent with plasminogen deficiency type 1 (e.g., ligneous conjunctivitis, ligneous gingivitis or gingival overgrowth, vision abnormalities, respiratory distress and/or obstruction, abnormal wound healing); and

2. Ryplazim® must be prescribed by, or in consultation with, a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency (or an advanced care practitioner with a supervising physician who is a hematologist, pulmonologist, ophthalmologist, geneticist, or other specialist with expertise in the treatment of plasminogen deficiency); and
3. Prescriber must verify that members at high risk for bleeding and/or confirmed or suspected airway disease will be monitored by a health care provider for 4 hours after receiving the first dose; and
4. Documented vaccination history to hepatitis A and B must be provided or provider must verify member has received the first vaccine dose and is scheduled to receive the second vaccine dose; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Initial approvals will be for 6 months, after which time the prescriber must document improvement in clinical symptoms, partial or complete lesion resolution, and increased plasminogen activity level; and
7. Subsequent approvals will be for the duration of 1 year and will require documentation from the prescriber that member has not developed new or recurrent lesions while on Ryplazim® and that adequate plasminogen activity trough levels are being maintained.

Recommendation 7: Vote to Prior Authorize Citalopram Capsule, Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)], Fleqsuvy™ (Baclofen Oral Suspension), Lofena™ (Diclofenac Potassium Tablet), Loreev XR™ [Lorazepam Extended-Release (ER) Capsule], Norliqva® (Amlodipine Oral Solution), Seglentis® (Celecoxib/Tramadol Tablet), Sutab® (Sodium Sulfate/Magnesium Sulfate/Potassium Chloride Tablet), Tarpeyo™ [Budesonide Delayed-Release (DR) Capsule], Vuity™ (Pilocarpine 1.25% Ophthalmic Solution), and Xipere® (Triamcinolone Acetonide Injection)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the placement of citalopram capsules into the Special Prior Authorization (PA) Tier of the Antidepressants Product Based Prior Authorization (PBPA) category with the following additional criteria:

Citalopram Capsule Approval Criteria:

1. An FDA approved indication of major depressive disorder (MDD) in adults; and
2. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without prior authorization, in place of the capsule formulation must be provided; and
4. Citalopram capsules will not be approved for members 60 years of age or older; and
5. A quantity limit of 30 capsules per 30 days will apply.

The College of Pharmacy recommends the placement of Dartisla ODT™ (glycopyrrolate ODT) into the Special PA Tier of the Anti-Ulcer Medications PBPA category with the following additional criteria:

Dartisla ODT™ [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without prior authorization, must be provided; and
3. A quantity limit of 120 ODTs per 30 days will apply.

The College of Pharmacy recommends adding Fleqsuvy™ (baclofen oral suspension) to the current Ozobax® (baclofen oral solution) prior authorization with the changes shown in red:

Fleqsuvy™ 25mg/5mL (Baclofen Oral Suspension) and Ozobax® 5mg/5mL (Baclofen Oral Solution) Approval Criteria:

1. An FDA approved indication of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. 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.

The College of Pharmacy recommends the placement of Lofena™ (diclofenac potassium tablet) into the Special PA Tier of the NSAIDs PBPA category with the following additional criteria (changes shown in red):

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product.
4. Additionally, use of Tivorbex™ (indomethacin) will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.
5. 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.
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.

The College of Pharmacy recommends the prior authorization of Loreev XR™ (lorazepam ER capsule) with the following criteria:

Loreev XR™ [Lorazepam Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved indication for the treatment of anxiety disorders; and
2. Member must be 18 years of age or older; and
3. Member must be receiving a stable, evenly divided, 3 times daily dosing regimen of lorazepam tablets; and
4. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation must be provided; and
5. A quantity limit of 30 capsules per 30 days will apply.

The College of Pharmacy recommends the placement of Norliqva® (amlodipine oral solution) into the Special PA Tier of the Calcium Channel Blockers (CCBs) PBPA category with criteria similar to Katerzia® (amlodipine oral suspension) as follows (changes shown in red):

Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine 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. Coronary artery disease; or
   c. Chronic stable angina; or
   d. Vasospastic angina; and

2. A patient specific, clinically significant reason the member cannot use amlodipine oral tablets even when the tablets are crushed must be provided; and
3. A quantity limit of 300mL per 30 days will apply.

The College of Pharmacy recommends the placement of Seglentis® (celecoxib/tramadol) into the Special PA Tier of the Opioid Analgesics PBPA category with the following additional criteria:

Seglentis® (Celecoxib 56mg/Tramadol 44mg) Approval Criteria:

1. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
2. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
4. 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
5. A quantity limit of 28 tablets for a 7-day supply will apply.

The College of Pharmacy recommends the prior authorization of Sutab® (sodium sulfate/magnesium sulfate/potassium chloride tablet) with the following criteria:

Clenpiq®, ColPrep Kit®, OsmoPrep®, Plenvu®, Prepopik®, 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.
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 Tarpeyo™ (budesonide DR capsule) with the following criteria [changes shown in red indicate updates made based on guideline recommendations and Drug Utilization Review (DUR) Board recommendations]:

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 ~~have a~~ 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) ≥1.5 g/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 ~~the member cannot use~~ a 6-month trial of an alternative formulation of budesonide DR oral capsules (e.g., Entocort® EC) or alternative oral corticosteroids ~~available without prior authorization~~ 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.

The College of Pharmacy recommends the prior authorization of Vuity™ (pilocarpine 1.25% ophthalmic solution) with the following criteria:

Vuity™ (Pilocarpine 1.25% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication of the treatment of presbyopia in adults; and
2. Must be prescribed by an ophthalmologist or optometrist; and
3. Prescriber must verify the member does not have iritis; and
4. Prescriber must verify the member has been counseled on the risk of retinal detachment with use of Vuity™ and when to seek immediate medical care; and
5. Prescriber must verify the member has been advised to use caution with night driving and hazardous occupations in poor illumination as vision may not be clear in these conditions while using Vuity™; and
6. A patient-specific, clinically significant reason the member cannot use corrective lenses must be provided; and

7. A patient-specific, clinically significant reason the member cannot use generic pilocarpine ophthalmic solution (Isopto® Carpine) must be provided.

The College of Pharmacy recommends the prior authorization of Xipere® (triamcinolone acetonide injection) with the following criteria:

Xipere® (Triamcinolone Acetonide Injection) Approval Criteria:

1. An FDA approved indication for the treatment of macular edema associated with non-infectious uveitis; and
2. Member must be 18 years of age or older; and
3. Xipere® must be administered by an ophthalmologist; and
4. Prescriber must confirm that the member does not have an active ocular or periocular infection; and
5. Prescriber must confirm member does not have untreated ocular hypertension or uncontrolled glaucoma; and
6. A patient-specific, clinically significant reason why the member cannot use corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
7. A patient-specific, clinically significant reason the member cannot use Triesence® (triamcinolone acetonide injection) must be provided; and
8. Initial authorization will be for 12 weeks, with an additional dose approved at or after 12 weeks if the prescriber documents improvement from baseline in visual acuity.

Recommendation 8: Vote to Prior Authorize Camcevi™ (Leuprolide), Pluvicto™ (Lutetium Lu 177 Vipivotide Tetraxetan), Tivdak® (Tisotumab Vedotin-tftv), and Welireg™ (Belzutifan) and Update the Approval Criteria for the Genitourinary and Cervical/Endometrial Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Camcevi™ (leuprolide), Pluvicto™ (lutetium Lu 177 vipivotide tetraxetan), Tivdak® (tisotumab vedotin-tftv), and Welireg™ (belzutifan) with the following criteria listed in red:

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

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

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

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

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

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

Welireg™ (Belzutifan) Approval Criteria:

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

Additionally, the College of Pharmacy recommends updating the Cabometyx® (cabozantinib) prior authorization criteria based on the recent FDA approval (changes noted in red):

Cabometyx® (Cabozantinib) Approval Criteria:

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

Recommendation 9: Annual Review of Colorectal Cancer Medications and 30-Day Notice to Prior Authorize Alymsys® (Bevacizumab-maly), Lonsurf® (Trifluridine/Tipiracil), and Stivarga® (Regorafenib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2022.

Recommendation 10: Annual Review of Danyelza® (Naxitamab-gqgk), Koselugo® (Selumetinib), Pemazyre® (Pemigatinib), Qinlock® (Ripretinib), and Truseltiq® (Infigratinib)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Adlarity® (Donepezil Transdermal System) and Aduhelm® (Aducanumab-avwa)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2022.

Recommendation 12: Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Tlando® (Testosterone Undecanoate)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2022.

Recommendation 13: Annual Review of Various Systemic Antibiotics

NO ACTION REQUIRED.

Recommendation 14: Annual Review of Isturisa® (Osilodrostat) and 30-Day Notice to Prior Authorize Recorlev® (Levoketoconazole)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2022.

Recommendation 15: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

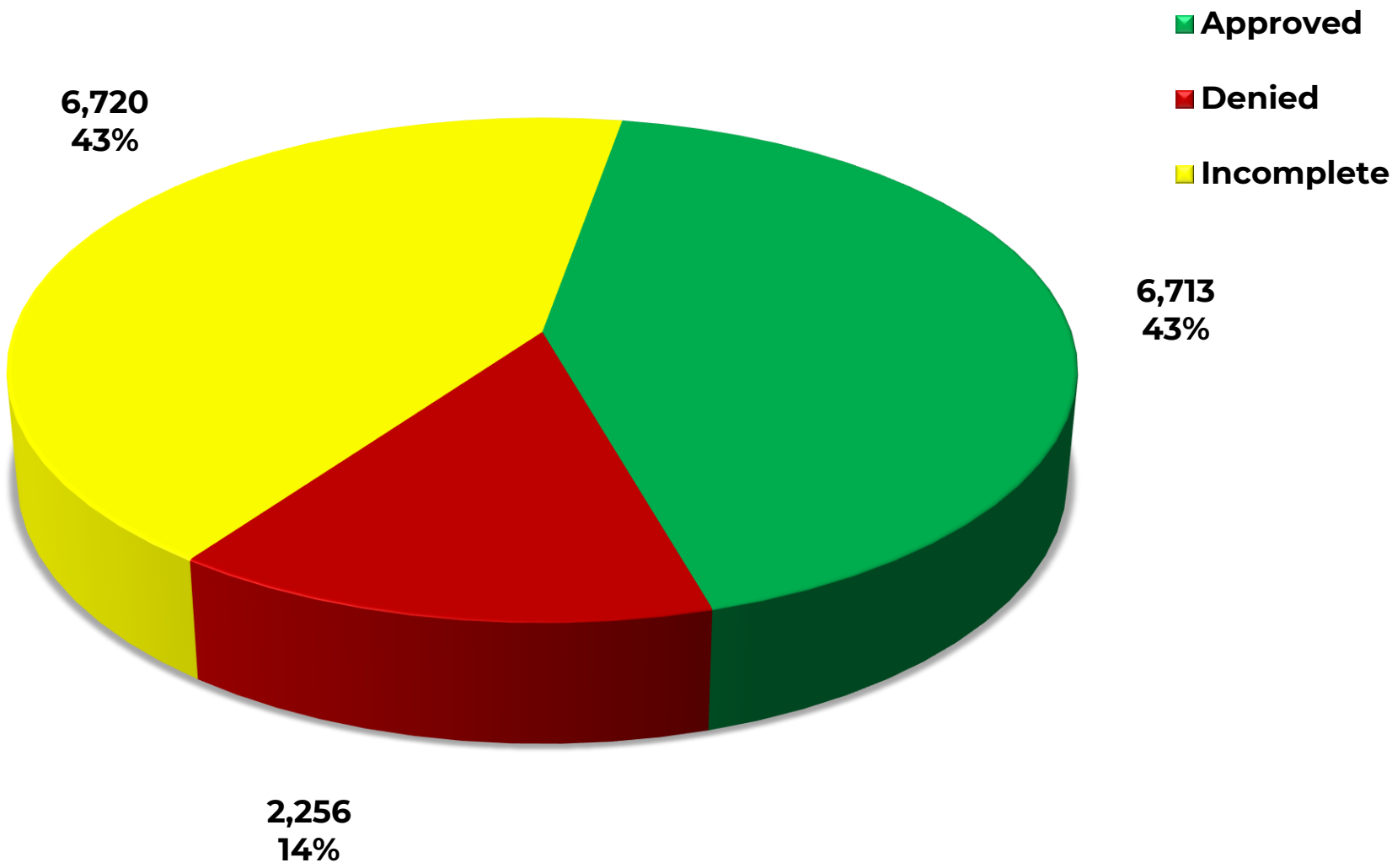
Recommendation 16: Future Business

No live DUR Board meeting is scheduled for August 2022. August 2022 will be a packet-only meeting.

NO ACTION REQUIRED.

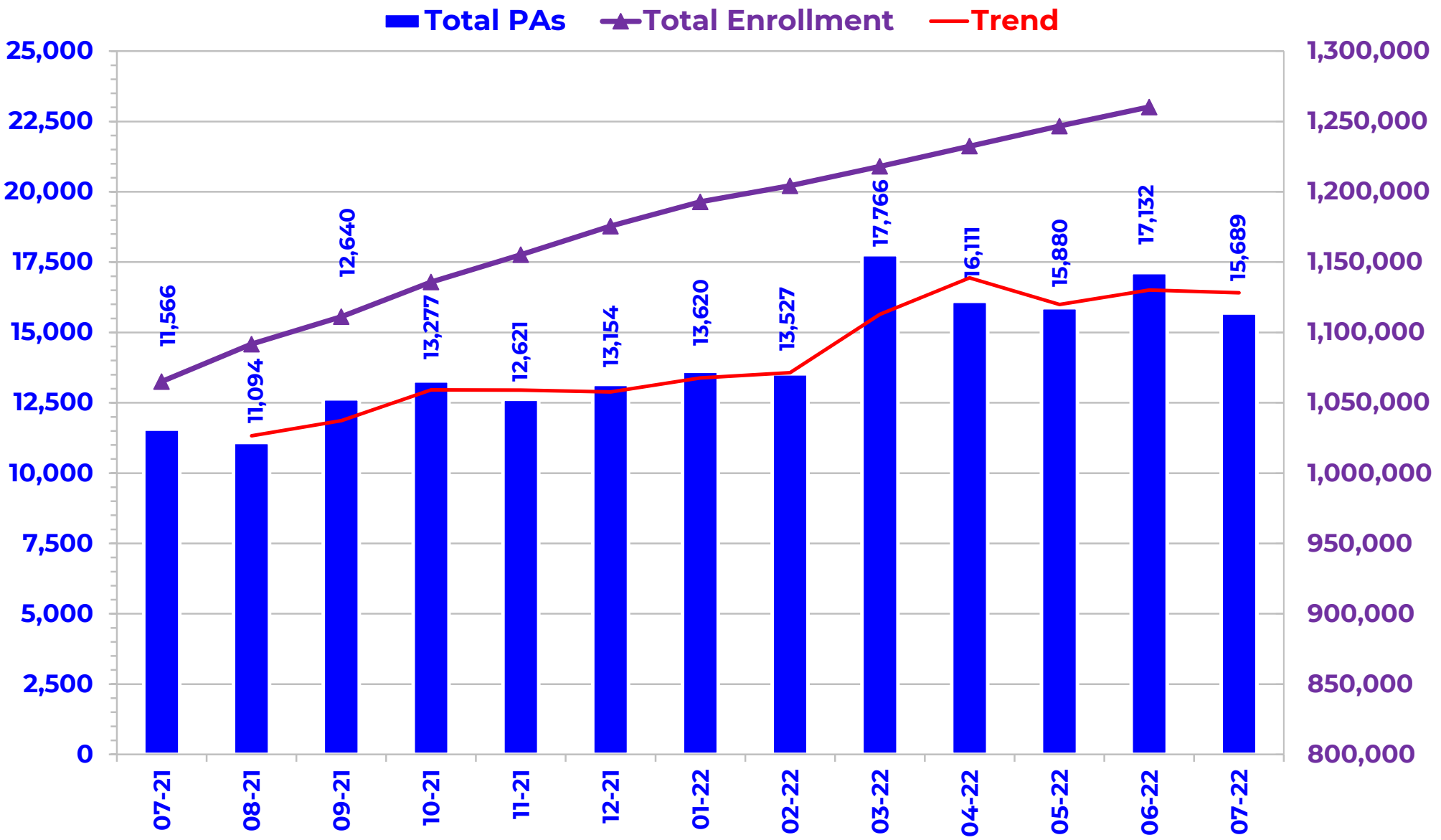
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JULY 2022



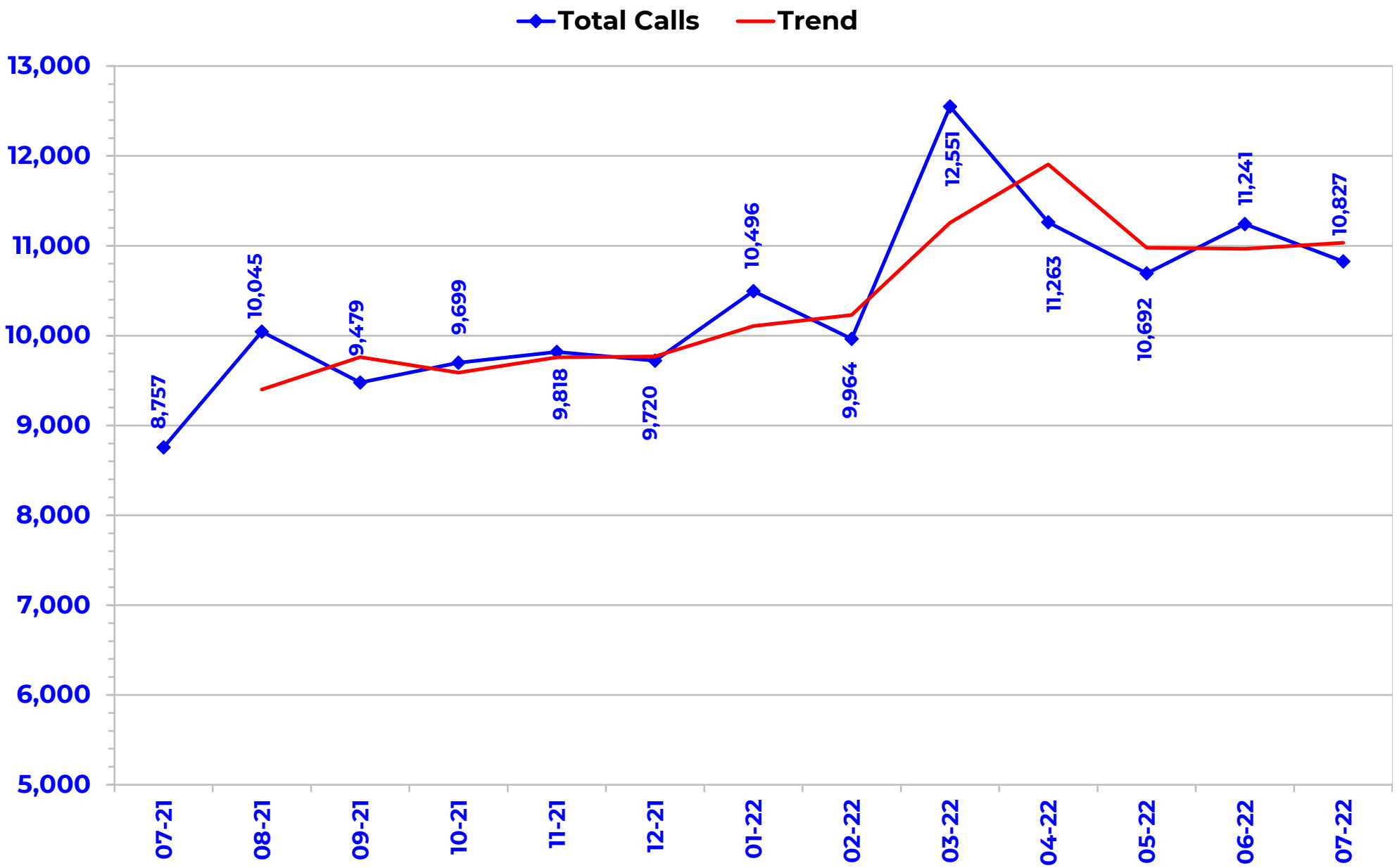
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: JULY 2021 – JULY 2022



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JULY 2021 – JULY 2022



Prior Authorization Activity

7/1/2022 Through 7/31/2022

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	108	25	10	73	345
Analgesic - NonNarcotic	23	2	4	17	268
Analgesic - Narcotic	347	133	42	172	150
Angiotensin Receptor Antagonist	15	0	4	11	0
Antiasthma	80	29	19	32	266
Antibiotic	55	25	2	28	223
Anticonvulsant	247	105	10	132	330
Antidepressant	439	96	60	283	326
Antidiabetic	1,554	527	297	730	356
Antifungal	11	3	1	7	73
Antigout	10	2	2	6	360
Antihemophilic Factor	23	13	0	10	278
Antihistamine	40	12	11	17	313
Antimalarial Agent	115	84	7	24	347
Antimigraine	669	100	219	350	243
Antineoplastic	234	150	11	73	174
Antiobesity	24	0	19	5	0
Antiparasitic	49	14	7	28	15
Antiparkinsons	14	0	8	6	0
Antiulcers	56	8	12	36	143
Anxiolytic	54	4	3	47	359
Atypical Antipsychotics	612	221	63	328	346
Benign Prostatic Hypertrophy	11	0	8	3	0
Biologics	379	204	49	126	290
Bladder Control	110	14	35	61	318
Blood Thinners	748	409	49	290	338
Botox	63	43	13	7	328
Buprenorphine Medications	98	38	8	52	84
Calcium Channel Blockers	33	5	6	22	291
Cardiovascular	122	54	17	51	319
Chronic Obstructive Pulmonary Disease	287	50	60	177	342
Constipation/Diarrhea Medications	294	53	72	169	220
Contraceptive	39	13	10	16	336
Corticosteroid	24	0	14	10	0
Dermatological	464	139	142	183	202
Diabetic Supplies	880	301	157	422	233
Endocrine & Metabolic Drugs	127	51	19	57	215
Erythropoietin Stimulating Agents	22	10	5	7	113
Fibric Acid Derivatives	10	1	0	9	358

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Fibromyalgia	16	3	1	12	360
Fish Oils	34	2	4	28	358
Gastrointestinal Agents	227	39	60	128	213
Glaucoma	24	8	2	14	155
Growth Hormones	108	74	8	26	157
Hematopoietic Agents	21	13	1	7	292
Hepatitis C	303	185	23	95	9
HFA Rescue Inhalers	18	1	1	16	56
Insomnia	105	1	25	79	176
Insulin	395	105	49	241	355
Miscellaneous Antibiotics	38	7	5	26	13
Multiple Sclerosis	83	37	12	34	222
Muscle Relaxant	81	2	29	50	191
Nasal Allergy	58	12	10	36	165
Neurological Agents	144	47	24	73	229
NSAIDs	54	2	11	41	359
Ocular Allergy	25	5	7	13	87
Ophthalmic	21	2	5	14	98
Ophthalmic Anti-infectives	24	13	2	9	19
Ophthalmic Corticosteroid	19	6	3	10	358
Osteoporosis	39	9	11	19	304
Other*	404	88	62	254	289
Otic Antibiotic	48	5	4	39	82
Pediculicide	12	3	1	8	13
Respiratory Agents	42	22	4	16	269
Statins	53	12	16	25	211
Stimulant	1,738	1,129	92	517	350
Synagis	78	41	18	19	48
Testosterone	163	37	47	79	334
Thyroid	43	17	6	20	306
Topical Antifungal	69	7	18	44	112
Topical Corticosteroids	88	6	54	28	262
Vitamin	146	20	60	66	127
Pharmacotherapy	81	71	0	10	222
Emergency PAs	0	0	0	0	
Total	**13,292**	**4,969**	**2,150**	**6,173**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	22	12	1	9	281
Compound	11	7	0	4	12
Diabetic Supplies	3	3	0	0	265
Dosage Change	424	388	0	36	16
High Dose	10	7	1	2	313
Ingredient Duplication	8	6	0	2	126
Lost/Broken Rx	175	147	11	17	18
MAT Override	280	236	3	41	73
NDC vs. Age	339	209	39	91	255
NDC vs. Sex	8	4	0	4	151
Nursing Home Issue	64	48	10	6	13
Opioid MME Limit	95	34	3	58	124
Opioid Quantity	42	27	4	11	165
Other	65	53	4	8	23
Quantity vs. Days Supply	747	494	23	230	250
STBS/STBSM	16	12	2	2	55
Step Therapy Exception	21	8	2	11	357
Stolen	24	20	0	4	24
Third Brand Request	43	29	3	11	14
Overrides Total	**2,397**	**1,744**	**106**	**547**	
Total Regular PAs + Overrides	**15,689**	**6,713**	**2,256**	**6,720**	

Denial Reasons	
Unable to verify required trials.	5,704
Does not meet established criteria.	2,301
Lack required information to process request.	1,049
Other PA Activity	
Duplicate Requests	1,112
Letters	33,615
No Process	0
Changes to existing PAs	1,170
Helpdesk Initiated Prior Authorizations	1,176
PAs Missing Information	1

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

Use of Statins in Members with Diabetes Mellitus (DM)

Oklahoma Health Care Authority
August 2022

Introduction[1,2,3]

Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality for individuals with DM, and an estimated $37.3 billion is spent annually on CV-related issues associated with DM. The American Diabetes Association (ADA) defines ASCVD as having either coronary heart disease (CHD), cerebrovascular disease, or peripheral arterial disease presumed to be of atherosclerotic origin. Subgroup analyses of patients with DM on statin therapy in larger clinical trials have shown significant primary and secondary prevention of ASCVD events and CHD death in patients with DM. Meta-analyses from data from over 18,000 patients with DM from 14 randomized trials of statin therapy have demonstrated a 9% proportional reduction in all-cause mortality and a 13% reduction in vascular mortality for each 1mmol/L (39mg/dL) reduction in low-density lipoprotein cholesterol (LDL-C).

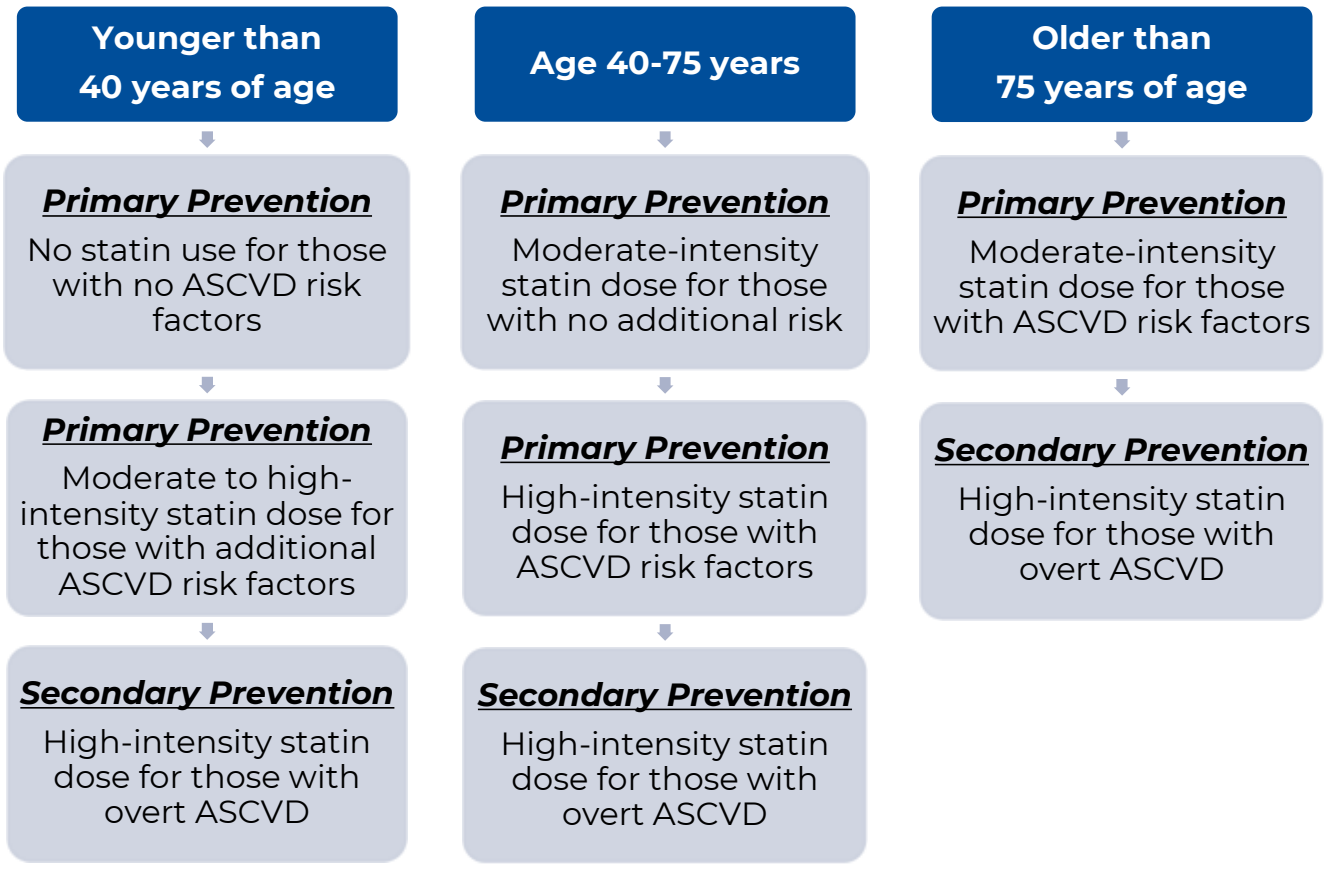
Statins are the drug of choice for LDL-C lowering. Depending on age and ASCVD risk factors, moderate-to-high intensity statins are generally recommended for prevention of ASCVD, while low-dose or low-intensity statin therapy is generally not recommended. High-intensity statin therapy will achieve approximately a ≥50% reduction in LDL-C, while moderate-intensity statin therapy will achieve a 30-49% reduction in LDL-C. For patients who are not able to tolerate the intended intensity of statin, the maximally tolerated dose should be used, which may include low-intensity statin therapy. Risk factors for ASCVD include hypertension, smoking, and overweight/obesity.

The 2022 ADA Standards of Medical Care in Diabetes guideline was updated to align with those of the American College of Cardiology (ACC) and the American Heart Association (AHA) guideline for the Comprehensive Management of Cardiovascular Risk Factors for Adults with Type 2 Diabetes (T2DM). The ADA guideline recommendations are divided into 3 different age groups (younger than 40 years of age, age 40-75 years, and older than 75 years of age) and have specific recommendations for primary prevention (patients without ASCVD) and secondary prevention (patients with ASCVD). It is important to note that the guidelines don't specify a specific LDL-C goal for primary prevention, but for secondary prevention in very high-risk patients with ASCVD who are already on high-intensity (and maximally tolerated) statin therapy and have an LDL-C level ≥70, the addition of non-statin LDL-

lowering therapy can be considered. These non-statin therapies include ezetimibe, PCSK9 inhibitors, and bempedoic acid. The guideline also addresses DM risk with statin use. Several studies have reported a modestly increased risk of incident DM with statin use which may be limited to those with risk factors for DM. An analysis of one of the initial studies suggest that although statin use was associated with DM risk, the CV event rate reduction with statins far outweighed the risk of incident DM even for patients at highest risk for DM.

Figure 1 below is a summary of the current recommendations for statin treatment for patients with either Type 1 DM (T1DM) or T2DM.

Figure 1: ADA Statin Treatment Recommendations



Statin Use in SoonerCare Members with DM in Calendar Year 2021 (CY21)[4]

In CY21, there were a total of 58,263 unique members with a diagnosis of either T1DM or T2DM 20 years of age and older in the SoonerCare population. Of these members, 24% had a diagnosis of ASCVD. ASCVD was defined as having an ICD-10 code of either chronic ischemic heart disease, peripheral vascular disease, or other cerebrovascular disease in the member's medical

claims history. When evaluating members with DM with ASCVD, more than 70% of these members were not on statin therapy for secondary prevention of ASCVD. For primary prevention in members with DM without ASCVD and between the age of 40-75 years, 72% of these members were not on statin therapy as recommended by the ADA guidelines. Statin use for primary prevention for members younger than 40 years of age or older than 75 years of age was not assessed since the number of ASCVD risk factors could not be calculated from the available claims data. Depending on the number of ASCVD risk factors, statin therapy may or may not be recommended, so these members were not included in the analysis.

Figure 2 below is a summary of the data for members with DM in calendar year 2021 for the SoonerCare population. The age of the member was determined as the current age at the beginning of the year.

Figure 2: DM in the SoonerCare Population

Data Point	Number of Members
Number of members with DM 20 years of age and older*	58,263
Number of members with DM without ASCVD	44,529
Number of members with DM with ASCVD	13,734
Number of members with DM with ASCVD on a statin	4,066
Number of members with DM with ASCVD not on a statin	9,668
Number of members with DM without ASCVD not on statin and between 40-75 years of age	23,226

ASCVD = atherosclerotic cardiovascular disease, DM = diabetes mellitus
*DM includes both Type 1 and Type 2 diabetes

Conclusions

The low utilization of statin therapy for primary prevention of ASCVD in SoonerCare members between the age of 40 and 75 years and for secondary prevention of ASCVD for members of all ages with DM and ASCVD is very concerning. Of the 58,263 SoonerCare members diagnosed with DM, over half of these members were not on statin therapy for primary or secondary prevention of ASCVD as directed by the ADA guidelines. The College of Pharmacy will provide outreach to the providers of these members in an effort to increase statin use in this population. Mailings will be sent out to prescribers to inform them about the statin recommendation from the ADA guidelines and will include a list of members not on a statin for those aged 40-75 years with DM without ASCVD (primary prevention) and for all members with DM already diagnosed with ASCVD and not on a statin (secondary prevention). The results of this mailing will be evaluated next year and will be presented at a future DUR Board meeting.

[1] Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019; 73(24):3168-3209. doi:10.1016/j.jacc.2018.11.002.

[2] American Diabetes Association Professional Practice Committee. 10. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes-2022 [published correction appears in *Diabetes Care*. 2022 Mar 07;:]. *Diabetes Care* 2022; 45(1):S144-S174. doi:10.2337/dc22-S010.

[3] Joseph, JJ, Deedwania P, Acharya T, et al. Comprehensive Management of Cardiovascular Risk Factors for Adults with Type 2 Diabetes: A Scientific Statement from the American Heart Association. *Circulation* 2022; 145(9):722-759. https://doi.org/10.1161/CIR.0000000000001040.

Appendix C

30-Day Notice to Prior Authorize Camzyos™ (Mavacamten)

Oklahoma Health Care Authority
August 2022

Introduction[1]

Hypertrophic cardiomyopathy (HCM) is often inherited and is the most common form of genetic heart disease. It is most often caused by abnormal genes in the heart muscle that cause the walls of the heart chamber to become thicker than normal. The walls may then become stiff which can reduce the amount of blood taken in and pumped out of the body. The most common form is obstructive HCM, where the thickened walls block or reduce the blood flow from the left ventricle to the aorta. Thickened heart muscle occurs in nonobstructive HCM, but it does not block blood flow out of the heart. It is estimated that 1 in every 500 people have HCM, but most are undiagnosed. Of the those diagnosed, about two-thirds of patients have obstructive HCM.

HCM can usually be detected by an echocardiogram or transesophageal echocardiogram. However, the condition often goes unnoticed because in the early stages many people are asymptomatic. If symptoms are present, they include chest pain (especially upon physical exertion), shortness of breath, fatigue, dizziness, fainting, and life-threatening arrhythmias or sudden death.

The current treatment for obstructive HCM is dependent on the patient's severity of symptoms and is focused on symptom relief and prevention of sudden cardiac death. First-line therapies typically consist of beta blockers and nondihydropyridine calcium channel blockers. However, these current pharmacological options only provide symptomatic relief and do not target the underlying pathophysiology of HCM.

In April 2022, the U.S. Food and Drug Administration (FDA) approved Camzyos™ (mavacamten) for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive HCM to improve functional capacity and symptoms. Camzyos™ is the first approved cardiac myosin inhibitor that targets the underlying pathophysiology of obstructive HCM.

Camzyos™ (Mavacamten) Product Summary[2,3]

Indication(s): A cardiac myosin inhibitor indicated for the treatment of adults with symptomatic NYHA class II-III obstructive HCM to improve functional capacity and symptoms.

How Supplied: 2.5mg, 5mg, 10mg, and 15mg oral capsules

Dosing and Administration:

- Dosage should be individualized based on clinical status and echocardiogram assessment of patient response.
- The recommended starting dose is 5mg once daily without regard to food.
- Regular left ventricular ejection fraction (LVEF) and Valsalva left ventricular outflow tract (LVOT) gradient assessment should be done for careful titration of mavacamten.
- Refer to the full *Prescribing Information* for the recommended initiation and maintenance dosing algorithm.

Boxed Warning: Risk of Heart Failure

- Mavacamten can cause heart failure due to systolic dysfunction.
  - Echocardiogram assessments of LVEF are required before and during use.
  - Initiation in patients with LVEF <55% is not recommended.
  - Treatment should be interrupted if LVEF <50% or if worsening clinical status.
- Concomitant use of mavacamten with certain cytochrome P450 inhibitors or discontinuation of certain cytochrome P450 inducers may increase the risk of heart failure due to systolic dysfunction; therefore, the use of mavacamten is contraindicated with the following:
  - Moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors
  - Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers
- Mavacamten is only available through the Risk Evaluation and Mitigation Strategy (REMS) program.

Warnings and Precautions:

- Heart Failure: Mavacamten reduces systolic contraction and can cause heart failure or totally block ventricular function. Patients who experience a serious intercurrent illness (e.g., serious infection) or arrhythmia (e.g., atrial fibrillation or other uncontrolled tachyarrhythmia) are at greater risk of developing systolic dysfunction

and heart failure. Interruption of mavacamten should be considered in patients with serious infections or arrhythmias.

- Drug Interactions Leading to Heart Failure or Loss of Effectiveness: Patients should be advised of potential drug interactions including over-the-counter medications (e.g., omeprazole, esomeprazole, cimetidine, St. John's wort).
- Embryo-Fetal Toxicity: Females of reproductive potential should be advised to use effective contraception until 4 months after the last dose. A contraceptive not affected by CYP450 enzyme induction [e.g., intrauterine device (IUD)] or nonhormonal contraception should be used.

Mechanism of Action: Mavacamten is an allosteric and reversible inhibitor selective for cardiac myosin. It modulates the number of myosin heads that can enter "on actin" (power-generating) states, thus reducing the probability of force-producing (systolic) and residual (diastolic) cross-bridge formation. Excess myosin actin cross-bridge formation and dysregulation of the super-relaxed state are mechanistic hallmarks of HCM. Mavacamten shifts the overall myosin population towards an energy-sparing, recruitable, super-relaxed state. In HCM patients, myosin inhibition with mavacamten reduces dynamic LVOT obstruction and improves cardiac filling pressures.

Contraindication(s):

- Moderate to strong CYP2C19 (e.g., proton pump inhibitors, clopidogrel, voriconazole, fluvoxamine) or strong CYP3A4 (e.g., itraconazole, ketoconazole, ritonavir) inhibitors
- Moderate to strong CYP2C19 (e.g., rifampicin, carbamazepine) or CYP3A4 (e.g., rifampin, carbamazepine, phenytoin) inducers

Use in Specific Populations:

- Pregnancy: Based on animal data, mavacamten may cause fetal harm when administered to a pregnant female. There is no human data on the use of mavacamten during pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.
- Lactation: The presence of mavacamten in human or animal milk, the drug's effects on the breastfed infant, and the effects on milk production are unknown.
- Females and Males of Reproductive Potential: Mavacamten may cause fetal harm when administered to a pregnant female. Absence of pregnancy should be confirmed in females of reproductive potential prior to initiation. Females of reproductive potential should use effective contraception during treatment and for 4 months after the last dose.

- Pediatric Use: The safety and effectiveness of mavacamten have not been established in pediatric patients.
- Geriatric use: Clinical trials of mavacamten included 263 patients 65 years of age and older. Safety, effectiveness, and pharmacokinetics were similar between elderly patients and younger patients.

Adverse Reactions: The most common adverse reactions reported in clinical studies (incidence >5%) were dizziness and syncope.

Efficacy: The approval of mavacamten was based on a Phase 3, double-blind, randomized study in 251 adults. Patients were randomized 1:1 to receive either mavacamten 5mg or placebo once daily for 30 weeks. All patients were initiated on 5mg once daily of mavacamten or placebo and the dose was adjusted periodically to optimize patient response and maintain LVEF ≥50%.

- Primary Endpoint: The primary composite functional endpoint was defined as the proportion of patients who achieved either improvement of peak oxygen consumption (pVO2) by ≥1.5mL/kg/min plus improvement in NYHA class by at least 1 class or improvement of pVO2 by ≥3.0 mL/kg/min plus no worsening in NYHA class.
- Results: A greater proportion of patients met the primary endpoint at week 30 in the mavacamten group compared to the placebo group [37% vs. 17%, respectively; difference of 19% (95% confidence interval: 9, 30; P=0.0005)].

Cost: The Wholesale Acquisition Cost (WAC) of Camzyos™ is $245.21 per tablet regardless of strength, resulting in an annual cost of $88,275.60 for the recommended dosage of 1 tablet once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Camzyos™ (mavacamten) with the following criteria:

Camzyos™ (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos™ must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or nondihydropyridine calcium channel blockers; and

7. Member must not be taking concurrent moderate to strong CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole, fluvoxamine), strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir), moderate to strong CYP2C19 inducers (e.g., rifampicin, carbamazepine), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and
8. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos™; and
9. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 4 months after the final dose of Camzyos™; and
10. Prescriber, pharmacy, and member must be enrolled in the Camzyos™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment.

[1] American Heart Association. Hypertrophic Cardiomyopathy. Available online at: https://www.heart.org/en/health-topics/cardiomyopathy/what-is-cardiomyopathy-in-adults/hypertrophic-cardiomyopathy. Last revised 05/13/2022. Last accessed 07/20/2022.
[2] Camzyos™ Prescribing Information. Bristol Myers Squibb. Available online at: https://packageinserts.bms.com/pi/pi_camzyos.pdf. Last revised 05/2022. Last accessed 07/20/2022.
[3] Bristol Myers Squibb. U.S. Food and Drug Administration Approves Camzyos™ (Mavacamten) for the Treatment of Adults with Symptomatic New York Heart Association Class II-III Obstructive Hypertrophic Cardiomyopathy (HCM) to Improve Functional Capacity and Symptoms. Available online at: https://news.bms.com/news/corporate-financial/2022/U.S.-Food-and-Drug-Administration-Approves-Camzyos-mavacamten-for-the-Treatment-of-Adults-With-Symptomatic-New-York-Heart-Association-Class-II-III-ObstructiveHypertrophic-Cardiomyopathy-HCM-to-Improve-Functional-Capacity-and-Symptoms/default.aspx. Issued 04/28/2022. Last accessed 07/20/2022.

Appendix D

Annual Review of Intravenous (IV) Iron Products

Oklahoma Health Care Authority
August 2022

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® or Venofer® must be provided.

Injectafer® (Ferric Carboxymaltose) 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® or Venofer® must be provided.

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® or Venofer® must be provided.

Utilization of IV Iron Products: Medical Claims

Comparison of Calendar Years

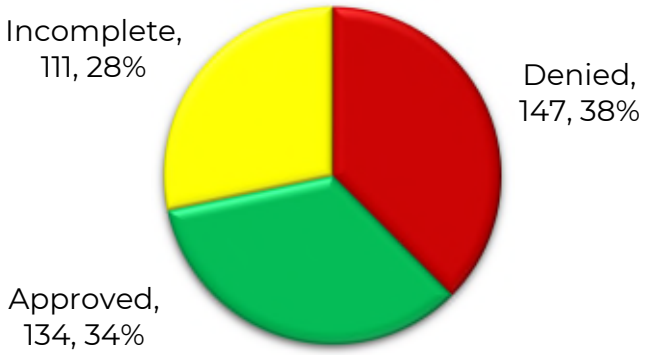
Calendar Year	Total Members*	Total Claims†	Total Cost	Cost/ Claim	Claims/ Member
2020	404	820	$228,260.89	$278.37	2.03
2021	667	927	$265,724.45	$286.65	1.39
% Change	**65.10%**	**13.05%**	**16.41%**	**2.97%**	**-31.53%**
Change	**263**	**107**	**$37,463.56**	**$8.28**	**-0.64**

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

Prior Authorization of IV Iron Products

There were 392 prior authorization requests submitted for IV iron products during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Injectafer® (ferric carboxymaltose injection): February 2028
- Monoferric® (ferric derisomaltose injection): August 2029

News:

- **July 2021:** Sandoz announced the launch of generic ferumoxytol in the United States. Ferumoxytol, a generic equivalent to Feraheme® (ferumoxytol injection), is approved to treat iron deficiency anemia (IDA) in adult patients who have an intolerance to oral iron, have had an unsatisfactory response to oral iron, or who have chronic kidney disease. Ferumoxytol is the first generic, high-dose IV iron available in the United States.

- **March 2022:** The findings of a multicenter cohort study of IV iron infusions administered to 12,237 patients with iron deficiency to evaluate rates of infusion reactions among 4 commonly used IV iron products and determine how readministration was managed in patients with a history of reaction were published in *JAMA Network Open*. The infusions included 22,309 iron sucrose doses, 9,067 iron dextran total doses (1,771 preceded by test dose, 56 test doses alone), 3,147 ferumoxytol doses, and 1,214 ferric carboxymaltose doses. With these infusions, the cumulative incidence of adverse events was 3.9% [N = 1,389; 95% confidence interval (CI): 3.7%, 4.1%]. Severe adverse events with documented epinephrine administrations occurred in 2 cases, both associated with iron dextran. The risk for infusion reactions differed significantly among IV iron products: 4.3% with iron sucrose, 3.8% with iron dextran, 1.8% with ferumoxytol, and 1.4% with ferric carboxymaltose. Among the 873 patients with a history of infusion reaction who underwent readministration, the majority received the same formulation, which was associated with significantly higher reaction rate particularly if premedication was administered (68% vs. 32%, respectively), compared with those who received an alternate formulation (21% vs. 5%, respectively; $P < 0.001$). Incidence of adverse events among those who received premedication was 23-fold higher compared with those who did not (38.6% vs. 1.7%; $P < 0.001$). This data and the published evidence suggest that IV iron is generally well tolerated with an exceedingly low risk of severe reaction, use of premedication and test doses are unnecessary, and that optimal prevention and management of infusion-related reactions warrant further study.
- **May 2022:** In a retrospective cohort study comparing risks for anaphylaxis among 5 commonly used IV iron products, using data from Medicare Part D of 167,925 new utilizers of IV iron who were older than 65 years of age, the adjusted rates for anaphylaxis per 10,000 administrations were 9.8 cases for iron dextran, 4.0 cases for ferumoxytol, 1.5 cases for ferric gluconate, 1.2 cases for iron sucrose, and 0.8 cases for ferric carboxymaltose. Compared with iron sucrose, iron dextran and ferumoxytol were associated with 8.3- and 3.4-fold increased odds for anaphylaxis, respectively. Hospitalization for anaphylactic reactions occurred only among patients receiving iron dextran or ferumoxytol. Anaphylaxis with cardiopulmonary resuscitation (CPR), hypotension, or epinephrine also occurred at higher rates among patients receiving iron dextran or ferumoxytol. The study authors concluded that factors guiding the choice of IV iron product should include not only the risk for anaphylaxis but also the patient's medical history, clinical indication, administration (e.g., setting,

dose, number of doses, treatment duration), risk for other adverse events, and cost.

Recommendations

The College of Pharmacy does not recommend any changes to the current IV iron products prior authorization criteria at this time.

Utilization Details of IV Iron Products: Calendar Year 2021

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J1750 IRON DEXTRAN INJ 50MG (INFED)	725	545	$182,493.55	$251.72
J1756 IRON SUCROSE INJ 1MG (VENOFER)	108	63	$5,420.85	$50.19
J1439 FERRIC CARBOXYMALTOSE INJ 1MG (INJECTAFER)	62	38	$53,258.25	$859.00
Q0138 FERUMOXYTOL INJ 1MG (NON-ESRD) (FERAHEME)	28	17	$14,626.80	$522.39
J1437 FERRIC DERISOMALTOSE INJ 10MG (MONOFERRIC)	4	4	$9,925.00	$2,481.25
TOTAL	**927**	**667**	**$265,724.45**	**$286.65**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
ESRD = end-stage renal disease; INJ = injection
Please note: Reimbursement of IV iron products for members with 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 07/2022. Last accessed 07/15/2022.
[2] Sandoz. Sandoz Launches First Generic High Dose Intravenous Iron, Ferumoxytol Injection, to Treat US Patients with Iron Deficiency Anemia. Available online at: https://www.sandoz.com/news/media-releases/sandoz-launches-first-gen0eric-high-dose-intravenous-iron-ferumoxytol-injection. Issued 07/16/2021. Last accessed 07/20/2022.
[3] Arastu AH, Elstrott BK, Martens KL, et al. Analysis of Adverse Events and Intravenous Iron Infusion Formulations in Adults with and without Prior Infusion Reactions. *JAMA Netw Open* 2022; 5(3):e224488. doi:10.1001/jamanetworkopen.2022.4488.
[4] Dave CV, Brittenham GM, Carson JL, et al. Risks for Anaphylaxis with Intravenous Iron Formulations. *Ann Intern Med*. Available online at: https://www.acpjournals.org/doi/10.7326/M21-4009. Issued 03/29/2022. Last accessed 07/20/2022. doi:10.7326/M21-4009.
[5] Persaud N. Anaphylaxis Rare with IV Iron Use, But Risk Varies by Formulation. *MPR*. Available online at: https://www.empr.com/home/news/anaphylaxis-risk-intravenous-iron-dextran-ferumoxytol/. Issued 04/05/2022. Last accessed 07/20/2022.

Appendix E

Calendar Year 2021 Annual Review of Ophthalmic Anti-Inflammatory Products

Oklahoma Health Care Authority
August 2022

Current Prior Authorization Criteria

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone 0.1% sus (Maxidex®)	fluorometholone 0.25% sus (FML Forte®)
dexamethasone sodium phosphate 0.1% sol	fluorometholone 0.1% oint (FML S.O.P®)
difluprednate 0.05% emu (Durezol®)	loteprednol 1% sus (Inveltys®)
fluorometholone 0.1% sus (Flarex®)	loteprednol 0.38% gel (Lotemax® SM)
fluorometholone 0.1% sus (FML Liquifilm®)	prednisolone acetate 1% sus (Pred Forte®)
loteprednol 0.5% gel, oint, sus (Lotemax®) – **Brand Preferred**	
prednisolone acetate 1% sus (Omnipred®)	
prednisolone acetate 0.12% sus (Pred Mild®)	
prednisolone sodium phosphate 1% sol	

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)
emu = emulsion; oint = ointment; sol = solution; sus = suspension

Ophthalmic Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic corticosteroids (from different product lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower-tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic corticosteroids lack.

Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria (Medical Only):

1. An FDA approved indication for the treatment of ocular inflammation and pain following ophthalmic surgery; and
2. Prescriber must verify that Dextenza® will be placed by a physician immediately following ophthalmic surgery; and
3. Date of ophthalmic surgery must be provided; and
4. A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used following ophthalmic surgery are not appropriate for the member must be provided; and
5. A quantity limit of 1 insert per eye every 30 days will apply.

Iluvien® (Fluocinolone Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved diagnosis of diabetic macular edema in members who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure; and
2. Iluvien® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Iluvien® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A quantity limit of 1 implant per eye every 36 months will apply.

Oxervate™ (Cenegermin-bkbj) Approval Criteria:

1. An FDA approved diagnosis of neurotrophic keratitis; and
2. Oxervate™ must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has persistent epithelial defect (PED) (stage 2 disease) or corneal ulceration (stage 3 disease) of at least 2 weeks duration that is refractory to 1 or more conventional non-surgical treatments for neurotrophic keratitis; and
    a. Specific non-surgical treatments and dates of trials must be listed on the prior authorization request; and
4. Prescriber must verify that the member has evidence of decreased corneal sensitivity within the area of the PED or corneal ulcer and outside of the area of the defect in at least 1 corneal quadrant; and
5. Prescriber must verify the member has been counseled on the proper administration and storage of Oxervate™; and
6. Approvals will be for a maximum duration of 8 weeks of total therapy per eye; and
7. A quantity limit of 2 weekly kits per 14 days will apply. A quantity limit override will be approved for 4 weekly kits per 14 days with prescriber documentation of treatment in both eyes.

Ozurdex® (Dexamethasone Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved indication for 1 of the following:
    a. Treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); or
    b. Treatment of non-infectious uveitis affecting the posterior segment of the eye; or
    c. Treatment of diabetic macular edema; and
2. Ozurdex® must be administered by an ophthalmologist; and

3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Ozurdex® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A quantity limit of 1 implant per eye every 3 months will apply.

Retisert® (Fluocinolone Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved diagnosis of chronic non-infectious posterior uveitis; and
2. Retisert® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Retisert® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A patient-specific, clinically significant reason why the member requires Retisert® in place of Ozurdex® or Yutiq® must be provided; and
7. A quantity limit of 1 implant per eye every 30 months will apply.

Xipere® (Triamcinolone Acetonide Injection) Approval Criteria:

1. An FDA approved indication for the treatment of macular edema associated with non-infectious uveitis; and
2. Member must be 18 years of age or older; and
3. Xipere® must be administered by an ophthalmologist; and
4. Prescriber must confirm that the member does not have an active ocular or periocular infection; and
5. Prescriber must confirm member does not have untreated ocular hypertension or uncontrolled glaucoma; and
6. A patient-specific, clinically significant reason why the member cannot use corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
7. A patient-specific, clinically significant reason the member cannot use Triesence® (triamcinolone acetonide injection) must be provided; and
8. Initial authorization will be for 12 weeks, with an additional dose approved at or after 12 weeks if the prescriber documents improvement from baseline in visual acuity.

Yutiq® (Fluocinolone Acetonide Intravitreal Implant) Approval Criteria (Medical Only):

1. An FDA approved diagnosis of chronic, non-infectious uveitis affecting the posterior segment of the eye; and
2. Yutiq® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Yutiq® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A patient-specific, clinically significant reason why the member requires Yutiq® in place of Ozurdex® must be provided; and
6. A quantity limit of 1 implant per eye every 36 months will apply.

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
Tier-1	**Tier-2**
diclofenac 0.1% sol (Voltaren®)	bromfenac 0.09% sol (Bromday®)
flurbiprofen 0.03% sol$^{\Delta}$ (Ocufen®)	bromfenac 0.075% sol (BromSite®)
ketorolac 0.5% sol (Acular®)	bromfenac 0.07% sol (Prolensa®)
	ketorolac 0.4% sol (Acular LS®)
	ketorolac 0.45% sol (Acuvail®)
	nepafenac 0.1% sus (Nevanac®)
	nepafenac 0.3% sus (Ilevro®)

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).
sol = solution; sus = suspension
$^{\Delta}$Not a required Tier-1 trial; does not have to be attempted for approval of a Tier-2 medication.

Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic NSAIDs (from different medication lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic NSAIDs lack.

Utilization of Ophthalmic Anti-Inflammatory Products: Calendar Year 2021

Comparison of Calendar Years: Ophthalmic Corticosteroids (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1,894	2,801	$221,414.74	$79.05	$3.05	18,746	72,600
2021	2,749	3,955	$294,423.07	$74.44	$2.78	26,495	106,048
% Change	**45.1%**	**41.2%**	**33.0%**	**-5.8%**	**-8.9%**	**41.3%**	**46.1%**
Change	**855**	**1,154**	**$73,008.33**	**-$4.61**	**-$0.27**	**7,749**	**33,448**

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

Comparison of Calendar Years: Ophthalmic Corticosteroids (Medical Claims)

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	24	34	$99,653.69	$2,930.99	1.42
2021	18	37	$75,668.34	$2,045.09	2.06
% Change	**-25.0%**	**8.82%**	**-24.07%**	**-30.23%**	**45.07%**
Change	**-6**	**3**	**-$23,985.35**	**-$885.90**	**0.64**

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

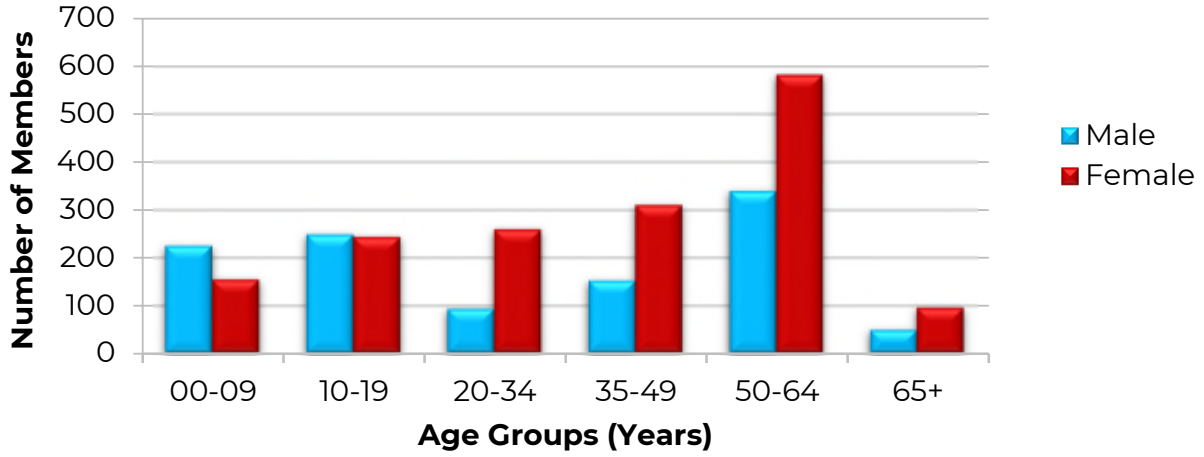
Comparison of Calendar Years: Ophthalmic NSAIDs (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	503	694	$45,866.57	$66.09	$2.73	3,708	16,822
2021	812	1,091	$53,516.95	$49.05	$1.87	5,710	28,567
% Change	**61.4%**	**57.2%**	**16.7%**	**-25.8%**	**-31.5%**	**54.0%**	**69.8%**
Change	**309**	**397**	**$7,650.38**	**-$17.04**	**-$0.86**	**2,002**	**11,745**

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

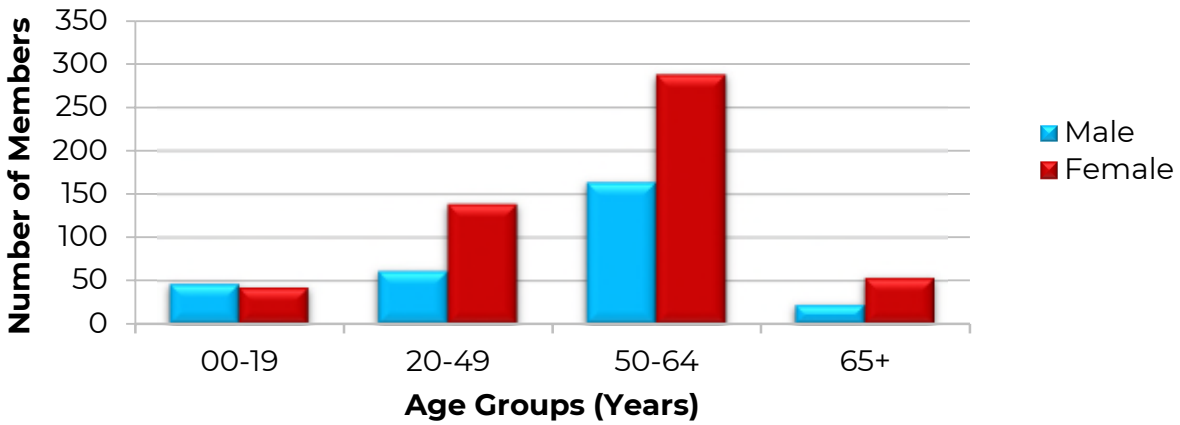
- The Ophthalmic Anti-Inflammatory Products medication category is influenced by federal rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
  - Aggregate drug rebates collected during calendar year 2021 for ophthalmic anti-inflammatory products: $189,593.52[Δ]

Demographics of Members Utilizing Ophthalmic Corticosteroids

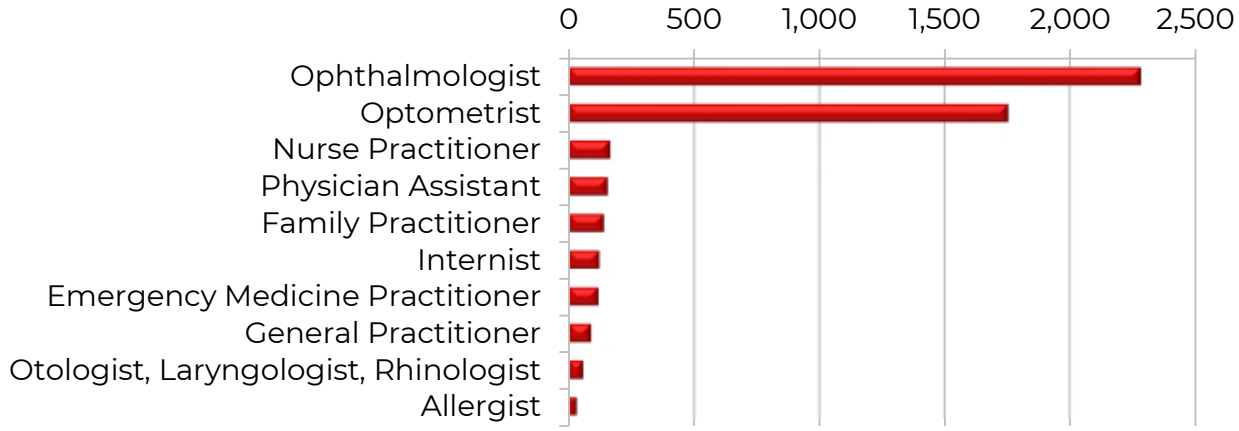


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Ophthalmic NSAIDs



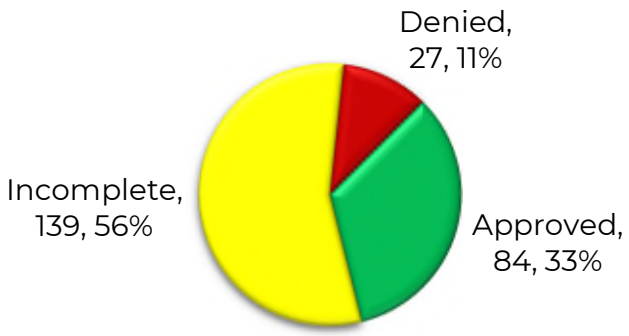
Top Prescriber Specialties of Ophthalmic Anti-Inflammatory Products by Number of Claims



Prior Authorization of Ophthalmic Anti-Inflammatory Products

There were 250 prior authorization requests submitted for ophthalmic anti-inflammatory products during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Ozurdex® (dexamethasone intravitreal implant): November 2023
- Nevanac® (nepafenac 0.1% ophthalmic suspension): January 2027
- Iluvien® (fluocinolone intravitreal implant): August 2027
- Yutiq® (fluocinolone intravitreal implant): August 2027
- Acular LS® (ketorolac 0.4% ophthalmic solution): November 2027
- Acuvail® (ketorolac 0.45% ophthalmic solution): August 2029
- BromSite® (bromfenac 0.075% ophthalmic solution): August 2029
- Dextenza® (dexamethasone ophthalmic insert): May 2030
- Ilevro® (nepafenac 0.3% ophthalmic suspension): March 2032
- Inveltys® (loteprednol 1% ophthalmic suspension): May 2033
- Prolensa® (bromfenac 0.07% ophthalmic solution): November 2033
- Xipere® (triamcinolone acetonide injectable suspension): May 2034
- Lotemax® SM (loteprednol 0.38% ophthalmic gel): December 2036

Recommendations

The College of Pharmacy recommends making Durezol® (difluprednate 0.05%) brand preferred based on net costs (changes are shown in red in the following Tier chart):

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone 0.1% sus (Maxidex®)	fluorometholone 0.25% sus (FML Forte®)
dexamethasone sodium phosphate 0.1% sol	fluorometholone 0.1% oint (FML S.O.P®)
difluprednate 0.05% emu (Durezol®) – **Brand Preferred**	loteprednol 1% sus (Inveltys®)
fluorometholone 0.1% sus (Flarex®)	loteprednol 0.38% gel (Lotemax® SM)
fluorometholone 0.1% sus (FML Liquifilm®)	prednisolone acetate 1% sus (Pred Forte®)
loteprednol 0.5% gel, oint, sus (Lotemax®) – **Brand Preferred**	
prednisolone acetate 1% sus (Omnipred®)	
prednisolone acetate 0.12% sus (Pred Mild®)	
prednisolone sodium phosphate 1% sol	

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)
emu = emulsion; oint = ointment; sol = solution; sus = suspension

Utilization Details of Ophthalmic Corticosteroids: Calendar Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
PREDNISOLONE PRODUCTS					
PREDNISOLONE SUS 1% OP	2,909	2,057	$136,076.03	$46.78	1.41
PRED MILD SUS 0.12% OP	10	7	$2,262.00	$226.20	1.43
PRED SOD PHO SOL 1% OP	3	3	$175.28	$58.43	1
SUBTOTAL	**2,922**	**2,067**	**$138,513.31**	**$47.40**	**1.41**
DIFLUPREDNATE PRODUCTS					
DUREZOL EMU 0.05%	320	208	$66,845.11	$208.89	1.54
DIFLUPREDNAT EMU 0.05%	31	25	$6,164.97	$198.87	1.24
SUBTOTAL	**351**	**233**	**$73,010.08**	**$208.01**	**1.51**
DEXAMETHASONE PRODUCTS					
DEXAMETH PHO SOL 0.1% OP	335	302	$18,755.06	$55.99	1.11
MAXIDEX SUS 0.1% OP	8	8	$636.86	$79.61	1
SUBTOTAL	**343**	**310**	**$19,391.92**	**$56.54**	**1.11**
FLUOROMETHOLONE PRODUCTS					
FLUOROMETHOL SUS 0.1% OP	154	100	$14,983.05	$97.29	1.54
FLAREX SUS 0.1% OP	25	21	$3,123.46	$124.94	1.19
FML LIQUIFLM SUS 0.1% OP	14	9	$2,754.99	$196.79	1.56
SUBTOTAL	**193**	**130**	**$20,861.50**	**$108.09**	**1.48**
LOTEPREDNOL PRODUCTS					
LOTEMAX SUS 0.5%	122	89	$37,256.49	$305.38	1.37
LOTEPREDNOL SUS 0.5%	2	1	$357.98	$178.99	2
SUBTOTAL	**124**	**90**	**$37,614.47**	**$303.34**	**1.38**
TIER-1 SUBTOTAL	**3,933**	**2,830**	**$289,391.28**	**$73.58**	**1.40**
TIER-2 UTILIZATION					
LOTEPREDNOL PRODUCTS					
LOTEMAX OIN 0.5%	7	4	$2,087.70	$298.24	1.75
LOTEMAX GEL 0.5%	7	6	$1,501.60	$214.51	1.17
LOTEPREDNOL GEL 0.5%	6	6	$886.85	$147.81	1
INVELTYS SUS 1%	2	1	$555.64	$277.82	2
SUBTOTAL	**22**	**17**	**$5,031.79**	**$228.72**	**1.29**
TIER-2 SUBTOTAL	**22**	**17**	**$5,031.79**	**$228.72**	**1.29**
TOTAL	**3,955**	**2,749***	**$294,423.07**	**$74.44**	**1.44**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
DEXAMETH = dextamethasone; EMU = emulsion; OIN = ointment; OP = ophthalmic; PHO = phosphate; PRED = prednisolone; SOD = sodium; SOL = solution; SUS = suspension

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
OZURDEX® (J7312)	34	17	$47,775.36	$1405.16
ILUVIEN® (J7313)	2	1	$18,656.1	$9,328.05
YUTIQ® (J7314)	1	1	$9,236.88	$9,236.88
TOTAL	**37†**	**18***	**$75,668.34**	**$2,045.09**

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

Utilization Details of Ophthalmic NSAIDs: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
KETOROLAC SOL 0.5%	897	674	$17,005.71	$18.96	1.33
DICLOFENAC SOL 0.1% OP	77	61	$1,358.23	$17.64	1.26
TIER-1 SUBTOTAL	**974**	**2,749**	**$18,363.94**	**$18.85**	**0.35**
TIER-2 UTILIZATION					
ILEVRO DRO 0.3% OP	117	94	$35,153.01	$300.45	1.24
TIER-2 SUBTOTAL	**117**	**94**	**$35,153.01**	**$300.45**	**1.24**
TOTAL	**1,091**	**812***	**$53,516.95**	**$49.05**	**1.34**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
DRO = drops; OP = ophthalmic; SOL = solution

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 07/2022. Last accessed 07/18/2022.

Appendix F

Calendar Year 2021 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications

Oklahoma Health Care Authority
August 2022

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®)	oxycodone/APAP ER tab (Xartemis® XR)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tramadol ER tab (Ultram ER®, Ryzolt®)	hydromorphone ER tab (Exalgo®)	
		methadone tab and oral soln (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		morphine ER tab (Arymo™ ER)	
		morphine ER tab (MorphaBond™)	
		oxycodone ER cap (Xtampza® ER)	
		oxycodone/ naltrexone ER cap (Troxyca® ER)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	oxymorphone IR tab (Opana®)	benzhydrocodone/ APAP tab (Apadaz®)	celecoxib 56mg/tramadol 44mg (Seglentis®)
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	tapentadol IR tab (Nucynta®)	dihydrocodeine/ APAP/caff cap (Trezix®)	levorphanol tab
codeine tab		hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	tramadol 100mg tab
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	tramadol oral soln (Qdolo™)
dihydrocodeine/ ASA/caff cap (Synalgos-DC®)		oxycodone tab (Oxaydo®)	
hydrocodone/ APAP tab (Norco®)		oxycodone tab (RoxyBond™)	
hydrocodone/IBU tab (Vicoprofen®, Ibudone®, Reprexain™)			
hydromorphone tab (Dilaudid®)			
morphine IR tab (MSIR®)			***Oncology Only:***
oxycodone/APAP tab (Percocet®)			fentanyl buccal film (Onsolis®)
oxycodone/ASA tab (Percodan®)			fentanyl buccal tab (Fentora®)
oxycodone IR cap (Oxy IR®)			fentanyl nasal spray (Lazanda®)
oxycodone IR tab (Roxicodone®)			fentanyl SL spray (Subsys®)
tramadol 50mg tab (Ultram®)			fentanyl SL tab (Abstral®)
tramadol/APAP tab (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.
- 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 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®, Lazanda®, Onsolis®, and Subsys® are approved for oncology-related diagnoses only.
   a.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:

    a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Hydrocodone/Acetaminophen (APAP) Unique Strengths Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) must be provided.
4. Levorphanol Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
5. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    c. A quantity limit of 2,400mL per 30 days will apply.
6. Seglentis® (Celecoxib 56mg/Tramadol 44mg) Approval Criteria:
    a. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
    b. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
    c. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
    d. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    e. A quantity limit of 28 tablets for a 7-day supply will apply.
7. Tramadol 100mg Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information

supporting the use of tramadol despite the medication being contraindicated for the member's age.

8. Xartemis® XR (Oxycodone/APAP ER Tablet) Approval Criteria:
    a. An acute pain condition requiring around-the-clock opioid treatment; and
    b. A patient-specific, clinically significant reason must be provided for all of the following:
        i. Why the member cannot use any other opioid medication for treatment of acute pain; and
        ii. Why the member requires a long-acting medication for an acute pain condition; and
        iii. Why the member cannot use Oxycontin® (oxycodone ER) and over-the-counter (OTC) APAP individual products in place of this combination product; and
    c. A quantity limit of 4 tablets per day will apply with a maximum approval duration of 10 days; and
    d. The member must not exceed 3,250mg of APAP per day from all sources; and
    e. Tier structure rules still apply.

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.

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

Bunavail® (Buprenorphine/Naloxone Buccal Film), 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 Bunavail®, 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. Buprenorphine products FDA approved for a diagnosis of opioid abuse/ dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
4. Member must have an FDA approved diagnosis of opioid abuse/ dependence; and
5. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
6. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
7. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 60 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.
    i. Bunavail® 2.1mg/0.3mg buccal films: A quantity limit of 90 buccal films per 30 days will apply.
    j. Bunavail® 4.2mg/0.7mg buccal films: A quantity limit of 60 buccal films per 30 days will apply.
    k. Bunavail® 6.3mg/1mg buccal films: A quantity limit of 30 buccal films 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.

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.

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

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder; and
2. Sublocade® must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
3. Member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; and
4. Concomitant treatment with opioids (including tramadol) will be denied; and
5. Sublocade® 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. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
8. A quantity limit of 1 dose (300mg or 100mg) per 28 days will apply.

Utilization of Opioid Analgesics and MAT Medications: Calendar Year 2021

Comparison of Calendar Years: Opioid Analgesics (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	62,671	210,393	$8,088,813.85	$38.45	$1.95	14,513,138	4,154,541
2021	78,663	232,420	$8,214,320.79	$35.34	$1.92	15,083,939	4,276,223
% Change	**25.50%**	**10.50%**	**1.60%**	**-8.10%**	**-1.50%**	**3.90%**	**2.90%**
Change	**15,992**	**22,027**	**$125,506.94**	**-$3.11**	**-$0.03**	**570,801**	**121,682**

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.

- There were no medical claims for opioid analgesics in calendar year 2021.

- The Opioid Analgesics Product Based Prior Authorization (PBPA) category is heavily influenced by federal and supplemental rebates. These 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.
    - Aggregate drug rebates collected during calendar year 2021 for opioid analgesics: $4,314,480.81[Δ]

Comparison of Calendar Years: MAT Medications (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	3,546	27,618	$7,082,809.98	$256.46	$9.73	1,404,487	728,146
2021	5,777	36,182	$3,136,232.30	$86.68	$3.38	1,716,109	928,563
% Change	**62.90%**	**31.00%**	**-55.70%**	**-66.20%**	**-65.30%**	**22.20%**	**27.50%**
Change	**2,231**	**8,564**	**-$3,946,577.68**	**-$169.78**	**-$6.35**	**311,622**	**200,417**

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.

Calendar Year 2021 Utilization: MAT Medications (Medical Claims)

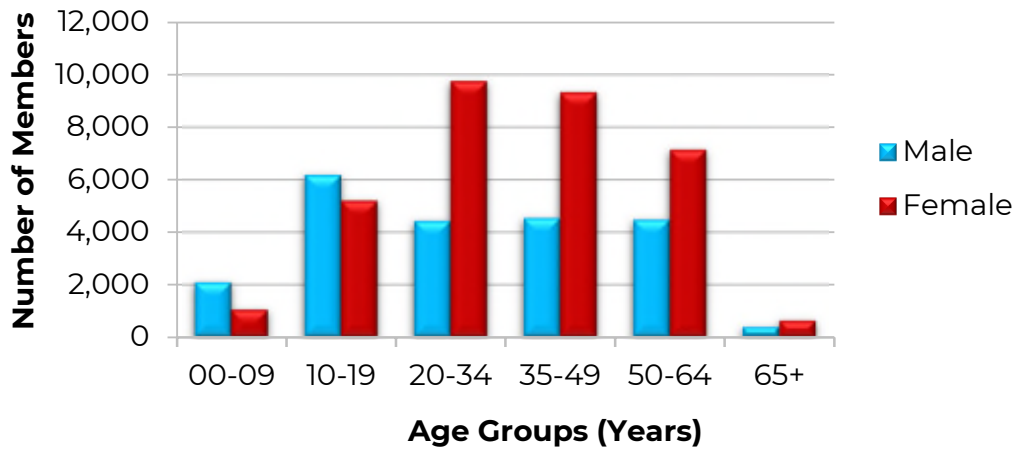
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	2	2	$6.50	$3.25	1
2021	2	3	$10.50	$3.50	1.5
% Change	**0.00%**	**50.00%**	**61.54%**	**7.69%**	**50.00%**
Change	**0**	**1**	**$4.00**	**$0.25**	**0.5**

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

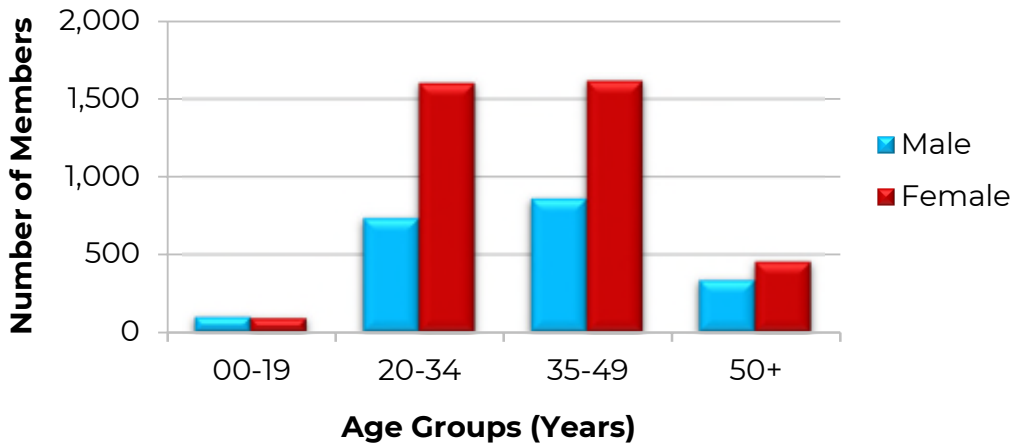
- The MAT medication category is influenced by federal rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
    - Aggregate drug rebates collected during calendar year 2021 for MAT medications: $580,098.97[Δ]

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

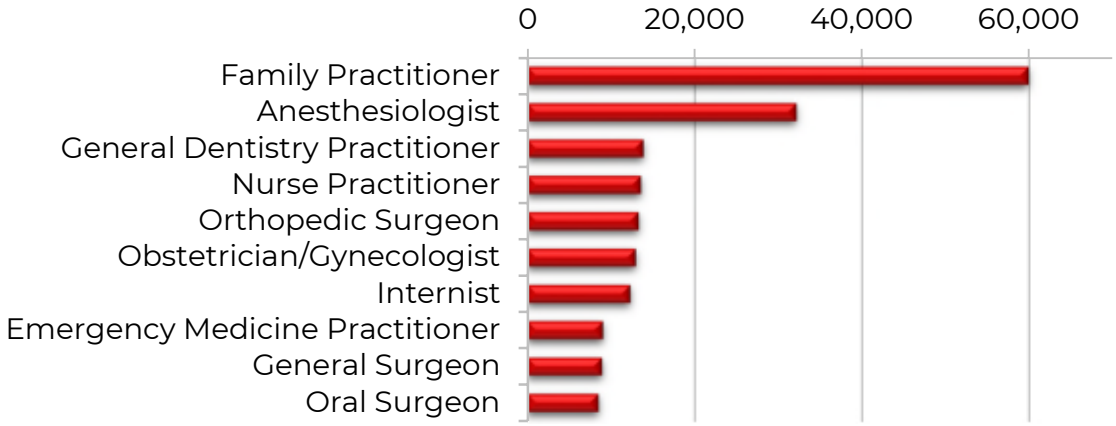
Demographics of Members Utilizing Opioid Analgesics



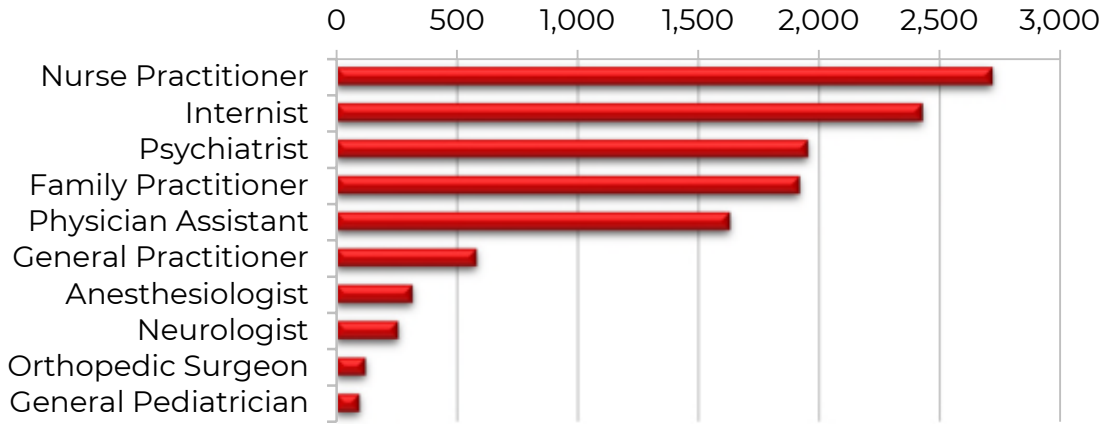
Demographics of Members Utilizing MAT Medications



Top Prescriber Specialties of Opioid Analgesics by Number of Claims



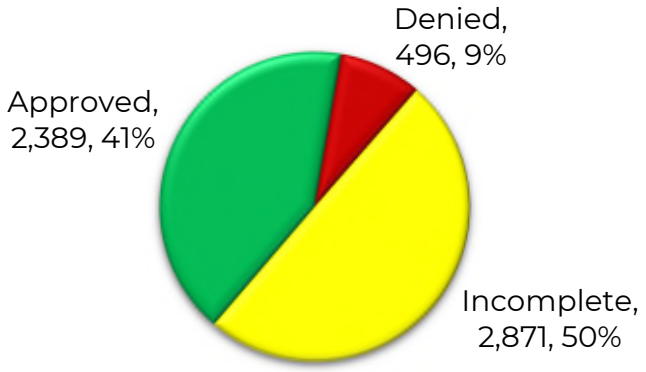
Top Prescriber Specialties of MAT Medications by Number of Claims



Prior Authorization of Opioid Analgesics and MAT Medications

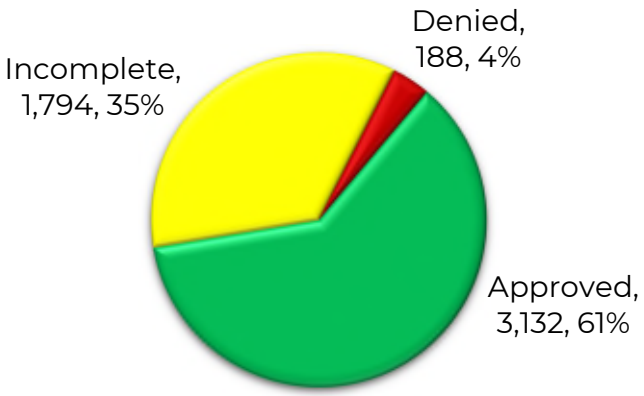
There were 5,756 prior authorization requests submitted for opioid analgesics during calendar year 2021. Computer edits are in place to detect diagnosis, quantity/day supply, and lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions: Opioid Analgesics



There were 5,114 prior authorizations submitted for MAT medications during calendar year 2021. 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 2021.

Status of Petitions: MAT Medications



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

Anticipated Patent Expiration(s):

- Oxaydo® [oxycodone immediate-release (IR) tablet]: March 2025
- Nucynta® (tapentadol IR tablet): June 2025
- Fentora® (fentanyl buccal tablet): June 2028
- MorphaBond™ [morphine extended-release (ER) tablet]: August 2028
- Nucynta® ER (tapentadol ER tablet): September 2028
- Subsys® [fentanyl sublingual (SL) spray]: April 2030
- Apadaz® [benzhydrocodone/acetaminophen (APAP) IR tablet]: February 2031
- Hysingla® ER (hydrocodone ER tablet): December 2031
- Lazanda® (fentanyl nasal spray): January 2032
- Zubsolv® (buprenorphine/naloxone 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

News:

- **June 2021:** Braeburn announced its New Drug Application (NDA) for Brixadi™ [buprenorphine extended-release (ER) injection] for moderate-to-severe opioid use disorder (OUD) was accepted by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) action date was set for December 15, 2021. Brixadi™ is an investigational, ER weekly (8mg, 16mg, 24mg, 32mg) and monthly (64 mg, 96mg, 128mg) subcutaneous (sub-Q) injection that is under review by FDA for the treatment of moderate-to-severe OUD in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. If approved, Brixadi™ would be used as part of a

complete treatment plan to include counseling and psychosocial support. Brixadi™ would be available through a risk evaluation and mitigation strategy (REMS) program and administered only by health care providers in a health care setting. In December 2021, Braeburn received a Complete Response Letter (CRL) from the FDA for its NDA for Brixadi™ (buprenorphine ER injection) for the treatment of OUD. The CRL is a result of continued quality related deficiencies at Braeburn's United States based third party manufacturer, identified by the FDA during a pre-approval inspection.

- **November 2021:** Provisional data from the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics indicate there were an estimated 100,306 drug overdose deaths in the United States during the 12-month period ending in April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before. The new data documents that estimated overdose deaths from opioids increased to 75,673 in the 12-month period ending in April 2021, up from 56,064 the year before. Overdose deaths from synthetic opioids (primarily fentanyl) and psychostimulants (such as methamphetamine) also increased in the 12-month period ending in April 2021. Cocaine deaths also increased, as did deaths from natural and semi-synthetic opioids (such as prescription pain medication). For Oklahoma, from February 2021 to February 2022 the provisional data shows the percent change in reported drug overdose deaths was 11.04% with an increase in deaths from 779 in 2021 to 865 in 2022. The CDC's National Center for Health Statistics indicated that provisional data are based on available records that meet certain data quality criteria at the time of analysis and may not include all deaths that occurred during a given time period. Therefore, they should not be considered comparable with final data and are subject to change. For comparison, data from the CDC for 2019-2020 show Oklahoma's drug overdose death rate for this period increased 16.4% from 645 in 2019 to 762 in 2020.
- **January 2022:** The FDA issued a warning that dental problems have been reported with medications containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues. The FDA indicated that despite these risks, buprenorphine is an important treatment option for OUD and pain, and the benefits of these medications clearly outweigh the risks. The FDA required that a new warning about the risk of dental problems be added to the *Prescribing Information* and the patient *Medication Guide* for all buprenorphine-containing medicines dissolved in the mouth. The FDA also required strategies in the prescribing and patient information on how to maintain or improve oral health while undergoing treatment with

these medications. These strategies include recommending that prescribers refer patients to dental care services and encourage them to have regular checkups while taking these products. The FDA recommends that patients tell their dentist about all medications they take, including buprenorphine.

- **May 2022:** The U.S. Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), is announcing a State Opioid Response (SOR) grant funding opportunity that will provide nearly $1.5 billion to states and territories to help address the nation's opioid addiction and overdose epidemic. In President Biden's 2022 State of the Union address, he named beating the opioid epidemic as a pillar of his Unity Agenda. The SOR program, along with the Tribal Opioid Response grant funding opportunity, are critical tools in President Biden's inaugural National Drug Control Strategy and the HHS Overdose Prevention Strategy. The SOR grant program provides formula funding to states and territories for increasing access to FDA-approved medications for the treatment of OUD and for supporting prevention, harm reduction, treatment, and recovery support services for OUD and other concurrent substance use disorders. The SOR program also supports care for stimulant misuse and use disorders, including for cocaine and methamphetamine. The purpose of the SOR program is to help reduce overdose deaths and close the gap in treatment needs across America by giving states and territories flexibility in funding evidence-based practices and supports across different settings to meet local community needs.

Recommendations

The College of Pharmacy recommends the following changes to the Opioid Analgesics PBPA category (changes noted in red in the following Tier chart and approval criteria; only criteria with changes are listed):

1. Moving hydrocodone/ibuprofen 10/200mg tablet (Ibudone®, Reprexain™) from Tier-1 to Tier-2 of the Short-Acting Opioid Analgesics category based on net cost

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	oxycodone/APAP ER tab (Xartemis® XR)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tramadol ER tab (Ultram ER®, Ryzolt®)	hydromorphone ER tab (Exalgo®)	
		methadone tab and oral soln (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		morphine ER tab (Arymo™ ER)	
		morphine ER tab (MorphaBond™)	
		oxycodone ER cap (Xtampza® ER)	
		oxycodone/ naltrexone ER cap (Troxyca® ER)	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	**hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)**	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
codeine tab	tapentadol IR tab (Nucynta®)	hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	tramadol oral soln (Qdolo™)
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	
dihydrocodeine/ ASA/caff cap (Synalgos-DC®)		oxycodone tab (Oxaydo®)	
hydrocodone/ APAP tab (Norco®)		oxycodone tab (RoxyBond™)	
hydrocodone/IBU tab **5/200mg, 7.5/200mg only** (Vicoprofen®, Ibudone®, Reprexain™)			
hydromorphone tab (Dilaudid®)			
morphine IR tab (MSIR®)			***Oncology Only:***
oxycodone/APAP tab (Percocet®)			fentanyl buccal film (Onsolis®)
oxycodone/ASA tab (Percodan®)			fentanyl buccal tab (Fentora®)
oxycodone IR cap (Oxy IR®)			fentanyl nasal spray (Lazanda®)
oxycodone IR tab (Roxicodone®)			fentanyl SL spray (Subsys®)
tramadol 50mg tab (Ultram®)			fentanyl SL tab (Abstral®)
tramadol/APAP tab (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

The College of Pharmacy recommends the following changes to the MAT medications approval criteria (changes noted in red in the following criteria; only criteria with changes are listed):

1. Removal of Bunavail® (buprenorphine/naloxone buccal film) based on product discontinuation

~~Bunavail® (Buprenorphine/Naloxone Buccal Film),~~ 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 ~~Bunavail®,~~ 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. Buprenorphine products FDA approved for a diagnosis of opioid abuse/dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
4. Member must have an FDA approved diagnosis of opioid abuse/dependence; and
5. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
6. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
7. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 60 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.

g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
h. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.
~~i. Bunavail® 2.1mg/0.3mg buccal films: A quantity limit of 90 buccal films per 30 days will apply.~~
~~j. Bunavail® 4.2mg/0.7mg buccal films: A quantity limit of 60 buccal films per 30 days will apply.~~
~~k. Bunavail® 6.3mg/1mg buccal films: A quantity limit of 30 buccal films per 30 days will apply.~~

Utilization Details of Opioid Analgesics: Calendar Year 2021

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 10-325MG	41,054	7,209	$823,117.88	$20.05	5.69
HYDROCOD/APAP TAB 5-325MG	36,014	25,990	$452,169.78	$12.56	1.39
HYDROCOD/APAP TAB 7.5-325MG	33,989	17,054	$514,875.01	$15.15	1.99
HYDROCOD/APAP SOL 7.5-325MG	4,284	3,906	$96,530.64	$22.53	1.1
HYDROCOD/IBU TAB 7.5-200MG	278	61	$6,621.47	$23.82	4.56
HYDROCOD/IBU TAB 10-200MG	54	8	$16,737.75	$309.96	6.75
HYDROCOD/IBU TAB 5-200MG	14	10	$1,593.83	$113.85	1.4
SUBTOTAL	**115,687**	**54,238**	**$1,911,646.36**	**$16.52**	**2.13**
IMMEDIATE-RELEASE OXYCODONE PRODUCTS					
OXYCOD/APAP TAB 10-325MG	17,011	3,205	$432,800.82	$25.44	5.31
OXYCOD/APAP TAB 5-325MG	13,771	9,945	$175,711.03	$12.76	1.38
OXYCOD/APAP TAB 7.5-325MG	8,529	3,389	$145,179.32	$17.02	2.52
OXYCODONE TAB 5MG	5,091	3,731	$62,323.63	$12.24	1.36
OXYCODONE TAB 15MG	5,019	765	$103,239.24	$20.57	6.56
OXYCODONE TAB 10MG	4,872	1,115	$92,770.73	$19.04	4.37
OXYCODONE TAB 20MG	1,418	252	$36,983.79	$26.08	5.63
OXYCODONE SOL 5MG/5ML	1,245	1,096	$23,394.45	$18.79	1.14
OXYCODONE TAB 30MG	577	109	$18,171.01	$31.49	5.29
OXYCODONE CAP 5MG	88	73	$2,006.93	$22.81	1.21
ENDOCET TAB 5-325MG	25	12	$279.24	$11.17	2.08
ENDOCET TAB 7.5-325MG	23	4	$457.58	$19.89	5.75
ENDOCET TAB 10-325MG	21	5	$563.63	$26.84	4.2
OXYCODONE CONC 100MG/5ML	13	6	$2,019.35	$155.33	2.17
OXYCOD/APAP TAB 2.5-325MG	9	7	$624.96	$69.44	1.29
SUBTOTAL	**57,712**	**23,714**	**$1,096,525.71**	**$19.00**	**2.43**
IMMEDIATE-RELEASE TRAMADOL PRODUCTS					
TRAMADOL HCL TAB 50MG	25,632	10,000	$274,385.64	$10.70	2.56

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TRAMADOL/APAP TAB 37.5-325MG	184	137	$2,488.41	$13.52	1.34
TRAMADOL HCL TAB 100MG	1	1	$94.30	$94.30	1
SUBTOTAL	**25,817**	**10,138**	**$276,968.35**	**$10.73**	**2.55**
CODEINE PRODUCTS					
APAP/CODEINE TAB 300-30MG	8,860	5,650	$108,541.18	$12.25	1.57
APAP/CODEINE TAB 300-60MG	5,448	1,533	$126,289.23	$23.18	3.55
BUT/APAP/CAF/COD 50/325/40/30MG	281	90	$14,029.66	$49.93	3.12
APAP/CODEINE TAB 300-15MG	124	105	$1,447.76	$11.68	1.18
BUT/ASA/CAF/COD 50/325/40/30MG	84	24	$6,658.89	$79.27	3.5
ASCOMP/COD CAP 30MG	48	19	$4,175.95	$87.00	2.53
CODEINE SULF TAB 30MG	36	9	$1,522.79	$42.30	4
APAP/CODEINE SOL 120-12MG/5ML	24	5	$577.85	$24.08	4.8
CODEINE SULF TAB 60MG	2	1	$209.10	$104.55	2
BUT/APAP/CAF/COD 50/300/40/30MG	1	1	$139.04	$139.04	1
SUBTOTAL	**14,908**	**7,437**	**$263,591.45**	**$17.68**	**2**
IMMEDIATE-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG	1,315	323	$41,373.59	$31.46	4.07
MORPHINE SULF TAB 30MG	303	62	$15,365.95	$50.71	4.89
MORPHINE SULF SOL 100MG/5ML	105	51	$2,667.31	$25.40	2.06
MORPHINE SULF SOL 10MG/5ML	82	30	$1,533.88	$18.71	2.73
MORPHINE SULF SOL 20MG/5ML	10	7	$155.06	$15.51	1.43
MORPHINE SULF SOL 20MG/ML	1	1	$20.85	$20.85	1
SUBTOTAL	**1,816**	**474**	**$61,116.64**	**$33.65**	**3.83**
IMMEDIATE-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 4MG	609	135	$11,008.77	$18.08	4.51
HYDROMORPHONE TAB 2MG	402	210	$5,553.28	$13.81	1.91
HYDROMORPHONE TAB 8MG	99	25	$4,214.93	$42.58	3.96
HYDROMORPHONE LIQ 1MG/ML	5	2	$551.75	$110.35	2.5
HYDROMORPHONE INJ 10MG/ML	2	1	$826.98	$413.49	2
SUBTOTAL	**1,117**	**373**	**$22,155.71**	**$19.84**	**2.99**
PENTAZOCINE PRODUCTS					
PENTAZ/NALOX TAB 50-0.5MG	202	56	$28,389.06	$140.54	3.61
SUBTOTAL	**202**	**56**	**$28,389.06**	**$140.54**	**3.61**
MEPERIDINE PRODUCTS					
MEPERIDINE TAB 50MG	139	119	$1,318.68	$9.49	1.17
MEPERIDINE INJ 100MG/ML	7	6	$166.01	$23.72	1.17
SUBTOTAL	**146**	**125**	**$1,484.69**	**$10.17**	**1.17**
IMMEDIATE-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG	51	5	$2,476.58	$48.56	10.2
OXYMORPHONE TAB 5MG	14	2	$336.90	$24.06	7
SUBTOTAL	**65**	**7**	**$2,813.48**	**$42.28**	**9.29**
IMMEDIATE-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA TAB 50MG	27	5	$18,414.99	$682.04	5.4

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**27**	**5**	**$18,414.99**	**$682.04**	**5.4**
SHORT-ACTING SUBTOTAL	**217,497**	**96,567**	**$3,683,106.44**	**$16.93**	**2.25**
LONG-ACTING OPIOID ANALGESICS					
EXTENDED-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG ER	2,558	442	$51,341.14	$20.07	5.79
MORPHINE SULF TAB 30MG ER	1,596	259	$44,982.18	$28.18	6.16
MORPHINE SULF TAB 60MG ER	236	49	$11,892.79	$50.39	4.82
MORPHINE SULF CAP 30MG ER	34	7	$5,762.06	$169.47	4.86
MORPHINE SULF CAP 10MG ER	33	7	$3,814.82	$115.60	4.71
MORPHINE SULF CAP 50MG ER	24	2	$5,847.04	$243.63	12
MORPHINE SULF CAP 20MG ER	18	5	$2,770.64	$153.92	3.6
MORPHINE SULF TAB 100MG ER	16	5	$1,302.04	$81.38	3.2
MORPHINE SULF CAP 60MG ER	1	1	$193.25	$193.25	1
SUBTOTAL	**4,516**	**777**	**$127,905.96**	**$28.32**	**5.81**
EXTENDED-RELEASE OXYCODONE PRODUCTS					
OXYCONTIN TAB 10MG ER	1,659	266	$365,782.42	$220.48	6.24
OXYCONTIN TAB 20MG ER	856	144	$371,844.31	$434.40	5.94
OXYCONTIN TAB 15MG ER	638	98	$219,573.39	$344.16	6.51
OXYCONTIN TAB 30MG ER	411	64	$268,903.40	$654.27	6.42
OXYCONTIN TAB 40MG ER	239	38	$199,332.65	$834.03	6.29
OXYCONTIN TAB 60MG ER	101	22	$116,933.18	$1,157.75	4.59
OXYCONTIN TAB 80MG ER	72	14	$126,583.96	$1,758.11	5.14
XTAMPZA ER CAP 9MG	43	11	$12,762.79	$296.81	3.91
XTAMPZA ER CAP 18MG	42	8	$18,434.79	$438.92	5.25
XTAMPZA ER CAP 13.5MG	34	5	$14,267.18	$419.62	6.8
XTAMPZA ER CAP 27MG	18	7	$13,571.68	$753.98	2.57
XTAMPZA ER CAP 36MG	10	2	$13,458.90	$1,345.89	5
OXYCODONE TAB 40MG ER	2	1	$359.68	$179.84	2
OXYCODONE TAB 20MG ER	1	1	$254.44	$254.44	1
SUBTOTAL	**4,126**	**681**	**$1,742,062.77**	**$422.22**	**6.06**
BUPRENORPHINE PAIN PRODUCTS					
BUTRANS DIS 20MCG/HR	897	173	$742,218.53	$827.45	5.18
BUTRANS DIS 10MCG/HR	840	376	$396,982.60	$472.60	2.23
BUTRANS DIS 15MCG/HR	709	214	$481,291.77	$678.83	3.31
BUTRANS DIS 5MCG/HR	254	136	$80,711.39	$317.76	1.87
BELBUCA MIS 450MCG	160	44	$117,960.85	$737.26	3.64
BELBUCA MIS 600MCG	137	34	$106,196.46	$775.16	4.03
BELBUCA MIS 900MCG	128	24	$111,752.93	$873.07	5.33
BELBUCA MIS 300MCG	117	49	$65,011.70	$555.66	2.39
BELBUCA MIS 150MCG	117	32	$40,301.26	$344.46	3.66
BELBUCA MIS 750MCG	99	23	$83,804.02	$846.51	4.3
BUTRANS DIS 7.5MCG/HR	98	49	$42,702.89	$435.74	2
BELBUCA MIS 75MCG	16	10	$5,599.30	$349.96	1.6

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUPRENORPHINE DIS 20MCG/HR	14	4	$5,982.15	$427.30	3.5
BUPRENORPHINE DIS 15MCG/HR	2	1	$604.90	$302.45	2
BUPRENORPHINE DIS 10MCG/HR	1	1	$213.38	$213.38	1
SUBTOTAL	**3,589**	**1,170**	**$2,281,334.13**	**$635.65**	**3.07**
EXTENDED-RELEASE FENTANYL PRODUCTS					
FENTANYL DIS 25MCG/HR	497	130	$20,174.69	$40.59	3.82
FENTANYL DIS 12MCG/HR	288	66	$23,689.77	$82.26	4.36
FENTANYL DIS 50MCG/HR	183	63	$10,798.69	$59.01	2.9
FENTANYL DIS 75MCG/HR	124	32	$11,917.66	$96.11	3.88
FENTANYL DIS 100MCG/HR	90	32	$8,778.59	$97.54	2.81
FENTANYL DIS 37.5MCG/HR	58	8	$25,135.31	$433.37	7.25
SUBTOTAL	**1,240**	**331**	**$100,494.71**	**$81.04**	**3.75**
EXTENDED-RELEASE TRAMADOL PRODUCTS					
TRAMADOL TAB 200MG ER	300	78	$19,189.12	$63.96	3.85
TRAMADOL TAB 100MG ER	276	81	$12,756.91	$46.22	3.41
TRAMADOL TAB 300MG ER	97	21	$7,872.76	$81.16	4.62
TRAMADOL TAB 200MG ER	14	6	$1,092.62	$78.04	2.33
TRAMADOL TAB 100MG ER	12	3	$670.30	$55.86	4
TRAMADOL TAB 300MG ER	2	2	$236.38	$118.19	1
TRAMADOL HCL CAP ER 300MG	1	1	$423.59	$423.59	1
SUBTOTAL	**702**	**192**	**$42,241.68**	**$60.17**	**3.66**
EXTENDED-RELEASE HYDROCODONE PRODUCTS					
HYSINGLA ER TAB 20MG	129	20	$38,770.02	$300.54	6.45
HYSINGLA ER TAB 40MG	120	13	$69,262.30	$577.19	9.23
HYSINGLA ER TAB 30MG	102	14	$42,820.83	$419.81	7.29
HYSINGLA ER TAB 60MG	42	5	$34,471.62	$820.75	8.4
HYSINGLA ER TAB 80MG	13	1	$14,350.61	$1,103.89	13
HYDROCODONE TAB 30MG ER	12	5	$3,831.57	$319.30	2.4
HYDROCODONE CAP 15MG ER	8	1	$3,367.40	$420.93	8
HYDROCODONE CAP 40MG ER	6	1	$2,675.21	$445.87	6
HYDROCODONE CAP 20MG ER	4	1	$2,027.32	$506.83	4
HYDROCODONE TAB 40MG ER	4	2	$1,872.68	$468.17	2
ZOHYDRO ER CAP 15MG	3	1	$1,265.09	$421.70	3
ZOHYDRO ER CAP 40MG	3	1	$1,427.43	$475.81	3
HYDROCODONE TAB 20MG ER	3	2	$745.41	$248.47	1.5
HYDROCODONE TAB 60MG ER	2	1	$1,294.84	$647.42	2
HYDROCODONE CAP 10MG ER	1	1	$449.96	$449.96	1
SUBTOTAL	**452**	**69**	**$218,632.29**	**$483.70**	**6.55**
METHADONE PRODUCTS					
METHADONE TAB 10MG	161	23	$2,901.47	$18.02	7
METHADONE TAB 5MG	56	15	$953.78	$17.03	3.73
METHADONE SOL 5MG/5ML	48	26	$572.81	$11.93	1.85
METHADONE SOL 10MG/5ML	2	2	$23.10	$11.55	1

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**267**	**66**	**$4,451.16**	**$16.67**	**4.05**
EXTENDED-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG ER	12	1	$3,891.26	$324.27	12
OXYMORPHONE TAB 20MG ER	12	1	$6,892.54	$574.38	12
SUBTOTAL	**24**	**2**	**$10,783.80**	**$449.33**	**12**
EXTENDED-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA ER TAB 50MG	6	3	$2,687.74	$447.96	2
SUBTOTAL	**6**	**3**	**$2,687.74**	**$447.96**	**2**
EXTENDED-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 32MG ER	1	1	$620.11	$620.11	1
SUBTOTAL	**1**	**1**	**$620.11**	**$620.11**	**1**
LONG-ACTING SUBTOTAL	**14,923**	**3,292**	**$4,531,214.35**	**$303.64**	**4.53**
OPIOID TOTAL	**232,420**	**78,663***	**$8,214,320.79**	**$35.34**	**2.95**

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; DIHYDROCO = dihydrocodeine; DIS = patch; ER = extended-release; HYDROCOD = hydrocodone; IBU = ibuprofen; INJ = injection; LIQ = liquid; LOZ = lozenge; MIS = film; NALOX = naloxone; OXYCOD = oxycodone; PENTAZ = pentazocine; SOL = solution; SULF = sulfate; TAB = tablet

Utilization Details of MAT Medications: Calendar Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUPRENORPHINE MAT PRODUCTS					
BUPREN/NALOX SUB 8-2MG	22,386	3,438	$1,414,682.95	$63.19	6.51
BUPRENORPHIN SUB 8MG	4,880	738	$252,652.45	$51.77	6.61
BUPREN/NALOX SUB 2-0.5MG	1,126	271	$58,829.93	$52.25	4.15
BUPREN/NALOX MIS 8-2MG	812	145	$198,418.73	$244.36	5.6
BUPRENORPHIN SUB 2MG	442	109	$13,440.49	$30.41	4.06
SUBOXONE MIS 8-2MG	230	87	$169,107.34	$735.25	2.64
ZUBSOLV SUB 5.7-1.4	124	14	$61,765.07	$498.11	8.86
SUBLOCADE INJ 300/1.5	71	37	$124,488.56	$1,753.36	1.92
SUBLOCADE INJ 100/0.5	58	15	$101,611.93	$1,751.93	3.87
ZUBSOLV SUB 8.6-2.1	51	7	$65,811.12	$1,290.41	7.29
BUPREN/NALOX MIS 12-3MG	15	3	$6,135.71	$409.05	5
ZUBSOLV SUB 2.9-0.71	15	2	$2,493.33	$166.22	7.5
BUPREN/NALOX MIS 2-0.5MG	15	4	$1,131.80	$75.45	3.75
ZUBSOLV SUB 11.4-2.9	15	1	$22,400.93	$1,493.40	15
BUPREN/NALOX MIS 4-1MG	13	7	$2,228.38	$171.41	1.86
SUBOXONE MIS 4-1MG	2	1	$787.09	$393.55	2
ZUBSOLV SUB 1.4-0.36	2	1	$145.27	$72.64	2
ZUBSOLV SUB 0.7-0.18	2	1	$124.82	$62.41	2

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**30,259**	**4,881**	**$2,496,255.90**	**$82.50**	**6.2**
NALTREXONE PRODUCTS					
NALTREXONE TAB 50MG	5,614	1,567	$215,124.75	$38.32	3.58
VIVITROL INJ 380MG	309	118	$424,851.65	$1,374.92	2.62
SUBTOTAL	**5,923**	**1,685**	**$639,976.40**	**$108.05**	**3.52**
MAT TOTAL	**36,182**	**5,777***	**$3,136,232.30**	**$86.68**	**6.26**

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; SUB = sublingual tablet; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NALTREXONE INJ J2315	3	2	$10.50	1.5	$3.50
TOTAL	**3**	**2**	**$10.50**	**1.5**	**$3.50**

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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[4] CDC. National Center for Health Statistics. Drug Overdose Deaths in the U.S. Top 100,000 Annually. Available online at: https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm. Issued 11/17/2021. Last accessed 07/20/2022.
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[7] U.S. Department of Health and Human Services (HHS). News. Biden Administration Announces $1.5 Billion Funding Opportunity for State Opioid Response Grant Program. Available online at: https://www.hhs.gov/about/news/2022/05/19/biden-administration-announces-15-billion-funding-opportunity-state-opioid-response-grant-program.html. Issued 05/19/2022. Last accessed 07/20/2022.

Appendix G

Calendar Year 2021 Annual Review of Topical Corticosteroids

Oklahoma Health Care Authority
August 2022

Current Prior Authorization Criteria

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

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
		halobetasol propionate/lactic acid 0.05%/10% (Ultravate X®)	C		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)	O,Spr, Sus	hydrocortisone valerate 0.2% (Westcort®)	C,O
betamethasone valerate 0.1% (Beta-Val®)	C,L,O	betamethasone valerate 0.12% (Luxiq®)	F		
fluticasone propionate 0.005% (Cutivate®)	O	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F		
fluticasone propionate 0.05% (Cutivate®)	C	clocortolone pivalate 0.1% (Cloderm®)	C		
mometasone furoate 0.1% (Elocon®)	C,L,O, So	desoximetasone 0.05% (Topicort LP®)	C,O		
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,LO		
		fluticasone propionate 0.05% (Cutivate®)	L		
		hydrocortisone butyrate 0.1%	C,L,O, So		
		hydrocortisone probutate 0.1% (Pandel®)	C		
		prednicarbate 0.1% (Dermatop®)	C,O		
		triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr		
		triamcinolone acetonide 0.05% (Trianex®)	O		

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

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

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 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 (foams, shampoos, sprays, kits, etc.); 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 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 (foams, shampoos, sprays, kits, etc.); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

Duobrii® (Halobetasol Propionate/Tazarotene 0.01%/0.045% Lotion) Approval Criteria:

1. An FDA approved indication of plaque psoriasis in adults; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. A patient-specific, clinically significant reason why the member cannot use individual components of tazarotene and a topical corticosteroid separately must be provided; and
4. A quantity limit of 100 grams per 30 days will apply.

Utilization of Topical Corticosteroids: Calendar Year 2021

Comparison of Calendar Years

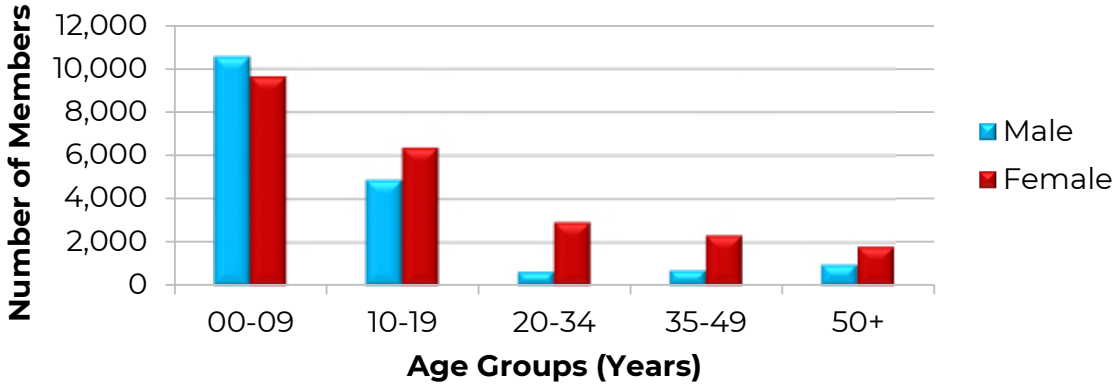
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	37,176	57,952	$1,115,153.90	$19.24	$1.10	4,019.681	1,013,739
2021	40,644	62,222	$1,098,892.84	$17.66	$0.98	4,565,887	1,125,234
% Change	**9.3%**	**7.4%**	**-1.5%**	**-8.2%**	**-10.0%**	**13.6%**	**11.0%**
Change	**3,468**	**4,270**	**-$16,261.06**	**-$1.58**	**-$0.12**	**546,206**	**111,495**

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

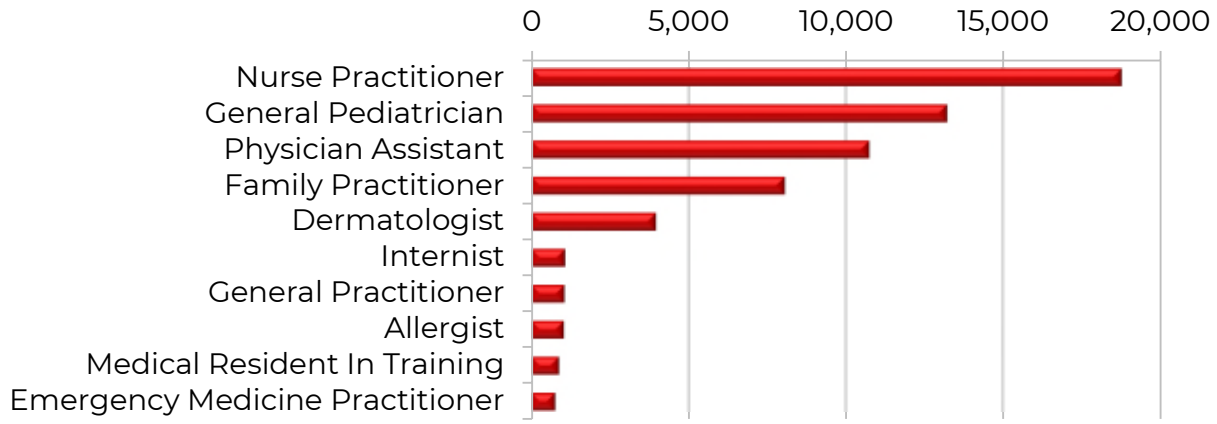
- The Topical Corticosteroid Product Based Prior Authorization (PBPA) category is influenced by federal rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
  - Aggregate drug rebates collected during calendar year 2021 for topical corticosteroids: $59,064.69[Δ]

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

Demographics of Members Utilizing Topical Corticosteroids



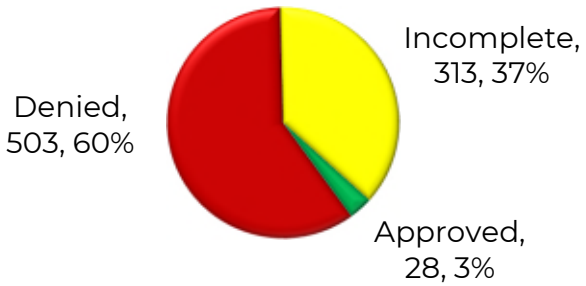
Top Prescriber Specialties of Topical Corticosteroids by Number of Claims



Prior Authorization of Topical Corticosteroids

There were 844 prior authorization requests submitted for topical corticosteroids during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Impeklo™ (clobetasol propionate 0.05% lotion), Capex® (fluocinolone 0.01% shampoo), Texacort® (hydrocortisone 2.5% topical solution), Halog® (halcinonide 0.1% solution and ointment), Cordran® (flurandrenolide 4mcg/cm^2 tape), Pandel® (hydrocortisone 0.1% cream), and U-Cort® (hydrocortisone/urea 1%/10% cream) have no unexpired patents or exclusivities, but are not available generically.
- Verdeso® (desonide 0.05% foam): August 2027
- Topicort® (desoximetasone 0.25% spray): September 2028
- Sernivo® (betamethasone dipropionate 0.05% topical spray): August 2030
- Bryhali® (halobetasol propionate 0.01% lotion): November 2031
- Enstilar® (calcipotriene/betamethasone dipropionate 0.64%/0.005% foam): December 2031
- Ultravate® (halobetasol 0.05% lotion): June 2033
- Impoyz® (clobetasol propionate 0.025% cream): March 2035
- Duobrii® (halobetasol propionate/tazarotene 0.01%/0.045% lotion): June 2036

Recommendations

The College of Pharmacy recommends the following changes to the topical corticosteroids PBPA Tier chart based on net costs (changes shown in red in the following Tier chart):

1. Ultra-High to High Potency:
    a. Augmented betamethasone 0.05% gel from Tier-1 to Tier-2; and
    b. Augmented betamethasone 0.05% ointment from Tier-2 to Tier-1; and
    c. Betamethasone dipropionate 0.05% cream and ointment from Tier-2 to Tier-1; and
    d. Clobetasol propionate 0.05% lotion from Tier-1 to Tier-2; and
    e. Desoximetasone 0.25% cream and ointment from Tier-3 to Tier-1; and
    f. Fluocinonide 0.1% cream from Tier-2 to Tier-1; and
    g. Halobetasol 0.05% ointment from Tier-2 to Tier-1.
2. Medium-High to Medium Potency:
    a. Betamethasone valerate 0.1% lotion from Tier-1 to Tier-2; and
    b. Desoximetasone 0.05% cream and ointment from Tier-2 to Tier-3.
3. Low Potency:
    a. Alclometasone 0.05% ointment from Tier-2 to Tier-3.
    b. Desonate® (desonide 0.05%) gel from Tier-1 to Tier-3; and
    c. Desonide emollient 0.05% cream and ointment from Tier-3 to Tier-1; and

d. Fluocinolone 0.01% solution from Tier-2 to Tier-1; and
e. Fluocinolone 0.01% oil from Tier-3 to Tier-2.

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (**Diprolene®,** Diprolene AF®)	C,~~**G,O**~~	amcinonide 0.1%	C,L	clobetasol propionate 0.05% (Clobex®)	Sh,Spr
betamethasone dipropionate 0.05% (Diprosone®)	**C,O**	augmented betamethasone dipropionate 0.05% (Diprolene®, **Diprolene AF®**)	**G**,L,~~**O**~~	clobetasol propionate 0.05% (Olux®, Olux-E®, Tovet®)	F
~~**clobetasol propionate 0.05% (Clobex®)**~~	~~**L**~~	~~**betamethasone dipropionate 0.05% (Diprosone®)**~~	~~**C,O**~~	clobetasol propionate 0.05% (Impeklo™)	L
clobetasol propionate 0.05% (Temovate®)	C,O,So	**clobetasol propionate 0.05% (Clobex®)**	**L**	desoximetasone 0.25% (Topicort®)	~~**C,O**~~,Spr
desoximetasone 0.25% (Topicort®)	**C,O**	clobetasol propionate 0.05% (Temovate®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
fluocinonide 0.05%	C,O,So	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon E®)	C
fluocinonide 0.1% (Vanos®)	**C**	fluocinonide 0.05%	G	halobetasol propionate 0.01% (Bryhali®)	L
halobetasol propionate 0.05% (Ultravate®)	C,**O**	~~**fluocinonide 0.1% (Vanos®)**~~	~~**C**~~	halobetasol propionate 0.05% (Lexette®)	F
		flurandrenolide tape 0.05% (Cordran®)	Tape		
		halcinonide 0.1% (Halog®)	C,O,So		
		halobetasol propionate 0.05% (Ultravate®)	L,~~**O**~~		
		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,~~L~~,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**		
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	~~**desoximetasone 0.05% (Topicort LP®)**~~	~~**C,O**~~		
triamcinolone acetonide 0.1%	C,L,O	fluocinolone acetonide 0.025% (Synalar®)	C,O		
triamcinolone acetonide 0.5%	C,O	fluocinonide emollient 0.05% (Lidex E®)	C		
		flurandrenolide 0.05%	C,LO		
		fluticasone propionate 0.05% (Cutivate®)	L		
		hydrocortisone butyrate 0.1%	C,L,O, So		
		hydrocortisone probutate 0.1% (Pandel®)	C		
		prednicarbate 0.1% (Dermatop®)	C,O		
		triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr		
		triamcinolone acetonide 0.05% (Trianex®)	O		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Low Potency					
		alclometasone dipropionate 0.05% (Aclovate®)	C,~~O~~	**alclometasone dipropionate 0.05% (Aclovate®)**	**O**
~~**desonide 0.05% (Desonate®)**~~	~~**G**~~	fluocinolone acetonide 0.01% (Synalar®)	C,~~So~~	~~**fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®)**~~	~~**Oil**~~
desonide emollient 0.05%	**C,O**	**fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®)**	**Oil**	desonide 0.05%	L
fluocinolone acetonide 0.01% (Capex®)	Sh	hydrocortisone 2.5% (Texacort®)	So	~~**desonide emollient 0.05%**~~	~~**C,O**~~
fluocinolone acetonide 0.01% (Synalar®)	**So**	hydrocortisone/ pramoxine 1%/1% (Pramosone®)	C,L	**desonide 0.05% (Desonate®)**	**G**
hydrocortisone acetate 1%	C,O				
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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
LOW POTENCY PRODUCTS						
HYDROCORTISONE CR 2.5%	4,379	3,561	$55,670.53	$12.71	1.23	5.07%
TRIAMCINOLONE CR 0.025%	3,861	3,130	$51,213.06	$13.26	1.23	4.66%
HYDROCORTISONE OINT 2.5%	3,175	2,138	$53,157.62	$16.74	1.49	4.84%
HYDROCORTISONE CR 1%	793	672	$8,799.66	$11.10	1.18	0.80%
HYDROCORTISONE OINT 1%	553	497	$7,234.35	$13.08	1.11	0.66%
HYDROCORTISONE LOT 2.5%	413	326	$11,498.86	$27.84	1.27	1.05%
TRIAMCINOLONE LOT 0.025%	91	88	$3,084.79	$33.90	1.03	0.28%
HYDROCORTISONE POW	75	53	$1,460.47	$19.47	1.42	0.13%
HYDROCORTISONE MICRO POW	41	28	$503.03	$12.27	1.46	0.05%
DESONATE GEL 0.05%	35	26	$20,949.09	$598.55	1.35	1.91%
TRIAMCINOLONE POW ACETONID	28	22	$672.18	$24.01	1.27	0.06%
SUBTOTAL	**13,444**	**10,541**	**$214,243.64**	**$15.94**	**1.28**	**19.51%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE CR 0.1%	21,000	16,213	$299,481.75	$14.26	1.3	27.25%
TRIAMCINOLONE OINT 0.1%	12,791	9,395	$209,188.46	$16.35	1.36	19.04%
TRIAMCINOLONE OINT 0.025%	2,271	1,811	$34,762.27	$15.31	1.25	3.16%
TRIAMCINOLONE CR 0.5%	2,198	1,647	$36,060.15	$16.41	1.33	3.28%
TRIAMCINOLONE OINT 0.5%	1,084	827	$21,999.44	$20.29	1.31	2.00%
MOMETASONE CR 0.1%	881	632	$20,006.51	$22.71	1.39	1.82%
FLUTICASONE CR 0.05%	586	388	$15,526.43	$26.50	1.51	1.41%
BETAMETH VAL CR 0.1%	389	275	$12,914.42	$33.20	1.41	1.18%
TRIAMCINOLONE LOT 0.1%	386	300	$12,200.54	$31.61	1.29	1.11%
MOMETASONE OINT 0.1%	367	227	$7,189.70	$19.59	1.62	0.65%
BETAMETH VAL OINT 0.1%	219	164	$8,039.00	$36.71	1.34	0.73%
MOMETASONE SOL 0.1%	195	109	$5,425.29	$27.82	1.79	0.49%
BETAMETH DIP LOT 0.05%	160	114	$5,652.92	$35.33	1.4	0.51%
FLUTICASONE OINT 0.005%	146	87	$4,100.75	$28.09	1.68	0.37%
BETAMETH VAL LOT 0.1%	35	25	$1,746.75	$49.91	1.4	0.16%
SUBTOTAL	**42,708**	**32,214**	**$694,294.38**	**$16.26**	**1.33**	**63.16%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL SOL 0.05%	1,438	847	$46,656.11	$32.45	1.7	4.25%
CLOBETASOL CR 0.05%	1,246	870	$37,614.59	$30.19	1.43	3.42%
CLOBETASOL OINT 0.05%	1,098	714	$32,196.38	$29.32	1.54	2.93%
AUG BETAMETH CR 0.05%	932	676	$16,660.07	$17.88	1.38	1.52%
FLUOCINONIDE SOL 0.05%	520	313	$20,552.34	$39.52	1.66	1.87%
FLUOCINONIDE OIN 0.05%	363	225	$11,662.58	$32.13	1.61	1.06%
FLUOCINONIDE CR 0.05%	210	123	$10,998.99	$52.38	1.71	1.00%
CLOBETASOL EMOL CR 0.05%	109	70	$5,514.43	$50.59	1.56	0.50%
HALOBETASOL CR 0.05%	57	33	$2,578.59	$45.24	1.73	0.23%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AUG BETAMETH GEL 0.05%	31	21	$3,205.35	$103.40	1.48	0.29%
CLOBETASOL LOT 0.05%	13	13	$930.47	$71.57	1	0.08%
SUBTOTAL	**6,017**	**3905**	**$188,569.90**	**$31.34**	**1.54**	**17.15%**
TIER-1 TOTAL	**62,169**	**46,660**	**$1,097,107.92**	**$17.65**	**1.33**	**99.82%**
TIER-2 UTILIZATION						
LOW POTENCY PRODUCTS						
FLUOCINOLONE ACT SOL 0.01%	44	35	$1,323.37	$30.08	1.26	0.12%
ALCLOMETASONE OINT 0.05%	1	1	$36.26	$36.26	1	0.00%
TEXACORT SOL 2.5%	1	1	$55.45	$55.45	1	0.01%
SUBTOTAL	**46**	**37**	**$1,415.08**	**$30.76**	**1.24**	**0.13%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
BETAMETH VAL AER 0.12%	2	1	$141.32	**$70.66**	**2**	**0.01%**
SUBOTOTAL	**2**	**1**	**$141.32**	**$70.66**	**2**	**0.01%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
BETAMETH DIP CR 0.05%	1	1	$24.22	**$24.22**	**1**	**0.00%**
SUBOTOTAL	**1**	**1**	**$24.22**	**$24.22**	**1**	**0.00%**
TIER-2 TOTAL	**49**	**39**	**$1,580.62**	**$32.26**	**1.26**	**0.14%**
TIER-3 UTILIZATION						
LOW POTENCY PRODUCTS						
DESONIDE CR 0.05%	3	1	$170.16	**$56.72**	**3**	**0.02%**
SUBTOTAL	**3**	**1**	**$170.16**	**$56.72**	**3**	**0.02%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL AER FOAM 0.05%	1	1	$34.14	$34.14	1	0.00%
SUBTOTAL	**1**	**1**	**$34.14**	**$34.14**	**1**	**0.00%**
TIER-3 TOTAL	**4**	**2**	**$204.30**	**$51.08**	**2**	**0.02%**
TOTAL	**62,222**	**40,644***	**$1,098,892.84**	**$17.66**	**1.33**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = acetonide; AER = aerosol; AUG = augmented; BETAMETH = betamethasone; CR = cream; DIP = dipropionate; EMOL = emollient; LOT = lotion; MICRO = micronized; OINT = ointment; POW = powder; SOL = solution; 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/default.cfm?resetfields=1. Last revised 07/2022. Last accessed 07/18/2022.

Appendix H

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates (additional information can be found at http://www.fda.gov/Drugs/default.htm)

FDA NEWS RELEASE

For Immediate Release: July 29, 2022

FDA Provides Update on Agency Response to Monkeypox Outbreak

The FDA is providing an update on its multipronged response to monkeypox in the United States, including its efforts in the areas of diagnostics, vaccines and therapeutics. The FDA has also established a dedicated website to provide important information about the FDA's ongoing regulatory activities related to monkeypox along with frequently asked questions. The FDA will provide updates as developments occur and will continue to work with federal public health partners and industry to ensure timely access to all available medical countermeasures.

The monkeypox virus is part of the same family of viruses as variola virus, the virus that causes smallpox (a virus that has been eradicated globally). Both monkeypox and smallpox fall into the category of "orthopoxviruses." Monkeypox is generally not fatal and typically resolves on its own without treatment. The current outbreak in the U.S. usually presents as a rash on the body, face, or genital area. Although there is a very low risk of dying, there have been reported complications including severe pain, at times requiring hospital admission.

Diagnostics

Since the first case of monkeypox in the U.S. was detected, the FDA has been working with commercial laboratories and manufacturers to make monkeypox tests more readily available to consumers who need them. The Centers for Disease Control and Prevention (CDC) has an FDA-cleared non-variola orthopoxvirus test that can detect monkeypox by a swab from a monkeypox lesion (rash or growth). At this time, this is the only FDA-cleared test. The FDA is not aware of clinical data supporting the use of other sample types, such as blood or saliva, for monkeypox virus testing. In July 2022, the FDA issued a safety communication advising people to use swab samples taken directly from a lesion when testing for the monkeypox virus.

The FDA-cleared monkeypox test is being offered by the CDC and throughout many laboratories that include the CDC's public health Laboratory Response Network. In addition, federal public health authorities have worked with industry to make the test available through 5 large commercial laboratories. The FDA is working closely with the CDC to increase production of its FDA-cleared test and the FDA has cleared the use of additional reagents and instruments to increase the throughput of the CDC test.

The FDA will continue to work with the diagnostic community to augment access to accurate testing to support the response.

Vaccines

In 2019, the FDA approved the Jynneos vaccine for the prevention of smallpox and monkeypox in adults 18 years of age and older determined to be at high risk of infection. Jynneos is the only vaccine approved for the prevention of monkeypox in the United States. Although clinical trials and data are limited because of the small number of cases until now, the immunological response to vaccine administration is consistent with effective prevention of the disease.

Following the emerging public health crisis closely, the FDA was aware that there were close to 800,000 doses of this vaccine pending release this fall following approval of additional manufacturing capabilities at 1 of the plants where the vaccine is made. With this in mind, the FDA worked with Health and Human Services (HHS) partners and expedited the submission of the required application for the company's manufacturing changes in order to make these doses available to those in need. After accelerating the timeline for an inspection of the plant from fall to earlier this month, the FDA has finished its evaluation of the required information to validate product quality and has determined that the vaccine meets its quality standards.

On July 26, the FDA approved a supplement to the biologics license for the Jynneos vaccine, to allow for additional manufacturing capabilities at the facility. Given the emerging public health need, the FDA previously facilitated the shipment of manufactured doses to the United States so that they would be ready to be distributed once the manufacturing changes were approved. With the supplement approval, those manufactured doses may now be further distributed and administered. Additional doses manufactured at this plant can help address the need for this vaccine moving forward.

Therapeutics

There is no FDA-approved or authorized medicine for the treatment of monkeypox disease; however, Tpoxx® (tecovirimat), an antiviral medication, is being made available through the CDC under an FDA authority called Expanded Access or "compassionate use." The FDA continues to work with the CDC to streamline their Expanded Access Program for monkeypox to facilitate access.

There are currently no human data demonstrating the efficacy of Tpoxx® for the treatment of monkeypox, or the safety and pharmacokinetic profile. Although expanded access program is available, conducting randomized, controlled trials to assess the safety and efficacy of Tpoxx® in humans with monkeypox infections is essential.

FDA NEWS RELEASE

For Immediate Release: July 13, 2022

Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted

The FDA issued an EUA for the Novavax COVID-19 Vaccine, Adjuvanted for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

The FDA has determined that the Novavax COVID-19 Vaccine, Adjuvanted has met the statutory criteria for issuance of an EUA. The data support that the known and potential benefits of the vaccine outweigh its known and potential risks in people 18 years of age and older, and that this vaccine may be effective in preventing COVID-19. In making this determination, the FDA can assure the public and medical community that a thorough analysis and evaluation of the available safety and effectiveness data and manufacturing information have been conducted.

The Novavax COVID-19 Vaccine, Adjuvanted is administered as a 2-dose primary series, 3 weeks apart. The vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual. The spike protein in this vaccine is produced in insect cells; the Matrix M-adjuvant contains saponin extracts from the bark of the Soapbark tree that is native to Chile.

FDA Evaluation of Available Effectiveness Data

The vaccine was assessed in an ongoing randomized, blinded, placebo-controlled study conducted in the United States and Mexico. The effectiveness of the vaccine was assessed in clinical trial participants 18 years of age and older who did not have evidence of SARS-CoV-2 infection through 6 days after receiving the second vaccine dose. Among these participants, approximately 17,200 received the vaccine and approximately 8,300 received saline placebo. Overall, the vaccine was 90.4% effective in preventing mild, moderate or severe COVID-19, with 17 cases of COVID-19 occurring in the vaccine group and 79 cases in the placebo group. No cases of moderate or severe COVID-19 were reported in participants who received the vaccine, compared with 9 cases of moderate COVID-19 and 4 cases of severe COVID-19 reported in placebo recipients. In the subset of participants 65 years of age and older, the vaccine was 78.6% effective. The clinical trial was conducted prior to the emergence of delta and omicron variants.

FDA Evaluation of Available Safety Data

The safety of the vaccine was assessed in approximately 26,000 clinical trial participants who received the vaccine and approximately 25,000 who received placebo. The most commonly reported side effects by vaccine recipients included pain/tenderness, redness and swelling at the injection site, fatigue, muscle pain, headache, joint pain, nausea/vomiting and fever. Approximately 21,000 vaccine recipients had at least 2 months of safety follow-up after their second dose.

The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) includes a warning that clinical trial data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted. The Fact Sheet for Recipients and Caregivers informs that in most people who have had myocarditis or pericarditis after receiving the vaccine, symptoms began within 10 days following vaccination and that vaccine recipients should seek medical attention right away if they experience any of the following symptoms after vaccination: chest pain, shortness of breath, feelings of having a fast-beating, fluttering, or pounding heart.

As part of this authorization, it is mandatory for the company, Novavax Inc., and vaccination providers to report the following to the Vaccine Adverse Event Reporting System (VAERS): serious adverse events, cases of Multisystem Inflammatory Syndrome and cases of COVID-19 that result in hospitalization or death.

It is also mandatory for vaccination providers to report all vaccine administration errors to VAERS for which they become aware and for Novavax Inc. to include a summary and analysis of all identified vaccine administration errors in monthly safety reports submitted to the FDA.

The FDA has evaluated the pharmacovigilance plan submitted by the company to monitor the safety of Novavax COVID-19 Vaccine, Adjuvanted as it will be used under EUA to ensure that any safety concerns are identified and evaluated in a timely manner. As a condition of authorization, the company will conduct studies to further assess its safety, including studies to further assess the risks of myocarditis and pericarditis.

In addition, the FDA and the CDC have several systems in place to continually monitor COVID-19 vaccine safety and allow for the timely detection and investigation of potential safety concerns.

The FDA also expects Novavax Inc. to continue their clinical trials to obtain additional safety and effectiveness data and pursue approval (licensure). The EUA was issued to Novavax Inc. The authorization will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and

biologics for prevention and treatment of COVID-19 is terminated. The EUA may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance.

FDA NEWS RELEASE

For Immediate Release: July 6, 2022

Coronavirus (COVID-19) Update: Coronavirus (COVID-19) Update: FDA Authorizes Pharmacists to Prescribe Paxlovid™ with Certain Limitations

The FDA revised the EUA for Paxlovid™ (nirmatrelvir and ritonavir), to authorize state-licensed pharmacists to prescribe Paxlovid™ to eligible patients, with certain limitations to ensure appropriate patient assessment and prescribing of Paxlovid™.

When testing positive for COVID-19, patients should first consider seeking care from their regular health care provider or locating a Test-to-Treat site in their area. While this action allows state-licensed pharmacists to prescribe Paxlovid™ with certain limitations as described below, community pharmacies not already participating as a Test-to-Treat site can decide if or how they will offer this service to patients.

Patients who have tested positive for COVID-19 and are seeking to determine their eligibility for receiving Paxlovid™ at locations where prescribing by state-licensed pharmacists is available should bring the following information to ensure that the state-licensed pharmacist has sufficient information to determine their eligibility to receive Paxlovid™:

- Electronic or printed health records <12 months old, including the most recent reports of laboratory blood work for the state-licensed pharmacist to review for kidney or liver problems. State-licensed pharmacists could also receive this information through a consult with the patient's health care provider.
- A list of all medications they are taking, including over-the-counter medications so the state-licensed pharmacist can screen for drugs with potentially serious interactions with Paxlovid™.

Under the limitations outlined in the authorization, the state-licensed pharmacist should refer patients for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is needed due to a potential drug interaction.
- Paxlovid™ is not an appropriate therapeutic option based on the current Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

Paxlovid™ is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing ≥40kg) with positive results of direct SARS-CoV-2 viral testing, who are at high risk for progression to severe COVID-19, including hospitalization or death. Patients in the authorized population who report a positive home test result from a rapid antigen diagnostic test, or a positive PCR test, to their provider are eligible for Paxlovid™ under the EUA. Confirmation of a positive home rapid antigen diagnostic test with additional direct SARS-CoV-2 viral testing, such as a PCR, is not required. Antibody tests are not considered to be direct SARS-CoV-2 viral tests.

FDA NEWS RELEASE

For Immediate Release: June 30, 2022

Coronavirus (COVID-19) Update: FDA Recommends Inclusion of Omicron BA.4/5 Component for COVID-19 Vaccine Booster Doses

The FDA's independent experts on the Vaccines and Related Biological Products Advisory Committee met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines for booster doses is necessary for the 2022 fall and winter seasons.

The COVID-19 vaccines that the FDA has approved and authorized for emergency use have made a tremendous difference to public health and have saved countless lives in the United States and globally. However, SARS-CoV-2 virus has evolved significantly, with recent surges around the world associated with the rapid spread of highly transmissible variants such as omicron.

Current available vaccines have helped reduce hospitalization and death caused by COVID-19, but results from post-authorization observational studies have shown that effectiveness of primary vaccination wanes over time against certain variants, including omicron. And while initial booster doses have helped restore protection against severe disease and hospitalization associated with omicron, studies have also indicated waning effectiveness of first booster doses over time.

The American public can be assured that any COVID-19 vaccine authorized or approved by the FDA meets standards for safety and effectiveness. The FDA also encourages those who are currently eligible for a booster to get one.

As we move into the fall and winter, it is critical that there are safe and effective vaccine boosters that can provide protection against circulating and emerging variants to prevent the most severe consequences of COVID-19. Following a thorough discussion on June 28, 2022, an overwhelming majority of the advisory committee voted in favor of including a SARS-CoV-2 omicron component in COVID-19 vaccines that would be used for boosters in the United States beginning in fall 2022.

Following the vote, and striving to use the best available scientific evidence, the FDA has advised manufacturers seeking to update their COVID-19 vaccines that they should develop modified vaccines that add an omicron BA.4/5 spike protein component to the current vaccine composition to create a bivalent booster vaccine, so that the modified vaccines can potentially be used starting in early to mid-fall 2022.

As the FDA expects this coming year to be a transitional period when this modified booster vaccine may be introduced, they have not advised manufacturers to change the vaccine for primary vaccination, since a primary series with the FDA-authorized and approved COVID-19 vaccines provides a base of protection against serious outcomes of COVID-19 caused by circulating strains of SARS-CoV-2.

Vaccine manufacturers have already reported data from clinical trials with modified vaccines containing an omicron BA.1 component and the FDA has advised them that they should submit these data for evaluation prior to any potential authorization of a modified vaccine containing an omicron BA.4/5 component. Manufacturers will also be asked to begin clinical trials with modified vaccines containing an omicron BA.4/5 component, as these data will be of use as the pandemic further evolves.

The FDA has been planning for the possibility that vaccines would need to be modified to address circulating variants and previously provided guidance to industry on how to do so efficiently. As has been the case with all COVID-19 vaccines throughout the pandemic, the FDA will evaluate all relevant data to inform the safety, effectiveness, and

manufacturing quality of modified vaccines under consideration for authorization or approval to ensure that they meet the FDA's standards.

FDA NEWS RELEASE

For Immediate Release: June 27, 2022

FDA Introduces Innovative Proposal to Advance Consumer Access to Nonprescription Drugs

The FDA issued a proposed rule titled, "Nonprescription Drug Product with an Additional Condition for Nonprescription Use," which is intended to broaden the range of marketed nonprescription drugs available to consumers, empowering them to self-treat certain common conditions and improving public health.

Nonprescription drug products are used by consumers without the supervision of a health care professional and require the ability of the consumer to determine that they have the condition for which the drug is to be used, and to appropriately use the drug. Consumers are likely familiar with the "Drug Facts Labeling" on nonprescription drug packaging as the primary source for information about a product's intended use, directions for use, and important safety information, all designed in understandable language that is tested for consumer comprehension.

The proposed rule, if finalized, would expand options for consumers by establishing the requirements for a drug company that submits a new application to bring a nonprescription drug product to market with an additional condition for nonprescription use. Under the proposed rule, when the FDA finds that labeling alone is not sufficient to ensure that the consumer can appropriately self-select and use a drug product in a nonprescription setting, an applicant may submit an application proposing an additional condition for nonprescription use that a consumer must successfully fulfill to obtain the nonprescription drug product.

An additional condition for nonprescription use is 1 or more FDA-approved conditions that an applicant of a nonprescription drug product must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers of the nonprescription drug product. For example, an applicant could propose an additional condition for nonprescription use that requires a consumer to respond with specific answers to a set of questions on a self-selection test available by either a phone "app" or an automated telephone response system in order to purchase the nonprescription drug product. Under the proposed rule, if the FDA finds that the additional condition for nonprescription use will permit appropriate self-selection and/or appropriate actual use of the product, and consumers can use the product safely and effectively without the supervision of a health care practitioner, it may approve the product for nonprescription use with the additional condition for nonprescription use. As with all proposals, the safety of patients remains a top priority.

The FDA encourages public comment for this proposed rule. The comment period will end 120 days after the date of publication in the Federal Register. After the comment period closes, the FDA will review and consider comments as it develops the final rule. The timing of the final rule will depend on the number and substance of the comments.

FDA NEWS RELEASE

For Immediate Release: June 23, 2022

FDA Releases Action Plan for Rare Neurodegenerative Diseases, Including ALS

The FDA unveiled its action plan for rare neurodegenerative diseases including amyotrophic lateral sclerosis (ALS) – a 5-year strategy for improving and extending the lives of people living with rare neurodegenerative diseases by advancing the

development of safe and effective medical products and facilitating patient access to novel treatments.

The action plan is a blueprint for how the FDA will move forward in aggressively tackling challenges in drug development for rare neurodegenerative diseases, including ALS, in order to improve patients' health. Specific actions include regulatory science initiatives, enhancements to existing programs and new policy initiatives. The plan has been developed in accordance with the provisions of the Accelerating Access to Critical Therapies for ALS Act, or ACT for ALS, that President Biden signed into law on December 23, 2021.

Within a 5-year span, the plan will focus on bolstering scientific advancement and promoting innovation for rare neurodegenerative diseases by engaging in targeted activities including:

- Establishing the FDA Rare Neurodegenerative Diseases Task Force (FY 22)
- Establishing the public-private partnership for rare neurodegenerative diseases (FY 22)
- Developing disease-specific science strategies (FY 22 – FY 26)
- Leveraging ongoing FDA regulatory science efforts

The ALS Science Strategy is an element of the plan focused specifically on ALS. It provides a forward leaning framework for FDA activities to assess key regulatory science priorities. The focus areas of the ALS Science Strategy are to:

- Improve characterization of disease pathogenesis and natural history – including quantifying disease progression, predictive and prognostic biomarkers, and efficient translation and implementation of basic science discovery is needed
- Facilitate patient access to new drugs whenever possible and promote greater participation in clinical trials by reducing barriers and burdens faced by diverse populations; utilizing digital health technologies and decentralized trial designs; and ensuring mechanisms for expanded access (generally outside of a clinical trial) are appropriately integrated into development programs
- Enhance clinical trial infrastructure and agility to enable early selection of promising therapeutic candidates for further development, optimize clinical trial design, improve access to the trials, streamline clinical trial operations, and reduce the time and cost of drug development

Key to the success of the FDA's implementation of the ALS Science Strategy will be patient engagement, public workshops, research projects, coordination across FDA centers and offices, and collaboration with the National Institutes of Health (NIH).

ACT for ALS also requires the Department of HHS to implement a Public-Private Partnership for Neurodegenerative Diseases between NIH, FDA, and 1 or more outside entities through cooperative agreements, contracts, or other appropriate mechanisms to advance the understanding of neurodegenerative diseases and foster development of treatments for ALS and other rare neurodegenerative diseases. It also directs the FDA to award grants and contracts to public and private entities to cover the costs of research and development of interventions that are intended to prevent, diagnose, mitigate, treat, or cure ALS and other rare neurodegenerative diseases.

Current Drug Shortages Index (as of July 27, 2022):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma.

Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amphetamine Oral Suspension, Extended Release	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Disodium Versenate Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chlordiazepoxide Hydrochloride Capsules	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Cortisone Acetate Tablets	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 5% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Diflunisal Tablets	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***

Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Epinephrine Injection, Auto-Injector	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Floxuridine for Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Iodixanol Injection	***Currently in Shortage***
Iohexol Injection	***Currently in Shortage***
Iomeprol injection	***Currently in Shortage***
Iopromide (Ultravist) Injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketoprofen Capsules	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Leuprolide Acetate Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Lipid Injection	***Currently in Shortage***
Lithium Oral Solution	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu 177 Dotatate (Lutathera) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***

Methyldopa Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Paclitaxel Injection (Protein-Bound Particles)	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***
Pentostatin Injection	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Promethazine (Phenergan) Injection	***Currently in Shortage***
Propofol Injectable Emulsion	***Currently in Shortage***
Protamine Sulfate Injection	***Currently in Shortage***
Remifentanil Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Wegovy®) Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection USP, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Streptozocin (Zanosar) Sterile Powder	***Currently in Shortage***
Streptozocin Powder for Injection	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Teprotumumab-trbw	***Currently in Shortage***
Thiothixene Capsules	***Currently in Shortage***
Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***

Triamcinolone Hexacetonide Injectable Suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vandetanib Tablets	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***