OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
July 14, 2021
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – July 14, 2021

DATE: July 7, 2021

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

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

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

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – Appendix A

Update on Medication Coverage Authorization Unit/Chronic Medication Adherence (CMA) Program Update – Appendix B

Action Item – Vote to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan) – Appendix C

Action Item – Vote to Prior Authorize Azstarys™ (Serdexmethylphenidate/ Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav™ (Calcium/ Magnesium/Potassium/Sodium Oxybates) – Appendix D

Action Item – Vote to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) – Appendix E

Action Item – Vote to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti™ (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/ Estetrol Tablet), Ozobax™ (Baclofen 5mg/mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel), RediTrex™ (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution) – Appendix F

Annual Review of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib) and 30-Day Notice to Prior Authorize Danyelza® (Naxitamab-gqgk) and Truseltiq™ (Infigratinib) – Appendix G

Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Qdolo™ (Tramadol Oral Solution) – Appendix H

Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Impeklo™ (Clobetasol Propionate 0.05% Lotion) – Appendix I

Annual Review of Ophthalmic Anti-Inflammatory Products – Appendix J

30-Day Notice to Prior Authorize Nulibry™ (Fosdenopterin) – Appendix K

30-Day Notice to Prior Authorize Feraheme® (Ferumoxytol), Injectafer® (Ferric Carboxymaltose), and Monoferric® (Ferric Derisomaltose) – Appendix L

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 14, 2021 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. Call to Order

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Stephen Anderson –	participating in person
Dr. Jennifer de los Angeles –	participating in person
Ms. Jennifer Boyett –	participating in person
Dr. Markita Broyles –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person

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

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 922 6217 2322
Passcode: 98317667

Public Comment for Meeting:

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

Items to be presented by Dr. Muchmore, Chairman:

2. Public Comment Forum

A. Acknowledgment of Speakers for Public Comment

Items to be presented by Dr. Muchmore, Chairman:

3. Action Item – Approval of DUR Board Meeting Minutes – See Appendix A

A. June 9, 2021 DUR Minutes – Vote
B. June 9, 2021 DUR Recommendation Memorandum

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

4. Update on Medication Coverage Authorization Unit/Chronic Medication Adherence (CMA) Program Update – See Appendix B

A. Pharmacy Helpdesk Activity for June 2021
B. Medication Coverage Activity for June 2021
C. CMA Program Update

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

5. Vote to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan) – See Appendix C

A. Market News and Updates
B. Lybalvi™ (Olanzapine/Samidorphan) Product Summary
C. College of Pharmacy Recommendations

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

6. Action Item – Vote to Prior Authorize Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav™ (Calcium/Magnesium/Potassium/Sodium Oxybates) – See Appendix D

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

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

7. Action Item – Vote to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) – See Appendix E

A. Market News and Updates
B. *Helicobacter Pylori* (*H. Pylori*) Product Summaries
C. Cost Comparison: *H. Pylori* Regimens
D. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti™ (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/Estetrol Tablet), Ozobax™ (Baclofen 5mg/mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/ Potassium Bitartrate Vaginal Gel), RediTrex™ (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution) – See Appendix F

A. Introduction
B. College of Pharmacy Recommendations

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

9. Annual Review of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib) and 30-Day Notice to Prior Authorize Danyelza® (Naxitamab-gqgk) and Truseltiq™ (Infigratinib) – See Appendix G

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib)
D. Prior Authorization of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib)
E. Market News and Updates
F. Product Summaries
G. College of Pharmacy Recommendations
H. Utilization Details of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib)

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

10. Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Qdolo™ (Tramadol 5mg/mL Oral Solution) – See Appendix H

A. Current Prior Authorization Criteria
B. Utilization of Opioid Analgesics and MAT Medications
C. Prior Authorization of Opioid Analgesics and MAT Medications
D. Market News and Updates
E. Qdolo™ (Tramadol 5mg/mL Oral Solution) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Opioid Analgesics
H. Utilization Details of MAT Medications

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

11. Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Impeklo® (Clobetasol Propionate 0.05% Lotion) – See Appendix I

A. Current Prior Authorization Criteria
B. Utilization of Topical Corticosteroids
C. Prior Authorization of Topical Corticosteroids
D. Market News and Updates
E. Impeklo® (Clobetasol Propionate 0.05% Lotion) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Topical Corticosteroids

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

12. Annual Review of Ophthalmic Anti-Inflammatory Products – See Appendix J

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 Corticosteroids
G. Utilization Details of Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

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

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

A. Introduction
B. Nulibry™ (Fosdenopterin) Product Summary
C. College of Pharmacy Recommendations

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

14. 30-Day Notice to Prior Authorize Feraheme® (Ferumoxytol), Injectafer® (Ferric Carboxymaltose), and Monoferric® (Ferric Derisomaltose) – See Appendix L

A. Introduction
B. Utilization of Intravenous (IV) Iron Products: Medical Claims
C. Market News and Updates
D. Product Summaries
E. Relative Risk of Serious Adverse Effects (SAEs)
F. Cost Comparison
G. College of Pharmacy Recommendations
H. Utilization Details of IV Iron Products

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

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

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

16. Future Business* (Upcoming Product and Class Reviews)
No DUR Board meeting scheduled for August 2021.

A. Breast Cancer Medications
B. Prostate Cancer Medications
C. Synagis® (Palivizumab)
D. Targeted Immunomodulator Agents

**Future product and class reviews subject to change.*

17. Adjournment

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING JUNE 9, 2021

BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.		x
Jennifer de los Angeles, Pharm.D., BCOP	x	
Jennifer Boyett, MHS; PA-C	x	
Markita Broyles, D.Ph.; MBA	x	
Theresa Garton, M.D.		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	
Rebekah Bargewell; Administrative Assistant		x
Wendi Chandler, Pharm.D.; Clinical Pharmacist	x	
Andrew Craig; Database Analyst	x	
Lisa Daniel, Pharm.D.; Pharmacy Resident	x	
Erin Ford, Pharm.D.; Clinical Pharmacist		x
Mark Fuelling; Client Support Analyst		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
Amy Miller; Operations Coordinator		x
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	x	
Karen O'Neill, Pharm.D.; Clinical Pharmacist		x
Wynn Phung, Pharm.D.; Clinical Pharmacist		x
Leslie Robinson, D.Ph.; Pharmacy PA Coordinator		x
Vickie Sams, CPhT.; Quality/Training Coordinator	x	
Grant H. Skrepnek, Ph.D.; Associate Professor		x
Regan Smith, Pharm.D.; Clinical Pharmacist	x	
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	x	
Devin Wilcox, D.Ph.; Pharmacy Director	x	
Justin Wilson, Pharm.D.; Clinical Pharmacist	x	
PA Oncology Pharmacists: Allison Baxley, Pharm.D., BCOP		x
Emily Borders, Pharm.D., BCOP	x	
Sarah Schmidt, Pharm.D., BCPS, 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 State Medicaid Director; 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	
Michael Herndon, D.O.; Chief Medical Officer		x
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Paula Root, M.D.; Senior Medical Director	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:	
Jerod Downing, Alkermes	Patrick Harvey, Supernus
Brent Parker, Merck	Chris Stanfield, Supernus
Mark Kaiser, Otsuka	Terry McCurren, Otsuka
Tara McKinley, Otsuka	Kristi Kemp, AbbVie
Joe Garcia, AbbVie	Marc Parker, Sunovion
Donna Birchette, Oncopeptides	Sarah Sanders, Novartis
Burl Beasley, OMES	Frank Alvarado, Johnson and Johnson
Audrey Rattan, Alkermes	Tom Yelle, Xcenda
Jomy Joseph, Sanofi	Andrew Delgado, Bristol Myers Squibb
Rhonda Clark, Indivior	Jason Dickerson, Jazz Pharmaceuticals
Jeff Knappen, Spark Therapeutics	Melanie Curlett, Takeda
Robert Greely, Biogen	Jim Dunlap, Dunlap Consultants
William Eicholzer, Alexion	Shellie Keast, Mercer
Brian Maves, Pfizer	Evan Rushing, Alkermes
Doug Wood, ViiV Healthcare	Glenn Cornish, Alkermes
Christine Dube, AstraZeneca	

PRESENT FOR PUBLIC COMMENT:	
Patrick Harvey	Supernus
Tara McKinley	Otsuka
Jerod Downing	Alkermes

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order. 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. 12 PATRICK HARVEY

2B: AGENDA ITEM NO. 13 TARA MCKINLEY

2C: AGENDA ITEM NO. 13 JEROD DOWNING

ACTION: NONE REQUIRED

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

3A: MAY 12, 2021 DUR MINUTES – VOTE

3B: MAY 12, 2021 DUR RECOMMENDATION MEMORANDUM

Materials included in agenda packet; presented by Dr. Muchmore
Dr. Mitchell moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 4:</u> MEDICATION THERAPY MANAGEMENT (MTM) PROGRAM UPDATE

4A: MTM PROGRAM UPDATE
4B: FOCUS ON ADHERENCE
4C: CASE STUDY
4D: SUMMARY

Materials included in agenda packet; presented by Dr. Smith

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/USE OF GLUCAGON-LIKE PEPTIDE-1 (GLP-1) AGONISTS/SODIUM-GLUCOSE CO-TRANSPORTER-2 (SGLT-2) INHIBITORS WITH CARDIOVASCULAR (CV) BENEFIT IN MEMBERS WITH TYPE 2 DIABETES (T2D) AND HIGH CV RISK OR ESTABLISHED ATHEROSCLEROTIC CV DISEASE (ASCVD) MAILING UPDATE

5A: PHARMACY HELPDESK ACTIVITY FOR MAY 2021
5B: MEDICATION COVERAGE ACTIVITY FOR MAY 2021
5C: USE OF GLP-1 AGONISTS/SGLT-2 INHIBITORS WITH CV BENEFIT IN MEMBERS WITH T2D AND HIGH CV RISK OR ESTABLISHED ASCVD MAILING UPDATE

Materials included in agenda packet; presented by Dr. Nawaz, Dr. Daniel

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE CABOMETYX® (CABOZANTINIB), FOTIVDA® (TIVOZANIB), JELMYTO® (MITOMYCIN), AND PADCEV® (ENFORTUMAB VEDOTIN-EJFV)

6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders
Dr. Broyles moved to approve; seconded by Dr. Mitchell

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> VOTE TO PRIOR AUTHORIZE GEMTESA® (VIBEGRON)

7A: INTRODUCTION
7B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE ZILXI® (MINOCYCLINE 1.5% TOPICAL FOAM)

8A: INTRODUCTION
8D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE KYNMOBI™ (APOMORPHINE) AND ONGENTYS® (OPICAPONE)**

9A: NEW U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S)
9B: PRODUCT SUMMARIES
9C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nawaz
Dr. Broyles moved to approve; seconded by Dr. Muñoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE FETROJA® (CEFIDEROCOL) AND KIMYRSA™ (ORITAVANCIN)**

10A: NEW U.S. FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL(S)
10B: PRODUCT SUMMARIES
10C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Ha
Dr. Mitchell moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: **ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT**

11A: SUMMARY
11B: MEDICAID DRUG REBATE PROGRAM
11C: ALTERNATIVE PAYMENT MODELS
11D: DRUG APPROVAL TRENDS
11E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
11F: TOP 10 TRADITIONAL THERAPEUTIC CLASSES BY REIMBURSEMENT
11G: TOP 10 SPECIALTY THERAPEUTIC CLASSES BY REIMBURSEMENT
11H: TOP 10 MEDICATIONS BY REIMBURSEMENT
11I: COST PER CLAIM
11J: MARKET PROJECTIONS
11K: CONCLUSION
11L: TOP 50 REIMBURSED DRUGS BY CALENDAR YEAR
11M: TOP 50 MEDICATIONS BY TOTAL NUMBER OF CLAIMS
11N: TOP 10 TRADITIONAL AND SPECIALTY THERAPEUTIC CATEGORIES BY CALENDAR YEAR
11O: CALENDAR YEAR AGE GROUP COMPARISON

Materials included in agenda packet; presented by Dr. Daniel

ACTION: NONE REQURIED

AGENDA ITEM NO. 12: **ANNUAL REVIEW OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AZSTARYS™ (SERDEXMETHYLPHENIDATE/DEXMETHYLPHENIDATE), QELBREE™ (VILOXAZINE), AND XYWAV™ (CALCIUM/MAGNESIUM/POTASSIUM/SODIUM OXYBATES)**

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
12C: PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
12D: OKLAHOMA RESOURCES
12E: MARKET NEWS AND UPDATES
12F: PRODUCT SUMMARIES
12G: COLLEGE OF PHARMACY RECOMMENDATIONS
12H: UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS

Materials included in agenda packet; presented by Dr. Wilson

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LYBALVI™ (OLANZAPINE/SAMIDORPHAN)

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
13C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
13D: OKLAHOMA RESOURCES
13E: MARKET NEWS AND UPDATES
13F: LYBALVI™ (OLANZAPINE/SAMIDORPHAN) PRODUCT SUMMARY
13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF VARIOUS SPECIAL FORMULATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ALKINDI® SPRINKLE (HYDROCORTISONE ORAL GRANULE), EYSUVIS® (LOTEPREDNOL 0.25% OPHTHALMIC SUSPENSION), GIMOTI™ (METOCLOPRAMIDE NASAL SPRAY), NEXTSTELLIS® (DROSPIRENONE/ESTETROL TABLET), OZOBAX® (BACLOFEN 5MG/ML ORAL SOLUTION), PHEXXI® (LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE VAGINAL GEL), REDITREX® (METHOTREXATE INJECTION), RELTONE™ (URSODIOL CAPSULE), AND THYQUIDITY™ (LEVOTHYROXINE ORAL SOLUTION)

14A: INTRODUCTION
14B: CURRENT PRIOR AUTHORIZATION CRITERIA
14C: UTILIZATION OF VARIOUS SPECIAL FORMULATIONS
14D: PRIOR AUTHORIZATION OF VARIOUS SPECIAL FORMULATIONS
14E: PRODUCT SUMMARIES
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF VARIOUS SPECIAL FORMULATIONS

Materials included in agenda packet; presented by Dr. Chandler

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HELIDAC® THERAPY (BISMUTH SUBSALICYLATE/METRONIDAZOLE/TETRACYCLINE DOSE PACK) AND PYLERA® (BISMUTH SUBCITRATE POTASSIUM/METRONIDAZOLE/TETRACYCLINE CAPSULE)

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTI-ULCER MEDICATIONS
15C: PRIOR AUTHORIZATION OF ANTI-ULCER MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: *HELICOBACTER PYLORI* (*H. PYLORI*) PRODUCT SUMMARIES
15F: COST COMPARISON: *H. PYLORI* REGIMENS
15G: COLLEGE OF PHARMACY RECOMMENDATIONS
15H: UTILIZATION DETAILS OF ANTI-ULCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Ha

ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: **ANNUAL REVIEW OF ISTURISA® (OSILODROSTAT)**

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ISTURISA® (OSILODROSTAT)
16C: PRIOR AUTHORIZATION OF ISTURISA® (OSILODROSTAT)
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Ha

ACTION: NONE REQUIRED

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

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

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

18A: INTRAVENOUS (IV) IRON PRODUCTS
18B: OPHTHALMIC ANTI-INFLAMMATORY PRODUCTS
18C: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
18D: TOPICAL CORTICOSTEROIDS

**Future business subject to change.*

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: **ADJOURNMENT**

The meeting was adjourned at 6:04pm.

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

Memorandum

Date: June 10, 2021

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

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

Subject: DUR Board Recommendations from Meeting on June 9, 2021

Recommendation 1: Medication Therapy Management (MTM) Program Update

NO ACTION REQUIRED.

Recommendation 2: Use of Glucagon-Like Peptide-1 (GLP-1) Agonists or Sodium-Glucose Co-Transporter-2 (SGLT-2) Inhibitors with Cardiovascular (CV) Benefit in Members with Type 2 Diabetes (T2D) and High CV Risk or Established Atherosclerotic CV Disease (ASCVD) Mailing Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Cabometyx® (Cabozantinib), Fotivda® (Tivozanib), Jelmyto® (Mitomycin), and Padcev® (Enfortumab Vedotin-ejfv)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Cabometyx® (cabozantinib), Fotivda® (tivozanib), Jelmyto® (mitomycin), and Padcev® (enfortumab vedotin-ejfv) with the following criteria:

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.
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.

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

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

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

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

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

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting.

Recommendation 4: Vote to Prior Authorize Gemtesa® (Vibegron)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the placement of Gemtesa® (vibegron) into the Special Prior Authorization (PA) Tier of the Bladder Control Medications Product Based Prior Authorization (PBPA) category, based on net costs, with the following additional criteria:

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Additionally, the College of Pharmacy recommends the placement of VESIcare LS™ (solifenacin oral suspension) into Tier-1 of the bladder control medications PBPA category, based on net costs, with an age restriction of 2 to 10 years of age. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

The College of Pharmacy also recommends the placement of Myrbetriq® (mirabegron granules for oral suspension) into Tier-3 of the bladder control medications PBPA category with an age restriction of 3 years of age and older in members weighing <35kg. Members weighing ≥35kg would require a patient-specific, clinically significant reason why the granule formulation of mirabegron is needed in place of the regular tablet formulation. Current Tier-3 criteria will also apply.

Finally, the College of Pharmacy recommends removing Noctiva™ (desmopressin acetate nasal spray) from the Tier chart based on product discontinuation (additions and changes shown in red):

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enablex®)	~~**desmopressin acetate nasal spray (Noctiva™)⁺**~~
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)Δ **tablets and granulesβ**	desmopressin acetate SL tablets (Nocdurna®)⁺
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	oxybutynin patch (Oxytrol®)⁺
solifenacin (VESIcare®)Δ		trospium ER (Sanctura XR®)	**vibegron (Gemtesa®)⁺**
solifenacin oral susp (VESIcare LS™)α			
trospium (Sanctura®)			

ER = extended-release; PA = prior authorization; SL = sublingual; susp = suspension
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

[+]Unique criteria specific to Gemtesa® (vibegron), Oxytrol® (oxybutynin patch), ~~Noctiva™ (desmopressin acetate nasal spray),~~ and Nocdurna® (desmopressin acetate SL tablets) applies.
[Δ]Unique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
[α]An age restriction of 2 to 10 years of age will apply for VESIcare LS™. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.
[β]The Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation. Current Tier-3 criteria applies.

Recommendation 5: Vote to Prior Authorize Zilxi® (Minocycline 1.5% Topical Foam)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Zilxi® (minocycline 1.5% topical foam) with the following criteria:

Zilxi® (Minocycline 1.5% Topical Foam) Approval Criteria:

1. An FDA approved diagnosis of inflammatory lesions of rosacea in adults; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole topical gel and cream 0.75%, erythromycin topical 2% solution, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
4. A quantity limit of 30 grams per 30 days will apply.

Additionally, the College of Pharmacy recommends updating the Aczone® (dapsone gel) approval criteria based on the FDA approved age expansion for the 7.5% gel with the following changes shown in red:

Aczone® (Dapsone Gel) Approval Criteria:

1. An FDA approved indication of acne vulgaris; and
2. For Aczone® 7.5% gel, the member must be 9 years of age or older; and
3. Aczone® is not covered for members older than 20 years of age; and
4. A previous trial of benzoyl peroxide or a patient-specific, clinically significant reason why benzoyl peroxide is not appropriate for the member must be provided; and
5. A previous trial of a topical antibiotic, such as clindamycin or erythromycin, or a patient-specific, clinically significant reason why a topical antibiotic is not appropriate for the member must be provided.

Next, the College of Pharmacy recommends updating the Tazorac® (tazarotene) approval criteria based on net costs and current product availability with the following changes in red:

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

1. An FDA approved indication of acne vulgaris or plaque psoriasis; and

2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
~~3. Authorization of tazarotene 0.1% cream will require a patient-specific, clinically significant reason why the member cannot use the other formulations of tazarotene (brand Tazorac® 0.05% cream, 0.05% gel, and 0.1% gel are preferred); and~~
4. For the diagnosis of acne vulgaris, the following must be met:
    a. Member must be 20 years of age or younger; and
    b. ~~Based on current net costs,~~ Tazorac® 0.1% cream, Tazorac® 0.05% gel, Tazorac® 0.1% gel, and tazarotene 0.1% cream will not require prior authorization for members 20 years of age or younger; and
5. A quantity limit of 100 grams per 30 days will apply.

Finally, College of Pharmacy recommends updating the Amzeeq® (minocycline 4% topical foam) approval criteria, based on net costs and to be consistent with the approval criteria for Zilxi®, with the following changes in red:

Amzeeq® (Minocycline 4% Topical Foam) Approval Criteria:

1. An FDA approved indication of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Amzeeq® is not covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution~~, or~~ clindamycin 1% topical solution, benzoyl peroxide, brand name Tazorac®, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products~~, which are available without prior authorization,~~ must be provided; and
5. A quantity limit of 30 grams per 30 days will apply.

Recommendation 6: Vote to Prior Authorize Kynmobi™ (Apomorphine) and Ongentys® (Opicapone)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Kynmobi™ (apomorphine) and Ongentys® (opicapone) with the following criteria:

Kynmobi™ [Apomorphine Sublingual (SL) Film] Approval Criteria:

1. An FDA approved indication of acute, intermittent treatment of "off" episodes in members with Parkinson's disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with Kynmobi™; and
3. Member should be experiencing at least 1 well defined "off" episode per day with a total daily "off" time duration of ≥2 hours during the waking day; and

4. Initial dose titration should occur in an "off" state and in a setting supervised by a health care provider to monitor blood pressure and heart rate; and
5. Member must not use apomorphine concomitantly with 5-HT_3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and
6. Prescriber must verify the member has been counseled on separating doses by at least 2 hours; and
7. The maximum single dose approvable is 30mg; and
8. A quantity limit of 5 doses per day will apply.

Ongentys® (Opicapone) Approval Criteria:

1. An FDA approved indication of adjunctive treatment to levodopa/carbidopa in members with Parkinson's disease (PD) experiencing "off" episodes; and
2. Member must be taking levodopa/carbidopa in combination with Ongentys®; and
3. Member must not use non-selective monoamine-oxidase inhibitors (MAOIs) concomitantly with Ongentys®; and
4. Member must not have a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; and
5. Prescriber must verify member has been counseled to avoid eating food 1 hour before and at least 1 hour after taking Ongentys®; and
6. For members with moderate hepatic impairment, the prescriber must verify the dose of Ongentys® will be reduced in accordance with package labeling; and
7. Prescriber must agree to monitor member for changes in heart rate, heart rhythm, and blood pressure in members concurrently taking medications known to be metabolized by catechol-O-methyltransferase (COMT); and
8. A patient-specific, clinically significant reason why the member cannot use entacapone must be provided; and
9. A quantity limit of 30 capsules per 30 days will apply.

Recommendation 7: Vote to Prior Authorize Fetroja® (Cefiderocol) and Kimyrsa™ (Oritavancin)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Fetroja® (cefiderocol) and Kimyrsa™ (oritavancin) with the following criteria:

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
    a. Complicated urinary tract infection (cUTI), including pyelonephritis; or

   b. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. The prescriber must verify that limited or no alternative treatment options are available; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta-lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on Fetroja® *Prescribing Information* and FDA approved dosing regimen(s).

Kimyrsa™ (Oritavancin) Approval Criteria:

1. An FDA approved indication for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by or suspected to be caused by susceptible isolates of designated gram-positive microorganisms; and
2. Member must be 18 years of age or older; and
3. The prescriber must verify that limited or no alternative treatment options are available; and
4. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Orbactiv® (oritavancin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on Kimyrsa™ *Prescribing Information* and FDA approved dosing regimen(s).

Recommendation 8: Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav™ (Calcium/Magnesium/Potassium/ Sodium Oxybates)

NO ACTION REQUIRED.

Recommendation 10: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Lybalvi™ (Olanzapine/Samidorphan)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti™ (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/Estetrol Tablet), Ozobax® (Baclofen 5mg/5mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel), RediTrex® (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution)

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule)

NO ACTION REQUIRED.

Recommendation 13: Annual Review of Isturisa® (Osilodrostat)

NO ACTION REQUIRED.

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

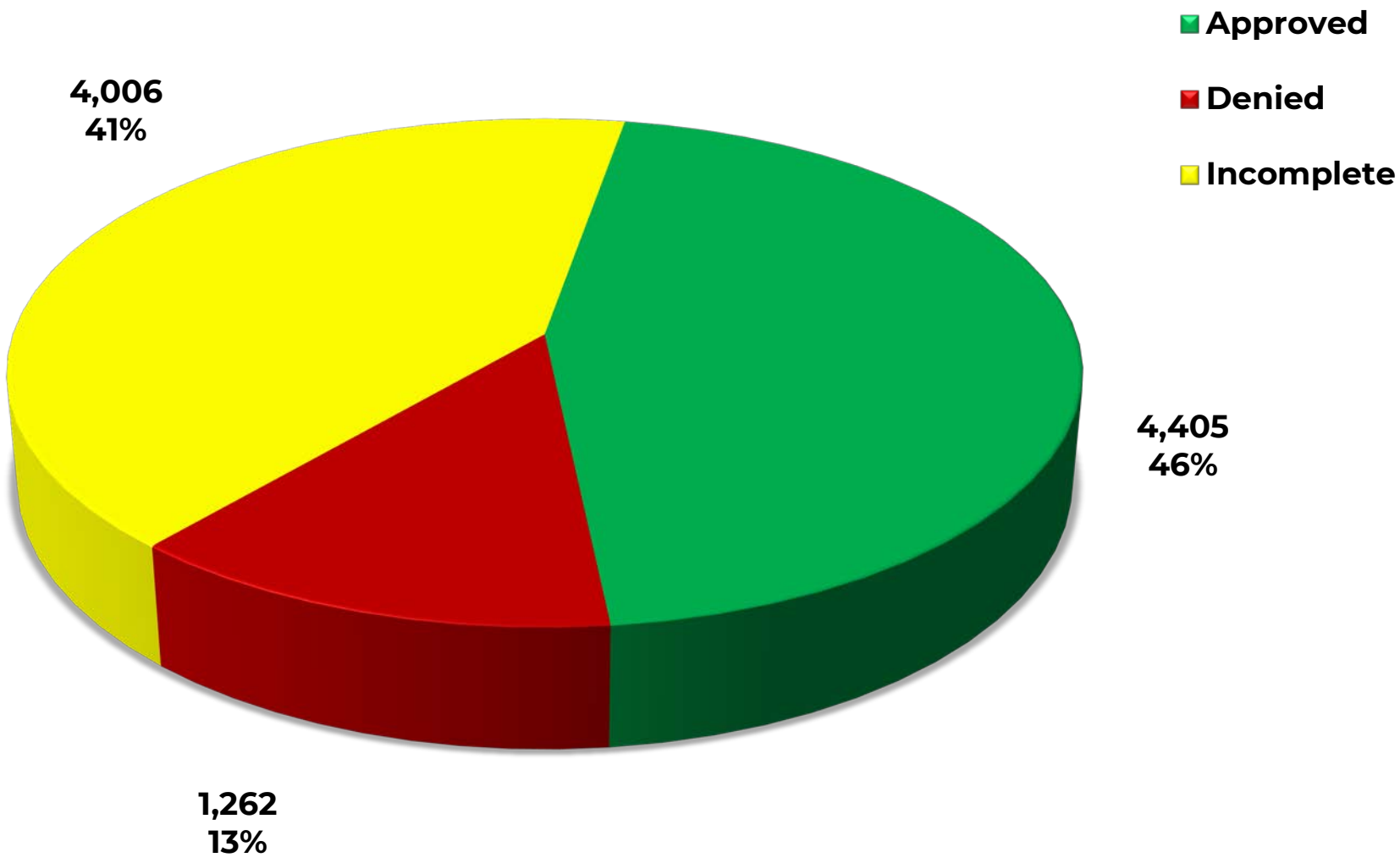
NO ACTION REQUIRED.

Recommendation 15: Future Business

NO ACTION REQUIRED.

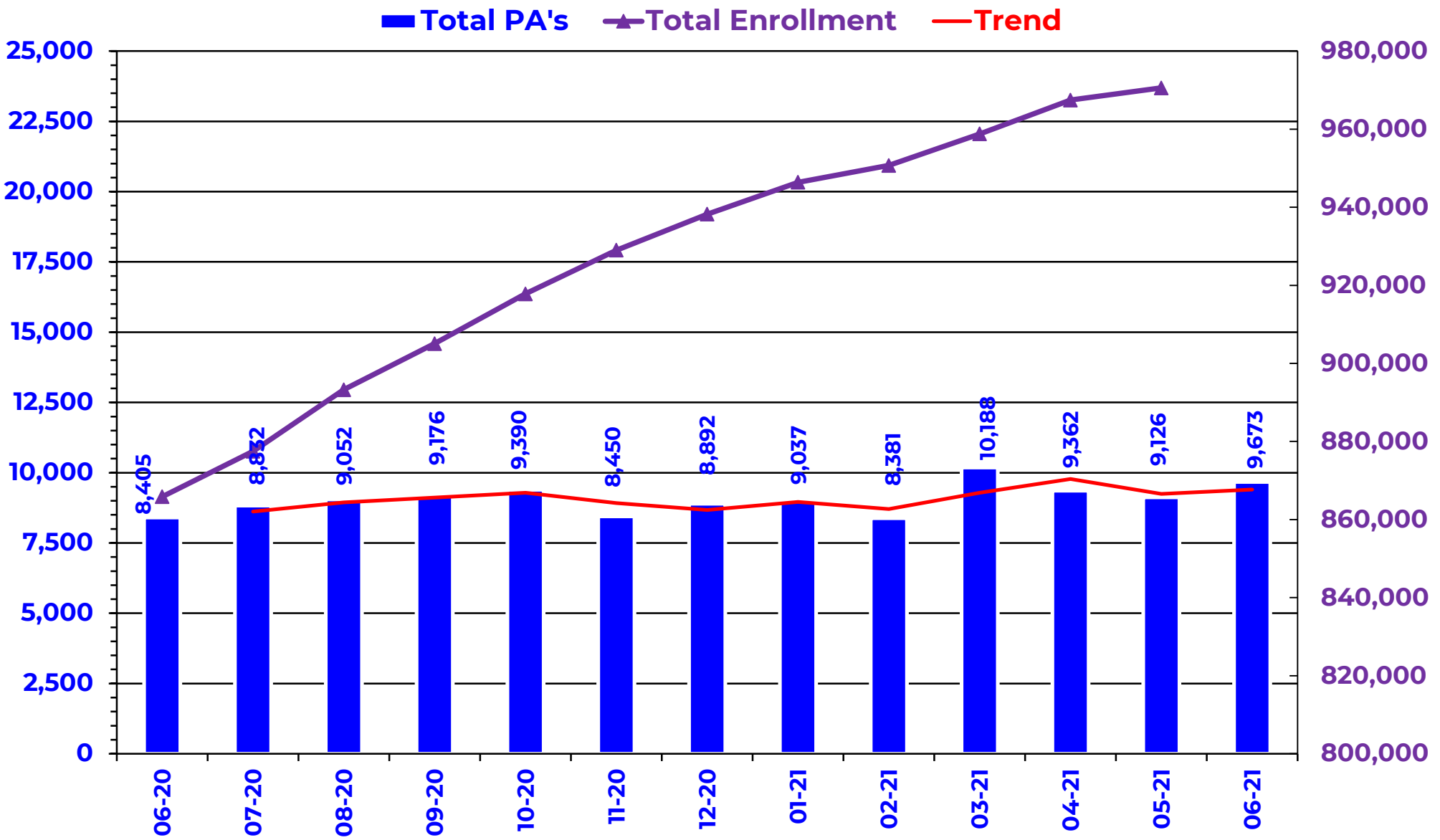
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JUNE 2021



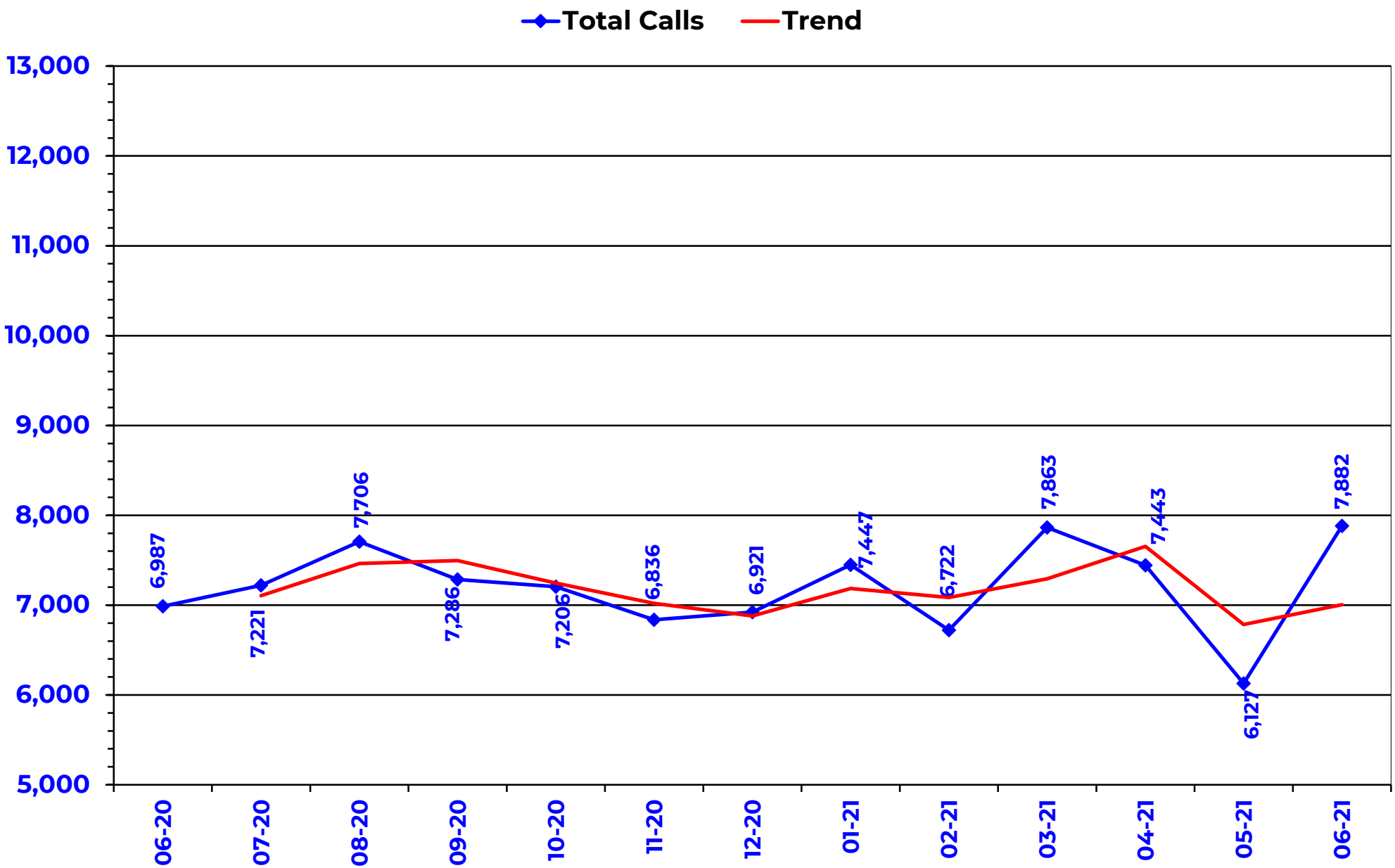
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JUNE 2020 – JUNE 2021



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JUNE 2020 – JUNE 2021



Prior Authorization Activity

6/1/2021 Through 6/30/2021

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	55	10	5	40	358
Analgesic, Narcotic	238	92	25	121	161
Antiasthma	84	25	25	34	274
Antibiotic	44	19	4	21	216
Anticonvulsant	187	91	10	86	309
Antidepressant	197	45	36	116	345
Antidiabetic	516	204	68	244	352
Antihistamine	38	7	15	16	358
Antimigraine	324	45	126	153	247
Antineoplastic	96	66	5	25	164
Antiparkinsons	10	1	6	3	347
Antiulcers	63	10	15	38	79
Anxiolytic	19	2	2	15	182
Atypical Antipsychotics	288	130	30	128	349
Biologics	233	121	28	84	310
Bladder Control	49	5	16	28	329
Blood Thinners	360	194	24	142	341
Botox	55	41	8	6	308
Buprenorphine Medications	107	32	12	63	68
Calcium Channel Blockers	13	4	3	6	188
Cardiovascular	71	33	5	33	329
Chronic Obstructive Pulmonary	224	44	60	120	336
Constipation/Diarrhea Medications	156	32	35	89	253
Contraceptive	32	16	4	12	357
Dermatological	358	99	90	169	217
Diabetic Supplies	877	451	83	343	263
Endocrine & Metabolic Drugs	97	48	11	38	172
Erythropoietin Stimulating Agents	22	10	1	11	97
Fibromyalgia	1	0	0	1	0
Fish Oils	26	4	7	15	358
Gastrointestinal Agents	134	37	19	78	207
Genitourinary Agents	10	1	5	4	54
Glaucoma	11	5	2	4	292
Growth Hormones	125	84	15	26	151
Hematopoietic Agents	25	11	3	11	260
Hepatitis C	152	85	22	45	8
HFA Rescue Inhalers	18	1	1	16	39
Insomnia	50	2	13	35	93
Insulin	170	64	19	87	351
Miscellaneous Antibiotics	17	4	1	12	11
Multiple Sclerosis	54	29	4	21	210
Muscle Relaxant	36	2	8	26	249
Nasal Allergy	115	16	39	60	119
Neurological Agents	89	25	22	42	239

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Neuromuscular Agents	14	6	2	6	263
Nsaids	47	2	10	35	358
Ocular Allergy	35	0	9	26	0
Ophthalmic Anti-infectives	21	3	4	14	22
Ophthalmic Corticosteroid	13	4	1	8	358
Osteoporosis	19	9	2	8	328
Other*	318	73	62	183	262
Otic Antibiotic	36	1	7	28	23
Pediculicide	20	8	1	11	19
Respiratory Agents	62	35	1	26	230
Statins	21	7	2	12	213
Stimulant	795	417	53	325	349
Testosterone	81	26	16	39	325
Thyroid	28	9	4	15	315
Topical Antifungal	30	3	2	25	42
Topical Corticosteroids	60	1	38	21	86
Vitamin	90	14	30	46	210
Pharmacotherapy	59	56	0	3	249
Emergency PAs	0	0	0	0	
Total	**7,595**	**2,921**	**1,176**	**3,498**	
Overrides					
Opioid MME Limit	1	0	0	1	0
Brand	42	26	2	14	294
Compound	11	10	0	1	23
Diabetic Supplies	17	16	0	1	124
Dosage Change	327	300	2	25	13
High Dose	2	2	0	0	221
Ingredient Duplication	8	7	0	1	9
Lost/Broken Rx	119	112	2	5	17
MAT Override	255	185	6	64	61
NDC vs. Age	357	225	30	102	256
NDC vs. Sex	10	6	0	4	132
Nursing Home Issue	81	78	0	3	19
Opioid MME Limit	1	1	0	0	178
Opioid MME Limit	136	37	9	90	127
Opioid Quantity	30	26	0	4	169
Other	62	51	0	11	13
Quantity vs. Days Supply	566	366	29	171	254
STBS/STBSM	18	11	4	3	43
Step Therapy Exception	3	1	2	0	360
Stolen	8	8	0	0	22
Third Brand Request	24	16	0	8	15
Overrides Total	**2,078**	**1,484**	**86**	**508**	
Total Regular PAs + Overrides	**9,673**	**4,405**	**1,262**	**4,006**	

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

Denial Reasons	
Unable to verify required trials.	3,348
Does not meet established criteria.	1,292
Lack required information to process request.	615
Other PA Activity	
Duplicate Requests	1,060
Letters	18,121
No Process	4
Changes to Existing PAs	745
Helpdesk Initiated Prior Authorizations	759
PAs Missing Information	1

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

Chronic Medication Adherence (CMA) Program Update

Oklahoma Health Care Authority
July 2021

Prescriber Mailing: Diabetes and Cardiovascular Maintenance Medications[1]

The CMA educational mailing is processed quarterly and sent to prescribers with members on chronic maintenance medications for diabetes mellitus (DM), blood pressure (BP), and cholesterol. The purpose of the CMA mailings is to encourage medication adherence and improve the quality of care for SoonerCare members on these medications. The CMA inclusion criteria at determination of the prescriber mailing list required the prescriber to have at least 7 SoonerCare members taking DM, BP, and cholesterol medications. The review period for each mailing is 1 year, and members are assigned to prescribers and included in the prescriber's patient list if they are the last prescriber of record for a maintenance medication on SoonerCare paid pharmacy claims.

Previously, prescribers were selected randomly to receive letters if they met the inclusion criteria for the mailing module. In February 2016, the CMA mailing changed to sending the educational letters to the same consistent prescribers, and in February 2018, the mailing was updated to include both cardiovascular (CV) and DM medications in each mailing rather than alternating with each mailing. Included prescribers receive 4 letters per year to better inform them of their SoonerCare members using chronic maintenance medications and as a convenient way to track their members' adherence over time, including any improvements or changes. The consistent prescriber list is updated approximately once every 2 years to account for prescribers who move out of state, retire, or no longer contract with SoonerCare. The CMA prescriber list was most recently updated in February 2020.

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

patient resources intended to offer prescribers methods to improve their patients' adherence.

Mailing Summaries

The following table outlines total letters mailed and total members included in each CMA mailing since February 2019 to the most recent mailing in May 2021:

Date Letter Processed	Total Letters Mailed	Total Members Included
February 2019	256	6,036
May 2019	240	5,557
August 2019	230	5,167
November 2019	222	4,783
February 2020*	243	7,777
May 2020	242	7,488
August 2020	241	7,262
November 2020	237	7,145
February 2021	214	6,470
May 2021	212	6,311

*CMA prescriber list updated

Star Ratings

The star ratings for the percentage of SoonerCare members that are adherent to CV or DM chronic maintenance medications are based on the 2021 Medicare Star Ratings. However, a rating of 0 stars is exclusive to SoonerCare. The following key is shown to illustrate the star ratings and adherence percentages for each star rating.

- **CV Star Ratings:** CV star ratings address adherence to maintenance renin angiotensin system (RAS) antagonists [i.e., angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), direct renin inhibitors] and HMG-CoA reductase inhibitors (i.e., statins). Adherence is shown in the Provider Summary Report as a percentage for RAS antagonists and as a percentage for statins, with a corresponding star rating for each category.
- **DM Star Ratings:** DM star ratings address adherence to maintenance medications for DM, excluding insulin and Symlin® (pramlintide). Adherence is shown in the Provider Summary Report as a percentage and corresponding star rating for DM medications.

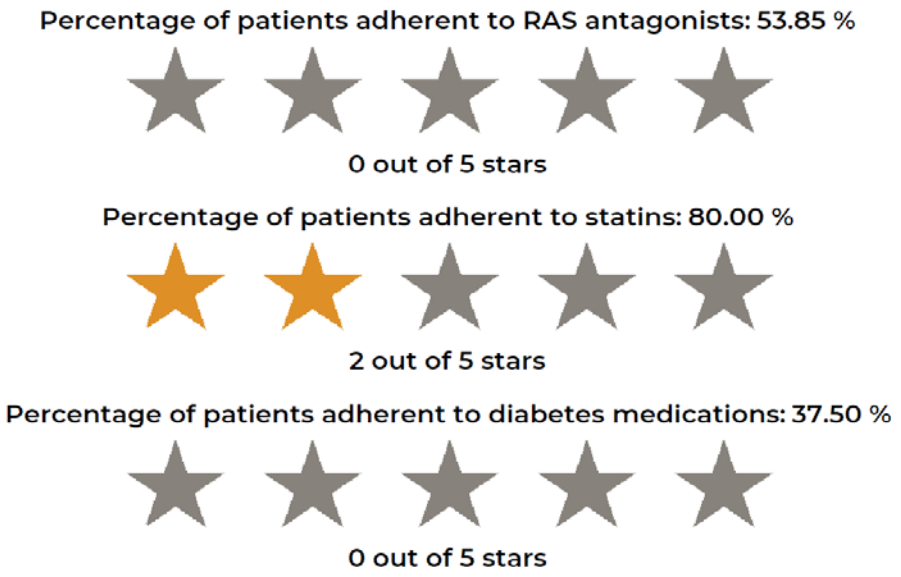
Star Ratings	RAS Antagonists	Statins	Diabetes Meds
★★★★★ **5 Stars: Excellent**	≥90%	≥88%	≥87%
★★★★☆ **4 Stars: Above Average**	≥88% to <90%	≥86% to <88%	≥85% to <87%
★★★☆☆ **3 Stars: Average**	≥86% to <88%	≥81% to <86%	≥82% to <85%
★★☆☆☆ **2 Stars: Below Average**	≥84% to <86%	≥78% to <81%	≥79% to <82%
★☆☆☆☆ **1 Star: Poor**	≥60% to <84%	≥60% to <78%	≥60% to <79%
☆☆☆☆☆ **0 Stars: Very Poor**	<60%	<60%	<60%

RAS = renin angiotensin system; meds = medications

Example Star Rating

Report date: <Report Date>
NPI: <Prescriber NPI>

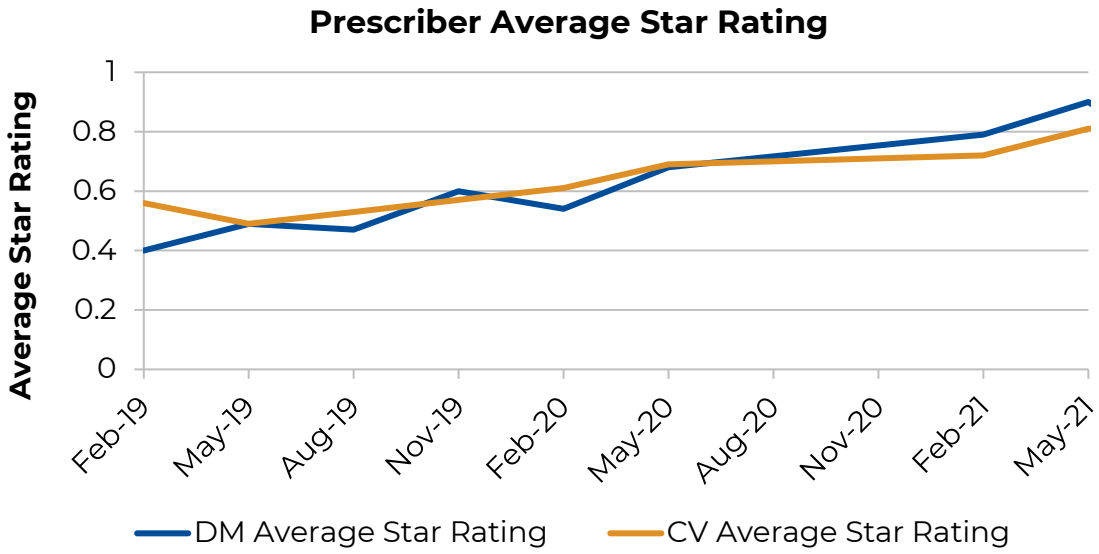
Provider: <Provider Name>
SoonerCare Provider ID: <Provider ID>



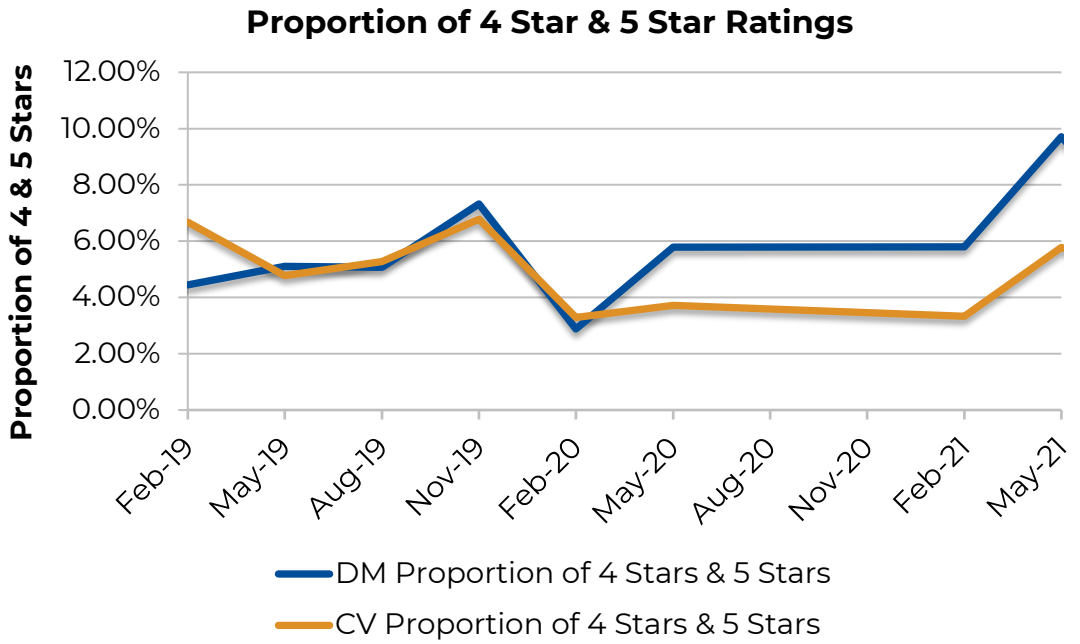
CMA Trends

The following line graph shows trends in the average star rating for prescribers included in the CMA mailing since February 2019. This graph is specific to those prescribers included in the mailings and differentiates between DM and CV (i.e., statins and RAS antagonists) modules. It is important to note that the prescriber mailing list was updated in February

2020 to include a larger number of prescribers as well as prescribers who were not previously receiving a mailing. An overall increase in the average star rating was seen for both mailing modules. Despite favorable increases in the average star ratings, opportunities for further enhancements continue to exist.

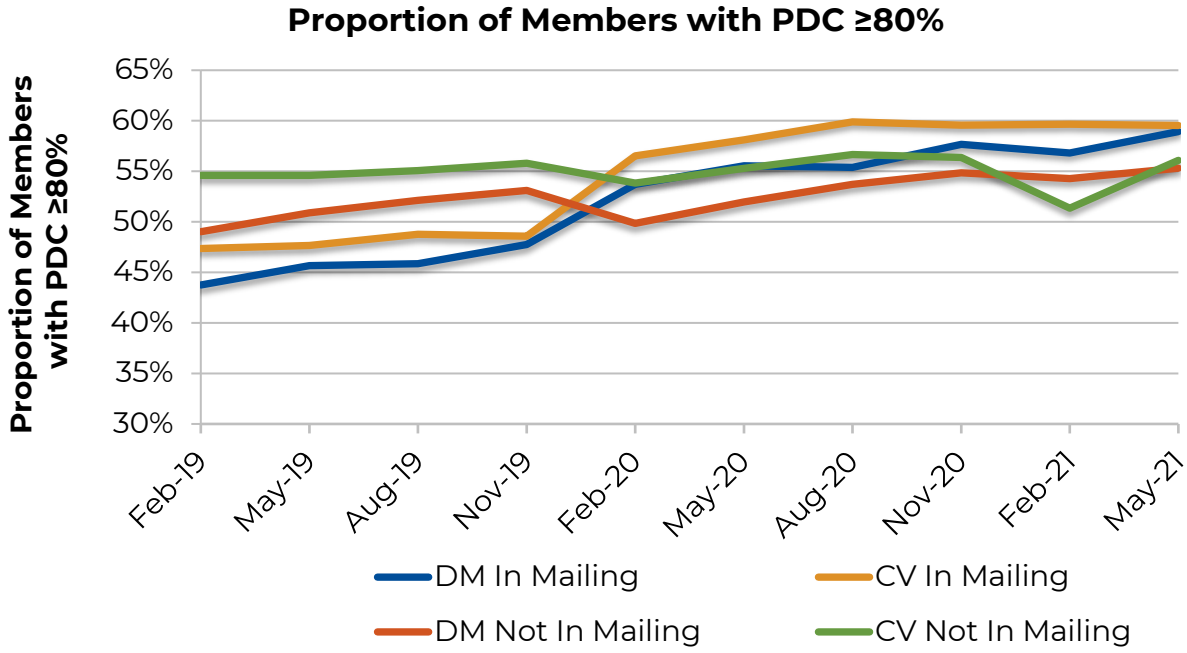


The following line graph shows trends in the proportion of prescribers with 4 star and 5 star ratings included in the CMA mailing since February 2019. An overall increase in the proportion of 4 star and 5 star ratings was seen for both mailing modules. Similar to the average star rating, while favorable increases were seen, opportunities for further enhancements continue to exist.



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

compared to those with prescribers not included in the mailing since February 2019. A member is considered adherent if their PDC is ≥80%. Please note, the vertical axis starts at 40% in order to reflect small changes.



Unlike prescribers included in the mailings, members included in the mailings are not consistent and may change over time due to medication discontinuations or changing to a prescriber not included in the mailing. Despite member variability, an increase in the proportion of members with a PDC ≥80% was seen for both modules for those prescribers included in the mailing compared to a relatively linear trend for prescribers not included in the mailing. This indicates prescriber mailings may have a positive impact on the proportion of members with PDC ≥80%.

Conclusions

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

[1] Centers for Medicare and Medicaid Services (CMS): *Medicare 2021 Part C & D Star Rating Technical Notes*. Available online at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData. Last revised 10/01/2020. Last accessed 06/19/2021.

Appendix C

Vote to Prior Authorize Lybalvi™ (Olanzapine/ Samidorphan)

Oklahoma Health Care Authority
July 2021

Market News and Updates[1]

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

- **June 2021:** The FDA approved Lybalvi™ (olanzapine/samidorphan) for the treatment of adults with schizophrenia, for the treatment of adults with bipolar I disorder as maintenance monotherapy, and for the acute treatment of adults with manic or mixed episodes of bipolar I disorder as monotherapy or as an adjunct to lithium or valproate. Lybalvi™ is a once-daily, oral medication composed of olanzapine, an established atypical antipsychotic agent, and samidorphan, a new chemical entity that is an opioid antagonist. The FDA approved Lybalvi™ under the 505(b)(2) regulatory pathway based on data from 27 clinical studies, including 18 studies evaluating Lybalvi™ and 9 studies evaluating samidorphan alone, as well as the FDA's findings of safety and effectiveness of olanzapine in the treatment of schizophrenia and bipolar I disorder. The efficacy of Lybalvi™ in the treatment of schizophrenia was evaluated in the ENLIGHTEN clinical development program, which included ENLIGHTEN-2 that compared the weight gain profile of Lybalvi™ to olanzapine over 6 months in 561 patients with stable schizophrenia. This study met its prespecified co-primary endpoints, demonstrating both a lower mean percentage weight gain from baseline at 6 months compared to the olanzapine group (P=0.003) and a lower proportion of patients who gained 10% or more of their baseline body weight at 6 months compared to the olanzapine group (P=0.003). The most common adverse effects (AEs) reported in the Lybalvi™ treatment group were weight gain, somnolence, and dry mouth; the most common AEs reported in the olanzapine treatment group were weight gain, somnolence, and increased appetite.

Lybalvi™ (Olanzapine/Samidorphan) Product Summary[2]

- **Therapeutic Class:** An atypical antipsychotic (olanzapine) combined with an opioid antagonist (samidorphan) to mitigate weight gain associated with the AEs of the atypical antipsychotic
- **Indication(s):**
  - Schizophrenia in adults; or
  - Bipolar I disorder in adults, including:

    - Maintenance monotherapy treatment; or
    - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
- **How Supplied:** 5/10mg, 10/10mg, 15/10mg, and 20/10mg olanzapine/samidorphan oral bilayer tablets
- **Dosing and Administration:**
    - Lybalvi™ should be administered once daily with or without food. Lybalvi™ tablets should not be combined or divided.
    - The recommended starting dosage is 5/10mg once daily in patients who have a predisposition to hypotensive reactions, have potential for slower metabolism of olanzapine, or may be more pharmacodynamically sensitive to olanzapine.
    - Dosage may be adjusted at weekly intervals of 5mg (based on the olanzapine component of Lybalvi™), depending upon clinical response and tolerability, up to the maximum recommended dosage of 20/10mg once daily.
    - Refer to the full *Prescribing Information* for the recommended titration and maximum recommended dosage specific to each indication.
    - Lybalvi™ can precipitate opioid withdrawal in patients who are dependent on opioids; concomitant use of Lybalvi™ with opioids is contraindicated. Prior to initiating Lybalvi™, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.
- **Cost:** The cost information for Lybalvi™ is not available at this time. Lybalvi™ is anticipated to be available in the fourth quarter of 2021.

Recommendations

The College of Pharmacy recommends adding Lybalvi™ (olanzapine/ samidorphan) to Tier-3 of the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category (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®)+

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
olanzapine (Zyprexa®)		clozapine oral susp (Versacloz®)+
paliperidone IM inj (Invega Sustenna®)		iloperidone (Fanapt®)
paliperidone IM inj (Invega Trinza®)**		lumateperone (Caplyta®)
quetiapine (Seroquel®)		olanzapine/fluoxetine (Symbyax®)+
quetiapine ER (Seroquel XR®)		**olanzapine/samidorphan (Lybalvi™)**
risperidone (Risperdal®)		paliperidone (Invega®)
risperidone IM inj (Risperdal Consta®)		
risperidone ER sub-Q inj (Perseris®)		
ziprasidone (Geodon®)		

ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; susp = suspension; sub-Q = subcutaneous
*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.
¥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 Trinza® requires members to have been adequately treated with the 1-month paliperidone ER 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.

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

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

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

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

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

    a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of all oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of Versacloz® (clozapine oral suspension) or Fazaclo® (clozapine orally disintegrating tablet) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
6. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

[1] Alkermes. Alkermes Announces FDA Approval of Lybalvi™ for the Treatment of Schizophrenia and Bipolar 1 Disorder. *PR Newswire*. Available online at: https://www.biospace.com/article/releases/alkermes-announces-fda-approval-of-lybalvi-for-the-treatment-of-schizophrenia-and-bipolar-i-disorder/. Issued 06/01/2021. Last accessed 06/16/2021.
[2] Lybalvi™ Prescribing Information. Alkermes. Available online at: https://www.alkermes.com/Alkermes2/media/Graphics/downloadables/lybalvi-pi-2021.pdf. Last revised 05/2021. Last accessed 06/16/2021.

Appendix D

Vote to Prior Authorize Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate), Qelbree™ (Viloxazine), and Xywav™ (Calcium/ Magnesium/Potassium/Sodium Oxybates)

Oklahoma Health Care Authority
July 2021

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

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

- **July 2020:** The FDA approved Xywav™ (calcium/magnesium/ potassium/sodium oxybates) oral solution for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. Xywav™ is a central nervous system (CNS) depressant similar to Xyrem® (sodium oxybate), but is formulated as a combination of oxybate salts, resulting in 92% less sodium content relative to Xyrem®. Accordingly, the *Prescribing Information* for Xywav™ does not contain any warnings about high sodium content. Xywav™ is a Schedule III controlled dangerous substance (CDS).
- **March 2021:** The FDA approved Azstarys™ (serdexmethylphenidate/ dexmethylphenidate), a once-daily CNS stimulant, for the treatment of attention-deficit/hyperactivity disorder (ADHD) in patients 6 years of age and older. Azstarys™ capsules are formulated to contain 70% serdexmethylphenidate, a prodrug of dexmethylphenidate, and 30% immediate-release dexmethylphenidate. Azstarys™ is a Schedule II CDS and should not be substituted for other methylphenidate-containing products on a milligram-per-milligram basis. Corium plans to launch Azstarys™ in the second half of 2021.
- **April 2021:** The FDA approved Qelbree™ (viloxazine) for the treatment of ADHD in pediatric patients 6 to 17 years of age. Viloxazine is a selective norepinephrine reuptake inhibitor and is the first novel, non-stimulant medication for ADHD approved by the FDA since 2002. Supernus launched Qelbree™ in May 2021.

Product Summaries[5,6,7,8]

Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate):

- **Indication(s):** Azstarys™ (serdexmethylphenidate/ dexmethylphenidate) is a CNS stimulant indicated for the treatment of ADHD in patients 6 years of age and older.

Boxed Warning: Abuse and Dependence

- CNS stimulants, including Azstarys™, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. The risk of abuse should be assessed prior to prescribing, and the patient should be monitored for signs of abuse and dependence while on therapy.

- **How Supplied:** 26.1mg/5.2mg, 39.2mg/7.8mg, and 52.3mg/10.4mg serdexmethylphenidate/dexmethylphenidate oral capsules
- **Dosing and Administration:**
  - Pediatric patients 6 to 12 years of age: Initial dose of 39.2mg/7.8mg once daily in the morning; dose may be increased to 52.3mg/10.4mg once daily or decreased to 26.1mg/5.2mg once daily after 1 week depending on response and tolerability
  - Adults and pediatric patients 13 to 17 years of age: Initial dose of 39.2mg/7.8mg once daily in the morning; dose may be increased to 52.3mg/10.4mg once daily after 1 week
  - Maximum recommended dose: 52.3mg/10.4mg once daily
  - May be taken with or without food; capsules may be swallowed whole, opened and sprinkled onto applesauce, or opened and added to water
  - To avoid substitution errors and overdosage, Azstarys™ should not be substituted for other methylphenidate products on a milligram-per-milligram basis; of switching from other methylphenidate products, the previous medication should be discontinued and the initial dose titration schedule for Azstarys™ should be followed
- **Contraindication(s):**
  - Known hypersensitivity to serdexmethylphenidate, dexmethylphenidate, or product components
  - Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days
- **Cost:** Cost information for Azstarys™ is not yet available.

Qelbree™ (Viloxazine):

- **Indication(s):** Qelbree™ (viloxazine) is a selective norepinephrine reuptake inhibitor indicated for the treatment of ADHD in pediatric patients 6 to 17 years of age.

Boxed Warning: Suicidal Thoughts and Behaviors

- In clinical studies, higher rates of suicidal thoughts and behavior were reported in pediatric patients with ADHD treated with Qelbree™ than patients treated with placebo. All Qelbree™-treated patients should be closely monitored for clinical worsening and for the emergence of suicidal thoughts and behaviors.

- **How Supplied:** 100mg, 150mg, and 200mg extended-release (ER) oral capsules
- **Dosing and Administration:**
  - Pediatric patients 6 to 11 years of age: Initial dose of 100mg once daily; may titrate in 100mg increments weekly to the maximum recommended dose of 400mg once daily
  - Pediatric patients 12 to 17 years of age: Initial dose of 200mg once daily; may titrate after 1 week, by an increment of 200mg, to the maximum recommended dose of 400mg once daily
  - Capsules may be swallowed whole or opened and sprinkled onto a teaspoonful of applesauce
- **Contraindication(s):**
  - Concomitant administration of MAOIs or within 14 days after discontinuing an MAOI
  - Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range
- **Cost:** The Wholesale Acquisition Cost (WAC) is $9.97 per capsule, resulting in a cost per 30 days of $598.20 at the maximum FDA approved dose of 400mg once daily.

Xywav™ (Calcium/Magnesium/Potassium/Sodium Oxybates):

- **Indication(s):** Xywav™ (calcium/magnesium/potassium/sodium oxybates) is a CNS depressant indicated for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy.

Boxed Warning: CNS Depression and Abuse and Misuse

- Xywav™ is a CNS depressant. Clinically significant respiratory depression and obtundation may occur in patients treated with Xywav™ at recommended doses. Many patients who received Xywav™ during clinical studies in narcolepsy were receiving CNS stimulants.
- The active moiety of Xywav™ is oxybate or gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.
- Because of the risks of CNS depression and abuse and misuse, Xywav™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Xywav™ and Xyrem® REMS.

- **How Supplied:** 0.5g/mL oral solution (equivalent to 0.413g/mL of oxybate)
- **Dosing and Administration:**
  - Administered as 2 divided doses nightly (taken at bedtime and then 2.5 to 4 hours later); dose should be titrated to effect

    - Adults: Initiate at 4.5g per night (2.25g per dose); recommended dosage range: 6g to 9g per night
    - Children 7 years of age and older: Recommended starting dose, titration regimen, and maximum nightly dose is based on body weight (refer to the full *Prescribing Information* for the complete weight-based dosing recommendations for pediatric patients)
  - Doses >9g per night have not been studied and ordinarily should not be administered
  - Patients should take the first nightly dose at least 2 hours after eating and should take each dose while in bed and lie down after dosing
  - For patients with hepatic impairment, the recommended dose is one-half the original dosage per night
- **Contraindication(s):**
  - Combination with sedative hypnotics or alcohol
  - Use in patients with succinic semialdehyde dehydrogenase deficiency
- **Cost:** The WAC is $28.39 per mL, resulting in a cost per 180mL bottle of $5,110.20.

Recommendations

The College of Pharmacy recommends the following changes to the ADHD and Narcolepsy Medications product based prior authorization (PBPA) category (changes noted in red in the following PBPA Tier chart and approval criteria):

1. The prior authorization of Azstarys™ (serdexmethylphenidate/ dexmethylphenidate) and placement into Tier-3 of the Long-Acting Methylphenidate category of the ADHD Medications PBPA Tier chart; current Tier-3 criteria will apply
2. The prior authorization of Qelbree™ (viloxazine) and placement into Tier-3 of the Non-Stimulants category of the ADHD Medications PBPA Tier chart; the following additional criteria will also apply
3. The prior authorization of Xywav™ (calcium/magnesium/potassium/ sodium oxybates) in the Narcolepsy Medications category with criteria similar to the current approval criteria for Xyrem® (sodium oxybate); the following additional criteria will also apply
4. Moving Quillivant XR® (methylphenidate ER suspension) from Tier-2 to Tier-3, moving Adderall XR® from Tier-2 to Tier-1, and moving Metadate ER® (methylphenidate ER tablet), Methylin ER® (methylphenidate ER tablet), and Ritalin SR® (methylphenidate ER tablet) from Tier-3 to Tier-1 of the ADHD Medications PBPA Tier chart based on net costs

5. Moving Kapvay® (clonidine ER tablet) from Tier-3 to Tier-2 of the Non-Stimulants category of the ADHD Medications PBPA Tier chart based on net cost, and updating the following additional criteria for Kapvay®

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			Adzenys ER™ (amphetamine ER susp) Adzenys XR-ODT® (amphetamine ER-ODT) Cotempla XR-ODT® (methylphenidate ER ODT) Desoxyn® (methamphetamine) Dexedrine® (dextro-amphetamine) Dexedrine Spansules® (dextroamphetamine ER) Dyanavel® XR (amphetamine ER susp) Evekeo® (amphetamine) Evekeo ODT™ (amphetamine ODT) Methylin® (methylphenidate chew tab) Mydayis® (amphetamine/ dextroamphetamine ER) ProCentra® (dextro-amphetamine)
Short-Acting			
Adderall® (amphetamine/ dextroamphetamine)			
Long-Acting			
Adderall XR® (amphetamine/ dextroamphetamine ER) Vyvanse® (lisdexamfetamine cap and chew tab)+	~~**Adderall XR® (amphetamine/ dextroamphetamine ER)**~~		
Methylphenidate			
Short-Acting			
Focalin® (dexmethylphenidate) Methylin® (methylphenidate tab and soln) Ritalin® (methylphenidate)			
Long-Acting			
Daytrana® (methylphenidate ER) Focalin XR® brand name only (dexmethylphenidate ER) Metadate CD® (methylphenidate ER) **Metadate ER® (methylphenidate ER)**	Concerta® (methylphenidate ER) dexmethylphenidate ER (generic Focalin XR®) ~~**Quillivant XR® (methylphenidate ER susp)**~~	Adhansia XR® (methylphenidate ER) Aptensio XR® (methylphenidate ER) **Azstarys™ (ser-dexmethylphenidate/ dexmethylphenidate)** Jornay PM® (methylphenidate ER)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Methylin ER® (methylphenidate ER) QuilliChew ER® (methylphenidate ER chew tab) Ritalin LA® (methylphenidate ER) **Ritalin SR® (methylphenidate ER)**		~~**Metadate ER® (methylphenidate ER)**~~ ~~**Methylin ER® (methylphenidate ER)**~~ methylphenidate ER 72mg **Quillivant XR® (methylphenidate ER susp)** ~~**Ritalin SR® (methylphenidate ER)**~~	Zenzedi® (dextro-amphetamine)
Non-Stimulants			
Intuniv® (guanfacine ER) Strattera® (atomoxetine)	**Kapvay® (clonidine ER)Δ**	~~**Kapvay® (clonidine ER)Δ**~~ **Qelbree™ (viloxazine)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 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.
4. A clinical exception may apply for special formulation products when there is a patient-specific, clinically significant reason why the member cannot use the available long-acting lower tiered formulations.
5. ~~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, a long-acting Tier-2 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.~~
6. Qelbree™ [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 to 17 years of age; and
    c. Previously failed trials (within the last 365 days) with a long-acting Tier-1 stimulant, a long-acting Tier-2 stimulant, Intuniv®, Strattera®, and Kapvay®, unless contraindicated, that did not yield adequate results; 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 and 150mg strengths and 60 capsules per 30 days will apply for the 200mg strength.

7. For 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.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Dyanavel® XR, and Evekeo ODT™ 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.

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, Methylin® oral solution, and Quillichew ER® chewable tablets, 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), ~~or~~ 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 (OSA) requires concurrent treatment for the OSA; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

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[1] Jazz Pharmaceuticals. Jazz Pharmaceuticals Announces U.S. FDA Approval of Xywav™ (Calcium, Magnesium, Potassium, and Sodium Oxybates) Oral Solution for Cataplexy or Excessive Daytime Sleepiness Associated with Narcolepsy. Available online at: https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-announces-us-fda-approval-xywavtm-calcium. Issued 07/22/2020. Last accessed 06/25/2021.

[2] Park B. Azstarys™, a Once-Daily Treatment for ADHD, Gets FDA Approval. *MPR*. Available online at: https://www.empr.com/home/news/azstarys-serdexmethylphenidate-dexmethylphenidate-attention-deficit-hyperactivity-disorder/. Issued 03/03/2021. Last accessed 06/25/2021.

[3] Supernus Pharmaceuticals, Inc. Supernus Announces FDA Approval of Qelbree™ (SPN-812) for the Treatment of ADHD. Available online at: https://ir.supernus.com/news-releases/news-release-details/supernus-announces-fda-approval-qelbreetm-spn-812-treatment-adhd. Issued 04/02/2021. Last accessed 06/25/2021.

[4] Park B. Qelbree™, a Nonstimulant Treatment for ADHD, Gets FDA Approval. *MPR*. Available online at: https://www.empr.com/home/news/qelbree-viloxazine-extended-release-serotonin-approved-attention-deficit-hyperactivity-disorder/. Issued 04/05/2021. Last accessed 06/25/2021.

[5] Azstarys™ (Serdexmethylphenidate/Dexmethylphenidate) Prescribing Information. Corium, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212994s000lbl.pdf. Last revised 03/2021. Last accessed 06/25/2021.

[6] KP415 Classroom Study in Children (6-12 Years of Age) With ADHD. *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/NCT03292952. Last revised 06/01/2020. Last accessed 06/25/2021.

[7] Qelbree™ (Viloxazine) Prescribing Information. Supernus Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211964s000lbl.pdf. Last revised 04/2021. Last accessed 06/25/2021.

[8] Xywav™ (Calcium, Magnesium, Potassium, and Sodium Oxybates) Prescribing Information. Jazz Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021196s035,212690s001s002lbl.pdf. Last revised 02/2021. Last accessed 06/25/2021.

Appendix E

Vote to Prior Authorize Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/ Metronidazole/Tetracycline Capsule)

Oklahoma Health Care Authority
July 2021

Market News and Updates[1]

News:

- **April 2020:** The U.S. Food and Drug Administration (FDA) has requested all manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine products from the market immediately due to a contaminant known as N-nitrosodimethylamine (NDMA). NDMA is a probable human carcinogen and third-party laboratories have confirmed that NDMA levels increase in ranitidine over time, even under normal storage conditions. Ranitidine stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling, have been shown to have significantly higher NMDA levels. To date, testing done by the FDA for famotidine, cimetidine, esomeprazole, lansoprazole, and omeprazole have not found any NDMA contaminants.

Helicobacter Pylori (*H. Pylori*) Product Summaries[2,3]

Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack):

- **Indication(s):** The components of Helidac® Therapy (bismuth subsalicylate/metronidazole/tetracycline dose pack), in combination with a histamine type 2 receptor (H_2) antagonist, are indicated for the eradication of *H. pylori* for treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or a history of duodenal ulcer).

Boxed Warning: Potential for Carcinogenicity

- Metronidazole has been shown to be carcinogenic in mice and rats. It is unknown whether metronidazole is associated with carcinogenicity in humans.

- **Dosing and Administration:**
  - The recommended dosing for Helidac® Therapy is bismuth subsalicylate [(2) 262.4mg chewable tablets], metronidazole [(1) 250mg tablet], and tetracycline [(1) 500mg capsule] taken 4 times

daily for 14 days plus an H_2 antagonist approved for the treatment of acute duodenal ulcer (e.g., famotidine).
- Helidac® Therapy doses should be taken at mealtimes and at bedtime. The bismuth subsalicylate tablets should be chewed and swallowed. The metronidazole tablet and tetracycline capsule should be swallowed whole with 8 ounces of water. Concomitantly prescribed H_2 antagonist therapy should be taken as directed.
- Helidac® Therapy is supplied in a carton containing 14 blister cards, each card containing 8 bismuth subsalicylate 262.4mg chewable tablets, 4 metronidazole 250mg tablets, and 4 tetracycline 500mg capsules.

Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Product Summary:

- **Indication(s):** Pylera® (bismuth subcitrate potassium/metronidazole/ tetracycline capsule) is a combination of metronidazole, tetracycline, and bismuth subcitrate potassium indicated for use, in combination with omeprazole, for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*.

Boxed Warning: Potential for Carcinogenicity

- Metronidazole has been shown to be carcinogenic in mice and rats. It is unknown whether metronidazole is associated with carcinogenicity in humans.

- **Dosing and Administration:**
  - The recommended dosing for Pylera® is 3 capsules 4 times a day (after meals and at bedtime) for 10 days.
  - Pylera® should be administered with omeprazole 20mg twice daily (after the morning and evening meals).
  - Each capsule of Pylera® contains 140mg of bismuth subcitrate potassium, 125mg of metronidazole, and 125mg of tetracycline. Pylera® is supplied in a 120 count bottle or blister pack for 10 days of therapy.

Cost Comparison: *H. Pylori* Regimens[4]

Product	Cost Per Unit	Cost Per Regimen*
Helidac® Therapy (bismuth subsalicylate/ metronidazole/tetracycline)	**$4.31**	**$965.44**
Pylera® (bismuth subcitrate potassium/ metronidazole/tetracycline capsule)	**$7.42**	**$890.40**
bismuth subsalicylate 262mg chewable tablet (generic)	$0.16+	$17.92+

Product	Cost Per Unit	Cost Per Regimen*
metronidazole 250mg tablet (generic)	$0.12	$6.72
tetracycline 500mg capsule (generic)	$1.54	$86.24
omeprazole 20mg capsule (generic)	$0.03	$0.84
famotidine 20mg tablet (generic)	$0.04	$1.12

Unit = capsule, chewable tablet, or tablet
*Cost per regimen based on recommended dosing duration for *H. Pylori* treatment for product listed.
⁺Cost for over-the-counter bismuth subsalicylate 262mg chewable tablets based on price available as of 06/25/2021 on Walgreens.com for store-brand product.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Recommendations

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

1. Moving rabeprazole tablets and brand name Prevacid® ODT from Tier-2 to Tier-1 based on net costs
2. The prior authorization of Helidac® Therapy (bismuth subsalicylate/ metronidazole/tetracycline) and Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline capsule) and placement into the Special Prior Authorization (PA) Tier with the following additional criteria
3. Updating the current approval criteria for sucralfate suspension unit dose cups based on net costs
4. Removing all ranitidine products from the Tier chart and Special PA criteria based on the FDA-requested market withdrawal
5. Updating the trial requirements for Axid® (nizatidine solution) based on the market withdrawal of ranitidine products

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
dexlansoprazole (Dexilant® caps)	~~**lansoprazole (Prevacid® ODT)**~~	esomeprazole (Nexium® I.V.)	**bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® capsule)**
esomeprazole (Nexium® caps)	pantoprazole (Protonix® I.V.)	esomeprazole strontium caps	**bismuth subsalicylate/ metronidazole/ tetracycline (Helidac® Therapy dose pack)**

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
esomeprazole (Nexium® packet) – **brand preferred**	~~**rabeprazole (Aciphex® tabs)**~~	omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
lansoprazole (Prevacid® ODT) – brand preferred		rabeprazole (Aciphex® sprinkles)	famotidine (Pepcid® susp)
omeprazole (Prilosec® caps)			glycopyrrolate (Glycate® tabs)
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/ amoxicillin/rifabutin (Talicia® caps)
sucralfate susp (Carafate®) – **brand preferred**			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			~~**ranitidine caps**~~
			sucralfate susp **(generic)** ~~**(unit dose cups)**~~

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

Axid® (Nizatidine Capsules) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine and~~ famotidine or a patient-specific, clinically significant reason why ~~ranitidine and~~ famotidine ~~are~~ is not appropriate for the member must be provided.

Axid® (Nizatidine Solution) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine syrup~~ famotidine suspension or a patient-specific, clinically significant reason why ~~ranitidine syrup~~ famotidine suspension is not appropriate for the member must be provided; and
2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

Generic Sucralfate Suspension ~~Unit Dose Cups~~ Approval Criteria:

1. Authorization consideration requires a patient specific, clinically significant reason why the member cannot use ~~the bulk medication~~ brand name Carafate® (sucralfate) suspension.

Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus an histamine type 2 receptor (H_2) antagonist], must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H_2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
5. For Helidac® Therapy a quantity limit of 224 tablets/capsules per 14 days will apply; and
6. For Pylera® a quantity limit of 120 capsules per 10 days will apply.

Pepcid® (Famotidine Suspension) Approval Criteria:

1. ~~A previous 14-day trial of ranitidine syrup or a patient-specific, clinically significant reason why ranitidine syrup is not appropriate for the member must be provided; and~~
2. Famotidine suspension will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.

~~**Ranitidine Capsules Approval Criteria:**~~

1. ~~A patient-specific, clinically significant reason why the member cannot use ranitidine tablets must be provided~~

Tagamet® (Cimetidine Tablets) Approval Criteria:

1. A previous 14-day trial of ~~ranitidine and~~ famotidine or a patient-specific, clinically significant reason why ~~ranitidine and~~ famotidine ~~are~~ is not appropriate for the member must be provided.

[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 05/2021. Last accessed 06/25/2021.

[2] Helidac® Therapy Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=eb651905-007d-4a56-b010-db4a4f7c405d. Last revised 06/2020. Last accessed 06/25/2021.

[3] Pylera® Prescribing Information. Allergan. Available online at: https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/product-prescribing/Pylera-Final-PI-10_2018.pdf. Last revised 03/2021. Last accessed 06/25/2021.

[4] Chey WD, Leontiadis GI, Howden CW, et al. ACG Clinical Guideline: Treatment of *Helicobacter Pylori* Infection. *Am J Gastroenterol* 2017; 112(2):212-239.

Appendix F

Vote to Prior Authorize Alkindi® Sprinkle (Hydrocortisone Oral Granule), Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension), Gimoti™ (Metoclopramide Nasal Spray), Nextstellis® (Drospirenone/Estetrol Tablet), Ozobax® (Baclofen 5mg/5mL Oral Solution), Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel), RediTrex® (Methotrexate Injection), Reltone™ (Ursodiol Capsule), and Thyquidity™ (Levothyroxine Oral Solution)

Oklahoma Health Care Authority
July 2021

Introduction[1,2,3,4,5,6,7,8,9]

Alkindi® Sprinkle (hydrocortisone oral granule) is a corticosteroid indicated as replacement therapy in pediatric patients with adrenocortical insufficiency. Alkindi® Sprinkle is supplied as oral granules contained within capsules available as 0.5mg, 1mg, 2mg, and 5mg strengths. The capsules should not be swallowed, nor the granules chewed or crushed. The capsule should be opened and its contents placed directly into the patient's mouth or sprinkled onto soft food and given immediately. The dose should be individualized, using the lowest possible dosage with a recommended starting dose of 8 to 10mg/m^2 daily. The total daily dose should be divided into 3 doses and administered 3 times daily.

- Other Formulation(s) Available: hydrocortisone tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Alkindi® Sprinkle 2mg (hydrocortisone oral granule)	**$27.95**	**$2,515.50***
hydrocortisone 5mg tablet (generic)	$0.18	$16.20[+]

Unit = granule-filled capsule or tablet
*Cost per 30 days for Alkindi® Sprinkle based on the U.S. Food and Drug Administration (FDA) recommended dose of 10mg/m^2 (divided into 3 doses/day) for a pediatric patient with a body surface area of 0.6m^2.
[+]Cost per 30 days for hydrocortisone generic tablet based on American Academy of Pediatrics guideline recommended pediatric fixed-dosing of 5mg 3 times daily.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Eysuvis® (loteprednol 0.25% ophthalmic suspension) is a corticosteroid indicated for short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease. Eysuvis® is supplied as 8.3mL of 0.25% sterile loteprednol etabonate ophthalmic suspension in a 10mL dropper bottle. After shaking the suspension, it is recommended to instill 1 to 2 drops of Eysuvis® into each eye 4 times daily for up to 2 weeks.

- Other Formulation(s) Available: Lotemax® (loteprednol 0.5% ophthalmic suspension) and Restasis® (cyclosporine 0.05% ophthalmic emulsion)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Eysuvis® (loteprednol 0.25% ophthalmic suspension)	**$56.02**	**$464.97**
Lotemax® (loteprednol 0.5% ophthalmic suspension)€	$52.94	$794.10
Restasis® (cyclosporine 0.05% ophthalmic emulsion)€	$9.83	$589.80

Unit = milliliter (mL) or single-use vial
€Brand name Lotemax® 0.5% suspension and Restasis® have supplemental rebates and are currently covered without prior authorization.
*Cost per package based on largest package size available for product listed.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Gimoti™ (metoclopramide nasal spray) is a dopamine-2 (D_2) antagonist indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. The recommended dosing for adults younger than 65 years of age is 1 spray (15mg) in 1 nostril, 30 minutes before each meal and at bedtime (maximum of 4 sprays daily) for 2 to 8 weeks, depending on symptomatic response. For adults 65 years of age or older, Gimoti™ is not recommended as initial therapy; if receiving an alternative metoclopramide product at a stable dosage of 10mg 4 times daily, the patient can be switched to Gimoti™ at the recommended dose and duration. Gimoti™ is supplied as a metoclopramide solution in a 10mL amber glass bottle fitted with a metered spray pump attachment that delivers 15mg of metoclopramide in each 70mcL spray. Each bottle contains 9.8mL which is sufficient for 4 weeks of 4 times daily use.

- Other Formulation(s) Available: metoclopramide tablets and metoclopramide oral solution

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 8 Weeks*
Gimoti™ (metoclopramide nasal spray)	**$178.57**	**$3,499.97**
metoclopramide 5mg/5mL oral solution (generic)	$0.03	$67.20
metoclopramide 10mg tablet (generic)	$0.04	$8.96

Unit = mL or tablet
*Cost per 8 weeks based on the maximum FDA recommended dosing for diabetic gastroparesis.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Nextstellis® (drospirenone/estetrol tablet) is a combination of drospirenone (a progestin) and estetrol (an estrogen) indicated for use by females of reproductive potential to prevent pregnancy. The recommended dose is 1 tablet by mouth at the same time every day for 28 consecutive days. Nextstellis® is supplied in a 28-day blister card with 24 pink, active film-coated tablets containing 3mg drospirenone/14.2mg estetrol and 4 white inert film-coated tablets.

- Other Formulation(s) Available: drospirenone/ethinyl estradiol (EE) 3mg/0.02mg tablets and drospirenone/EE 3mg/0.03mg tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Pack
Nextstellis® (drospirenone 3mg/estetrol 14.2mg tablet)	**$6.79**	**$190.12**
drospirenone 3mg/EE 0.02mg tablet (generic)	$0.40	$11.20
drospirenone 3mg/EE 0.03mg tablet (generic)	$0.31	$8.68

Unit = tablet; EE = ethinyl estradiol
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Ozobax® (baclofen 5mg/5mL oral solution) is a gamma-aminobutyric acid (GABA) agonist indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity; may also be of some value in patients with spinal cord injuries and other spinal cord diseases. The recommended dosing is to initiate treatment at 5mg 3 times daily for 3 days. The dose should be adjusted based on clinical response and tolerability up to a maximum of 80mg per day (20mg 4 times daily). Ozobax® is supplied as a 5mg/5mL grape-flavored oral solution in a 473mL stock bottle. Ozobax® must be stored refrigerated [2°C to 8°C (36°F to 46°F)].

- Other Formulation(s) Available: baclofen tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Ozobax® (baclofen 5mg/5mL oral solution)	**$1.73**	**$4,152.00**
baclofen 20mg tablet (generic)	$0.14	$16.80

Unit = mL or tablet
*Cost per 30 days based on the maximum FDA recommended dosing for baclofen.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Phexxi® (lactic acid/citric acid/potassium bitartrate vaginal gel) is a combination of lactic acid, citric acid, and potassium bitartrate indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception. The recommended dosing is to

administer 1 pre-filled single-dose applicator of Phexxi® (5 grams) vaginally immediately before (or up to 1 hour before) each act of vaginal intercourse. Phexxi® is supplied as vaginal gel containing 1.8% lactic acid, 1% citric acid, and 0.4% potassium bitartrate in individually wrapped 5 gram pre-filled single-dose vaginal applicators in sealed foil pouches along with a plunger. Phexxi® is available in a box containing 12 single doses.

- Other Formulation(s) Available: VCF® (nonoxynol 9 vaginal 28% film) and VCF® (nonoxynol 9 vaginal 12.5% foam)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Phexxi® (lactic acid/citric acid/potassium bitartrate vaginal gel)	**$4.28**	**$256.80**
VCF® (nonoxynol 9 vaginal 28% film)	$1.28	$11.52
VCF® (nonoxynol 9 vaginal 12.5% foam)	$0.67	$11.39

Unit = gram or film
*Cost per package based on largest package size available for product listed.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

RediTrex® (methotrexate injection) is a folate analog metabolic inhibitor indicated for the management of patients with severe, active rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or severe, recalcitrant, disabling psoriasis. RediTrex® is supplied in single-dose pre-filled syringes delivering sterile methotrexate solution for subcutaneous (sub-Q) injection in 8 strengths: 7.5mg/0.3mL, 10mg/0.4mL, 12.5mg/0.5mL, 15mg/0.6mL, 17.5mg/0.7mL, 20mg/0.8mL, 22.5mg/0.9mL, and 25mg/mL. The recommended dose for RediTrex® is once weekly via sub-Q administration in the abdomen or thigh. The recommended starting doses based on indication are as follows, for RA 7.5mg once weekly, for pJIA 10mg/m^2 once weekly, and for psoriasis 10mg to 25mg once weekly.

- Other Formulation(s) Available: methotrexate tablets and methotrexate injection

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 4 Weeks*
RediTrex® (10mg/0.4mL methotrexate injection)	**$75.00**	**$300.00**
Otrexup® (10mg/0.4mL methotrexate injection)	$162.44	$649.76
Rasuvo® (10mg/0.2mL methotrexate injection)	$123.25	$493.00
methotrexate 25mg/mL injection (generic)	$3.23‡	$6.46‡
methotrexate 2.5mg tablet (generic)	$0.23	$2.76

Unit = pre-filled syringe, auto-injector, mL, or tablet
‡Cost for methotrexate 25mg/mL injection based on use of multi-dose 2mL vial.
*Cost per 4 weeks is based on the FDA recommended dose for psoriasis (10mg once weekly).
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Reltone™ (ursodiol capsule) is a bile acid indicated for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery and prevention of gallstone formation in obese patients with rapid weight loss. The recommended dosing is based on diagnosis. For dissolution of radiolucent, noncalcified gallstones, the recommended dose is 8 to 10mg/kg/day given by mouth in 2 or 3 divided doses. For prevention of gallstone formation, the recommended dose is 600mg by mouth daily. Reltone™ is supplied in 2 strengths: 200mg and 400mg capsules. Safety of Reltone™ use beyond 24 months has not been established.

- Other Formulation(s) Available: ursodiol capsules and ursodiol tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Reltone™ 200mg (ursodiol capsule)	**$19.00**	**$1,710.00**
ursodiol 500mg tablet (generic)	$1.16	$69.60
ursodiol 300mg capsule (generic)	$0.58	$34.80

Unit = tablet or capsule
*Cost per 30 days based on the FDA recommended dose of 8mg/kg/day (2 or 3 divided doses) for gallstone dissolution for a 75kg adult patient.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Thyquidity™ (levothyroxine oral solution) is a levothyroxine sodium (T4) oral solution indicated for hypothyroidism and pituitary thyrotropin suppression. The recommended dosing for Thyquidity™ is once daily, preferably on an empty stomach, 30 minutes to 1 hour before breakfast and at least 4 hours before or after drugs that are known to interfere with absorption. The starting dose depends on a variety of factors, including age, body weight, cardiovascular status, concomitant medical conditions, concomitant medications, co-administered food, and the specific nature of the condition being treated. Peak therapeutic effect may not be attained for 4-6 weeks. Thyquidity™ is supplied as 100mcg/5mL (20mcg/mL) oral solution in 100mL bottles. The bottle must be used within 8 weeks of opening.

- Other Formulation(s) Available: levothyroxine tablets and Tirosint®-SOL (levothyroxine oral solution)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Thyquidity™ 100mcg/5mL (levothyroxine oral solution)	**$1.10**	**$110.00α**
Tirosint®-SOL 50mcg/mL (levothyroxine oral solution)	$4.44+	$133.20
levothyroxine 50mcg tablet (generic)	$0.21	$6.30

Unit = mL or tablet
*Cost per 30 days based on a dose of 50mcg daily. Cost for Thyquidity™ and levothyroxine tablets will vary based on dose required.
+Cost per mL is the same for all strengths of Tirosint®-SOL.
αThyquidity™ cost per 30 days for 50mcg daily requires the use of a 100mL bottle (as supplied), as it must be used within 8 weeks of opening.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Recommendations

The College of Pharmacy recommends the prior authorization of Alkindi® Sprinkle (hydrocortisone oral granule), Eysuvis® (loteprednol 0.25% ophthalmic suspension), and Gimoti™ (metoclopramide nasal spray) with the following criteria:

Alkindi® Sprinkle (Hydrocortisone Oral Granule) Approval Criteria:

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

Eysuvis® (Loteprednol 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. A documented trial of intermittent or regular artificial tear use within the past 3 months; and
3. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion), which is available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids including Lotemax® (loteprednol 0.5% suspension) must be provided; and
5. Member must not have any contraindications to Eysuvis®; and
6. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Gimoti™ (Metoclopramide Nasal Spray) Approval Criteria:

1. An FDA approved indication of acute or recurrent diabetic gastroparesis in adult members; and

2. A patient-specific, clinically significant reason why the member cannot use metoclopramide oral tablets and metoclopramide oral solution must be provided; and
3. For members 65 years of age or older, approvals will not be granted for initiation of metoclopramide therapy; and
4. For members 65 years of age or older requesting to switch from an alternative metoclopramide product to Gimoti™:
    a. Member must be taking a stable dose of metoclopramide 10mg 4 times daily for at least 10 days; and
    b. Duration of current metoclopramide treatment must be provided; and
5. A maximum approval duration of 8 weeks total from all sources will apply; and
6. A quantity limit of 9.8mL per 28 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Ozobax® (baclofen 5mg/5mL oral solution), Phexxi® (lactic acid/citric acid/ potassium bitartrate vaginal gel), and Reltone™ (ursodiol capsule) with the following criteria:

Ozobax® (Baclofen 5mg/5mL Oral Solution) Approval Criteria:

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

Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an over-the-counter (OTC) spermicide and all other forms of contraception (e.g., condoms, oral contraceptives) must be provided. Various OTC spermicides containing nonoxynol 9 are covered by SoonerCare without prior authorization.

Reltone™ (Ursodiol Capsule) Approval Criteria:

1. An FDA approved indication for the dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter or the prevention of gallstone formation in obese members experiencing rapid weight loss; and
2. For the indication of dissolution of radiolucent, noncalcified gallstones <20mm in greatest diameter:
    a. Prescriber must confirm member is not a candidate for elective cholecystectomy due to 1 or more of the following:

        i. Increased surgical risk due to systemic disease; or
        ii. Advanced age; or
        iii. Idiosyncratic reaction to general anesthesia; or
        iv. Member refuses surgery; and
    b. Prescriber must confirm the member does not have compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula; and
3. For the indication of prevention of gallstone formation in obese members experiencing rapid weight loss:
    a. Member's baseline body mass index (BMI) and weight must be provided; and
    b. Member's current weight must be provided supporting rapid weight loss compared to baseline; and
4. For both FDA approved indications, a patient-specific, clinically significant reason why the member cannot use other generic formulations of ursodiol must be provided; and
5. Initial approvals for the indication of dissolution of gallstones will be for the duration of 6 months, after which time the prescriber must confirm (via ultrasound imaging) partial or complete dissolution of gallstone(s). Subsequent approvals will be for the duration of 12 months; and
6. Approvals for prevention of gallstone formation in obese members experiencing rapid weight loss will be for 6 months, after which time the member's current weight must be provided to justify continued rapid weight loss and need for preventative treatment; and
7. Treatment duration will be limited to a maximum of 24 months for all diagnoses.

Finally, the College of Pharmacy recommends the addition of Nextstellis® (drospirenone/estetrol tablet) to the current Slynd® (drospirenone tablet) approval criteria, the addition of RediTrex® (methotrexate injection) to the current Otrexup® (methotrexate injection) and Rasuvo® (methotrexate injection) approval criteria along with updates due to net costs and to be consistent with current treatment guidelines, and the addition of Thyquidity™ (levothyroxine oral solution) to the current Tirosint® (levothyroxine capsule) and Tirosint®-SOL (levothyroxine oral solution) approval criteria along with the recommended Drug Utilization Review (DUR) Board update to redefine the dosing for the required 8 week trial of levothyroxine (proposed changes shown in red):

Nextstellis® (Drospirenone/Estetrol Tablet) and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided.

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

1. An FDA approved diagnosis of 1 of the following:
    a. Adults with severe, active rheumatoid arthritis (RA); or
    b. Children with active polyarticular juvenile idiopathic arthritis (pJIA); or
    c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
2. ~~Members with a diagnosis of RA or pJIA must have had an adequate trial of full dose nonsteroidal anti-inflammatory drugs (NSAIDs); and~~
3. A patient-specific, clinically significant reason why the oral tablets ~~or~~ and the generic injectable formulation cannot be used must be provided; and
4. Authorization of Otrexup® will also require a patient-specific, clinically significant reason why the member cannot use Rasuvo® or RediTrex®.

Thyquidity™ (Levothyroxine Oral Solution), Tirosint® (Levothyroxine Capsule), and Tirosint®-SOL (Levothyroxine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
    b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the oral solutions, a reason why the member cannot use the levothyroxine tablet, even when the tablets are crushed, must be provided; and
3. Prescriber must verify member has been compliant with levothyroxine tablets at ~~maximum dose~~ a greatly increased dose for at least 8 weeks; and
4. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite ~~maximum dosing~~ a greatly increased dose and compliance with levothyroxine tablets.

[1] Alkindi® Sprinkle Prescribing Information. Eton Pharmaceuticals, Inc. Available online at: https://www.alkindisprinkle.com/. Last revised 03/2021. Last accessed 06/14/2021.
[2] Eysuvis® Prescribing Information. Kala Pharmaceuticals, Inc. Available online at: https://www.eysuvis.com/pdf/prescribing-information.pdf. Last revised 10/2020. Last accessed 06/14/2021.
[3] Gimoti™ Prescribing Information. Evoke Pharma, Inc. Available online at: https://evokepharma.com/wp-content/uploads/Prescribing-Information-Gimoti-metoclopramide-nasal-spray.pdf. Last revised 01/2021. Last accessed 06/14/2021.
[4] Nextstellis® Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=c5270073-d083-4109-ae4b-156986175e0a&type=display. Last revised 04/2021. Last accessed 06/14/2021.
[5] Ozobax® Prescribing Information. Metacel Pharmaceuticals. Available online at: https://ozobax.com/wp-content/uploads/2020/08/P-010165-V1.pdf. Last revised 05/2020. Last accessed 06/14/2021.
[6] Phexxi® Prescribing Information. Evofem, Inc. Available online at: https://phexxi.com/themes/custom/phexxiDTC/dist/pdf/PhexxiUSPI.pdf. Last revised 05/2020. Last accessed 06/14/2021.
[7] RediTrex® Prescribing Information. Cumberland Pharmaceuticals, Inc. Available online at: https://reditrex.com/wp-content/uploads/2020/10/Reditrex-revised-PI_AUG2020-cleanJW.pdf. Last revised 08/2020. Last accessed 06/14/2021.
[8] Reltone™ Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d1c28b0b-8f3c-4d60-8182-24a4c659d762. Last revised 02/2021. Last accessed 06/14/2021.
[9] Thyquidity™ Prescribing Information. Vertice Specialty Group. Available online at: https://www.thyquidity.com/pdf/Prescribing-Information.pdf. Last revised 12/2020. Last accessed 06/14/2021.

Appendix G

Calendar Year 2020 Annual Review of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib) and 30-Day Notice to Prior Authorize Danyelza® (Naxitamab-gqgk) and Truseltiq™ (Infigratinib)

Oklahoma Health Care Authority
July 2021

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

Neurofibromatosis is a genetic disorder of the nervous system; types of neurofibromatosis include neurofibromatosis type 1 (NF1), neurofibromatosis type 2 (NF2), and schwannomatosis. NF1 is an autosomal dominant condition, although the estimated new mutation rate is high with approximately 42% of affected individuals having de novo mutations. This syndrome predisposes patients to benign or malignant tumors located in the central and peripheral nervous systems. Patients can present with cutaneous features such as skinfold freckling, cutaneous neurofibromas, or café-au-lait macules (CALMs). Plexiform neurofibromas (PN) are benign tumors of the peripheral nerve sheath affecting 40 to 50% of patients with NF1. PN can lead to pain, disfigurement, local compression, and loss of function of nerves, vessels, and airways, and can also transform into malignant peripheral nerve sheath tumors. Surgical resection can be performed; however, it can be challenging or not feasible in certain areas of the body. Selumetinib remains the only U.S. Food and Drug Administration (FDA) approved medical management for this condition.

Tumors that have been associated with NF1, but can arise anywhere in the sympathetic nervous system, are neuroblastomas. The adrenal gland is the most common primary site (40%), followed by abdominal (25%), thoracic (15%), cervical (5%), and pelvic sympathetic ganglia (5%). Neuroblastoma is almost exclusively a disease of children. It is the third most common childhood cancer, after leukemia and brain tumors, and is the most common solid extracranial tumor in children. More than 600 cases are diagnosed in the United States each year, and neuroblastoma accounts for approximately 15% of all pediatric cancer fatalities. The median age at diagnosis is 17.3 months, and 40% of patients are diagnosed before 1 year of age. Neuroblastomas are the most common extracranial solid malignant tumor diagnosed during the first 2 years of life and the most common cancer among infants younger than 12 months, in whom the incidence rate is almost twice that of leukemia (58 versus 37 per 1 million infants). Disialoganglioside (GD2) is a neuroblastoma

cell-specific antigen and is highly expressed in most neuroblastoma cells. Based on the overall response rates (ORR) from 2 clinical studies (45% and 34%) and a duration of response (DOR) of >6 months in the same 2 studies (30% and 23%), naxitamab-gqgk, a monoclonal antibody that targets GD2, was granted accelerated approval by the FDA in 2020 for the treatment of relapsed or refractory high-risk neuroblastoma.

Cholangiocarcinomas originate in the epithelium of the bile duct and can be divided into intrahepatic or extrahepatic cholangiocarcinomas. Complete resection is the only potentially curative treatment for patients with resectable disease, although many patients are not candidates for this due to the presence of advanced disease at diagnosis. Systemic treatment with chemotherapy can be given to patients not eligible for resection or with metastatic disease. There is an increasing role for molecular profiling of cholangiocarcinomas looking at *IDH1/IDH2* mutations, *KRAS* mutation, *BAP1* mutation, human epidermal growth factor receptor 2 (HER2) gene amplification, and fibroblast growth factor (FGF) receptor 2 (FGFR2) fusions. FGFR2 fusions are found in 8 to 14% of intrahepatic cholangiocarcinomas. FGF receptor mutations may be associated with a favorable prognosis, and pemigatinib, an FGF receptor inhibitor, was FDA approved in 2020 for the treatment of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement. Based on the ORR (23%) and a DOR of >6 months (32%), infigratinib, another FGF receptor inhibitor, was granted accelerated approval by the FDA in 2021 for the treatment of previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement.

Gastrointestinal stromal tumors (GIST) are the most common type of soft-tissue sarcoma of the gastrointestinal (GI) tract. Surgery and targeted therapies are the cornerstones of treatment of GIST, as traditional chemotherapy has been largely ineffective. *KIT* and *PDGFRA* are common activating mutations involved in the pathogenesis of GIST. Approximately 80% of all GIST are positive for *KIT* mutation and another 5 to 10% possess *PDGFRA* mutation, making these mutations rational therapeutic targets. Tyrosine kinase inhibitors (TKIs) specific for these mutations have improved 2-year overall survival to approximately 80%. Ripretinib, a TKI that inhibits both wild type and mutant forms of *KIT* and *PDGRA*, was FDA approved for advanced GIST in 2020.

Current Prior Authorization Criteria

Koselugo™ (Selumetinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:

1. Diagnosis of NF1 with symptomatic, inoperable plexiform neurofibromas.

Pemazyre® (Pemigatinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; and
2. Must have failed 1 or more prior therapies; and
3. Disease is positive for a fibroblast growth factor receptor 2 (FGFR2) fusion or other FGFR rearrangement.

Qinlock® (Ripretinib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of advanced GIST; and
2. Previously received ≥3 kinase inhibitors, including imatinib; and
3. As a single agent.

Utilization of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib): Calendar Year 2020

Comparison of Calendar Years

- There was no SoonerCare utilization of Koselugo™, Pemazyre®, and Qinlock® in calendar year 2019 to allow for a comparison to calendar year 2020 utilization. The utilization details for calendar year 2020 can be found at the end of this report.

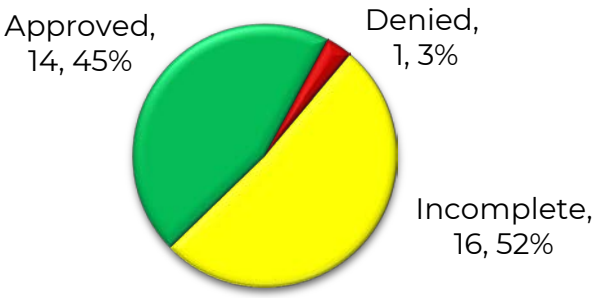
Demographics of Members Utilizing Koselugo™, Pemazyre®, and Qinlock®

- Due to the limited number of members utilizing Koselugo™, Pemazyre®, and Qinlock® during calendar year 2020, detailed demographic information could not be provided.

Prior Authorization of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib)

There were 31 prior authorization requests submitted for Koselugo™, Pemazyre®, and Qinlock® during calendar year 2020. The following chart shows the status of the submitted petitions for calendar year 2020.

Status of Petitions



Market News and Updates[8,9]

Anticipated Patent Expiration(s):

- Koselugo™ (selumetinib): December 2026
- Pemazyre® (pemigatinib): January 2035
- Qinlock® (ripretinib): August 2040

New U.S. FDA Approval(s):

- **November 2020:** The FDA granted accelerated approval to Danyelza® (naxitamab-gqgk) in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) for adult patients and pediatric patients 1 year of age and older with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy.
- **May 2021:** The FDA granted accelerated approval to Truseltiq™ (infigratinib) for adults with previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement.

Product Summaries[3,6]

Danyelza® (Naxitamab-gqgk):

- **Therapeutic Class:** GD2-binding monoclonal antibody
- **Indication(s):** For use in combination with a GM-CSF, for the treatment of adult patients and pediatric patients 1 year of age and older with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease on prior therapy
- **How Supplied:** Sterile, preservative-free 40mg/10mL (4mg/mL) solution in single-dose vials (SDVs)
- **Dose:**
  - 3mg/kg/day (up to 150mg/day), via intravenous (IV) infusion on days 1, 3, and 5 of each treatment cycle (4 weeks) until complete or partial response, followed by 5 additional cycles every 4 weeks; subsequent cycles may be repeated every 8 weeks

- **Cost:** The Wholesale Acquisition Cost (WAC) is $20,368 per SDV, resulting in a cost of $244,416 every 4 weeks for the maximum dose of 150mg/day on cycle days 1, 3, and 5.

Truseltiq™ (Infigratinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Previously treated, unresectable, locally advanced or metastatic cholangiocarcinoma with an FGFR2 fusion or other rearrangement
- **How Supplied:** 25mg and 100mg oral capsules supplied in 21-day blister pack dose presentations as follows:
  - 50mg daily dose: (42) 25mg capsules
  - 75mg daily dose: (63) 25mg capsules
  - 100mg daily dose: (21) 100mg capsules
  - 125mg daily dose: (21) 100mg capsules and (21) 25mg capsules
- **Dose:**
  - 125mg once daily for 21 consecutive days followed by 7 days off therapy in 28-day cycles
  - Dose reduction is recommended for mild or moderate hepatic impairment, mild or moderate renal impairment, and adverse reactions
- **Cost:** The WAC per capsule ranges from $341.27 to $1,023.81, resulting in an approximate cost of $21,500 per 21-day blister pack.

Recommendations

The College of Pharmacy recommends the prior authorization of Danyelza® (naxitamab-gqgk) and Truseltiq™ (infigratinib) with the following criteria:

Danyelza® (Naxitamab-gqgk) Approval Criteria [Neuroblastoma Diagnosis]:

1. Diagnosis of relapsed or refractory high-risk neuroblastoma in adult and pediatric members 1 year of age and older; and
2. Disease in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy (i.e., no progressive disease following most recent therapy); and
3. Must be given in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) according to package labeling (GM-CSF dosed at 250mcg/m^2/day daily starting 5 days prior to Danyelza® therapy and 500mcg/m^2/day daily on days 1 to 5 of Danyelza® therapy); and
4. Prescriber must agree to provide the member appropriate premedication for pain management and neuropathic pain (e.g., oral opioids, gabapentin); and

5. Prescriber must agree to provide the member appropriate premedication for infusion-related reactions and nausea/vomiting including an intravenous (IV) corticosteroid, a histamine 1 (H_1) antagonist, an H_2 antagonist, acetaminophen, and an antiemetic.

Truseltiq™ (Infigratinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable, locally advanced or metastatic cholangiocarcinoma; and
2. Presence of fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement; and
3. Disease has progressed on at least 1 prior systemic therapy; and
4. As a single agent.

Utilization Details of Koselugo™ (Selumetinib), Pemazyre® (Pemigatinib), and Qinlock® (Ripretinib): Calendar Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
KOSELUGO CAP 25MG	24	6	$327,423.84	$13,642.6	4
KOSELUGO CAP 10MG	24	5	$253,269.84	$10,552.91	4.8
TOTAL	**48**	**9***	**$580,693.68**	**$12,097.7**	**5.33**

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

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[1] Ly KI, Blakeley JO. The Diagnosis and Management of Neurofibromatosis Type 1. *Med Clin N Am* 2019; 103:1035-1054.
[2] Shohet JM, Nuchtern JG. Epidemiology, Pathogenesis, and Pathology of Neuroblastoma. *UpToDate*. Available online at: https://www.uptodate.com/contents/epidemiology-pathogenesis-and-pathology-of-neuroblastoma?search=neuroblastoma&topicRef=5187&source=see_link. Last revised 05/2021. Last accessed 06/28/2021.
[3] Danyelza® Prescribing Information. Y-mAbs Therapeutics, Inc. Available online at: https://labeling.ymabs.com/danyelza. Last revised 11/2020. Last accessed 06/11/2021.
[4] National Comprehensive Cancer Network (NCCN). Hepatobiliary Cancers (version 3.2020). Available online at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Last accessed 06/16/2021.
[5] Abou-Alfa GK, Sahai V, Hollebecque A, et al. Pemigatinib for Previously Treated, Locally Advanced or Metastatic Cholangiocarcinoma: A Multicenter, Open-Label, Phase 2 Study. *Lancet Oncol* 2020. doi: 10.1016/S1470-2045(20)30109-1.
[6] Truseltiq™ Prescribing Information. QED Therapeutics, Inc. Available online at: https://www.truseltiq.com/pdfs/prescribing-information.pdf. Last revised 05/2021. Last accessed 06/12/2021.
[7] NCCN. Soft-Tissue Sarcomas (version 2.2019). Available online at: https://www.nccn.org/professionals/physician_gls/default.aspx. Last accessed 06/16/2021.
[8] 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 06/2021. Last accessed 06/11/2021.
[9] U.S. FDA. Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last revised 05/28/2021. Last accessed 06/11/2021.

Appendix H

Calendar Year 2020 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Qdolo™ (Tramadol 5mg/mL Oral Solution)

Oklahoma Health Care Authority
July 2021

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
	morphine/ naltrexone ER cap (Embeda®)	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) **Brand Preferred**	hydrocodone ER tab (Vantrela™ ER)	
	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)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
		oxycodone/ naltrexone ER cap (Troxyca® ER)	
		tapentadol ER tab (Nucynta® ER)	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	oxymorphone IR tab (Opana®)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	tapentadol IR tab (Nucynta®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab
codeine tab		hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	
dihydrocodeine/ ASA/caff cap (Synalgos-DC®)		oxycodone/APAP tab (Primlev™, Xolox®)	
hydrocodone/ APAP tab (Norco®)		oxycodone tab (Oxaydo®)	
hydrocodone/IBU tab (Vicoprofen®, Ibudone®, Reprexain™)		oxycodone tab (Oxecta®)	
hydromorphone tab (Dilaudid®)		oxycodone tab (RoxyBond™)	
morphine IR tab (MSIR®)			***Oncology Only:***
oxycodone/APAP tab (Percocet®)			fentanyl buccal film (Onsolis®)
oxycodone/ASA tab (Percodan®)			fentanyl buccal tab (Fentora®)
oxycodone/IBU tab (Combunox™)			fentanyl nasal spray (Lazanda®)
oxycodone IR cap (Oxy IR®)			fentanyl SL spray (Subsys®)
oxycodone IR tab (Roxicodone®)			fentanyl SL tab (Abstral®)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
tramadol 50mg tab (Ultram®)			***Oncology Only:***
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.
2. Unique Strengths of Hydrocodone/Acetaminophen (APAP) 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.
3. 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 still apply.
4. 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.
5. 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.
6. Tramadol 100mg Tablet Approval Criteria:

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

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

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

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, and hemophilia diagnoses are excluded from the MME limit.

Current Prior Authorization Criteria: MAT Medications

Bunavail® (Buprenorphine/Naloxone Buccal Film), Cassipa® [Buprenorphine/Naloxone Sublingual (SL) Film], Suboxone® (Buprenorphine/Naloxone 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®, Cassipa®, 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. For Cassipa®, the member must have been titrated to a dose of 16mg buprenorphine using another buprenorphine product prior to approval; and
4. 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
5. Member must have an FDA approved diagnosis of opioid abuse/dependence; and

6. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
7. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
8. 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.
    l. Cassipa® 16mg/4mg SL films: A quantity limit of 30 SL films per 30 days will apply.

High-Dose Buprenorphine 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, a 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.

Probuphine® (Buprenorphine Implant) Approval Criteria:

1. An FDA approved indication of maintenance treatment of opioid dependence; and
2. Member must be currently on a maintenance dose of ≤8mg per day of a Subutex® or Suboxone® sublingual tablet or its transmucosal buprenorphine product equivalent; and

3. Member must have been stable on current transmucosal buprenorphine dose (of ≤8mg per day) for 3 months or longer without any need for supplemental dosing or adjustments; and
4. Member must have had no positive urine toxicology results or paid claims for opioids within the last 3 months. Concomitant treatment with opioids (including tramadol) will be denied; and
5. Probuphine® 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
6. Prescribers must verify they have considered the following factors in determining clinical stability and suitability for Probuphine®:
    a. Period free from illicit opioid drug use; and
    b. Stability of living environment; and
    c. Participation in a structured activity/job; and
    d. Consistency in participation in recommended behavioral therapy/peer support program; and
    e. Consistency in compliance with clinic visit requirements; and
    f. Minimal to no desire or need to use illicit opioids; and
    g. Period without episodes of hospitalizations (addiction or mental health issues), emergency room visits, or crisis interventions; and
    h. Social support system; and
7. The prescriber must verify enrollment in the Probuphine® Risk Evaluation and Mitigation Strategy (REMS) program; and
8. Approvals will be for 1 kit (4 implants) per 6 months. Reauthorizations for an additional 6 months may be granted if the member does not have ongoing use of supplemental dosing with transmucosal buprenorphine or opioid analgesics while utilizing Probuphine®.

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 2020

Comparison of Calendar Years: Opioid Analgesics (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	73,867	236,586	$9,029,315.07	$38.17	$1.99	16,114,292	4,539,613
2020	62,671	210,403	$8,088,956.52	$38.45	$1.95	14,513,364	4,154,571
% Change	**-15.20%**	**-11.10%**	**-10.40%**	**0.70%**	**-2.00%**	**-9.90%**	**-8.50%**
Change	**-11,196**	**-26,183**	**-$940,358.55**	**$0.28**	**-$0.04**	**-1,600,928**	**-385,042**

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

- The Opioid Analgesics Product Based Prior Authorization (PBPA) category is heavily influenced by 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 2020 for opioid analgesics: $4,421,269.15[Δ]
- There were no medical claims for the opioid analgesics in calendar year 2020.

Comparison of Calendar Years: MAT Medications (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	3,110	22,326	$6,197,497.38	$277.59	$10.56	1,215,739	586,818
2020	3,546	27,618	$7,082,809.98	$256.46	$9.73	1,404,487	728,146
% Change	**14.00%**	**23.70%**	**14.30%**	**-7.60%**	**-7.90%**	**15.50%**	**24.10%**
Change	**436**	**5,292**	**$885,312.60**	**-$21.13**	**-$0.83**	**188,748**	**141,328**

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

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

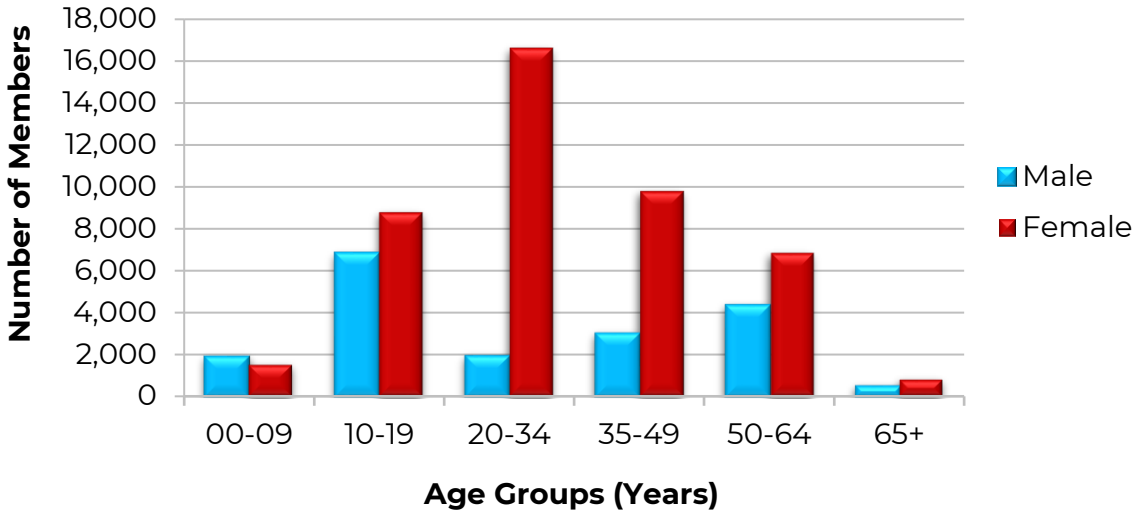
Calendar Year 2020 Utilization: MAT Medications (Medical Claims)

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2020	2	2	$6.50	$3.25	2

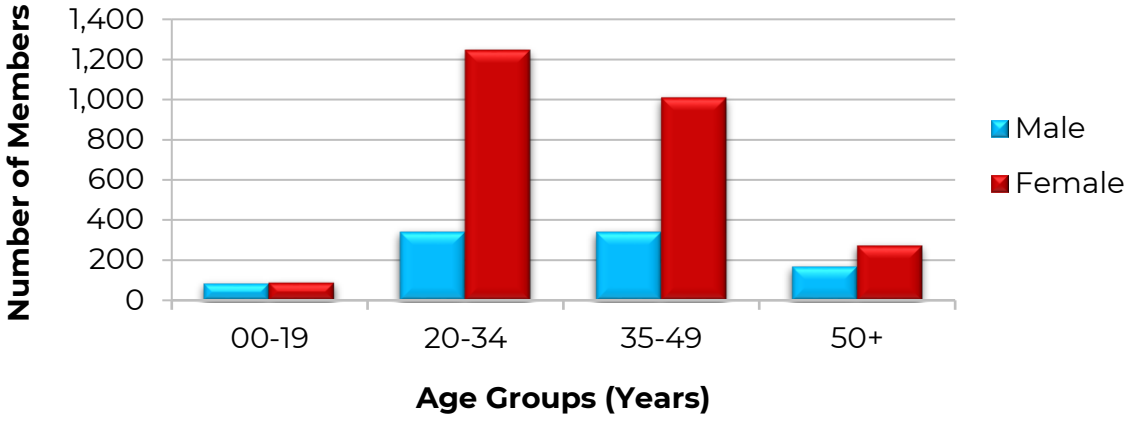
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Cost do not reflect rebated prices or net costs.

- There were no MAT medication medical claims in calendar year 2019 to allow for a comparison to calendar year 2020 utilization. The utilization details for calendar year 2020 can be found at the end of this report.

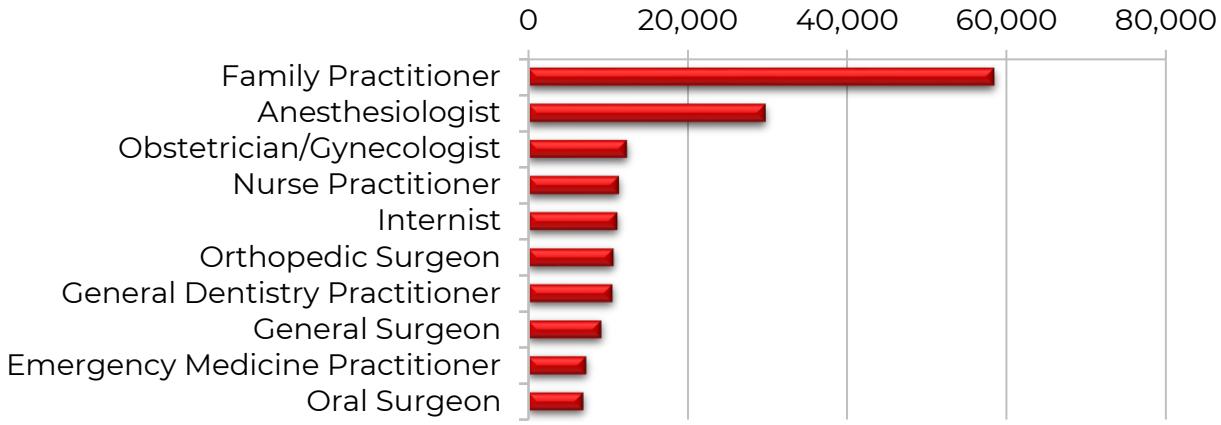
Demographics of Members Utilizing Opioid Analgesics



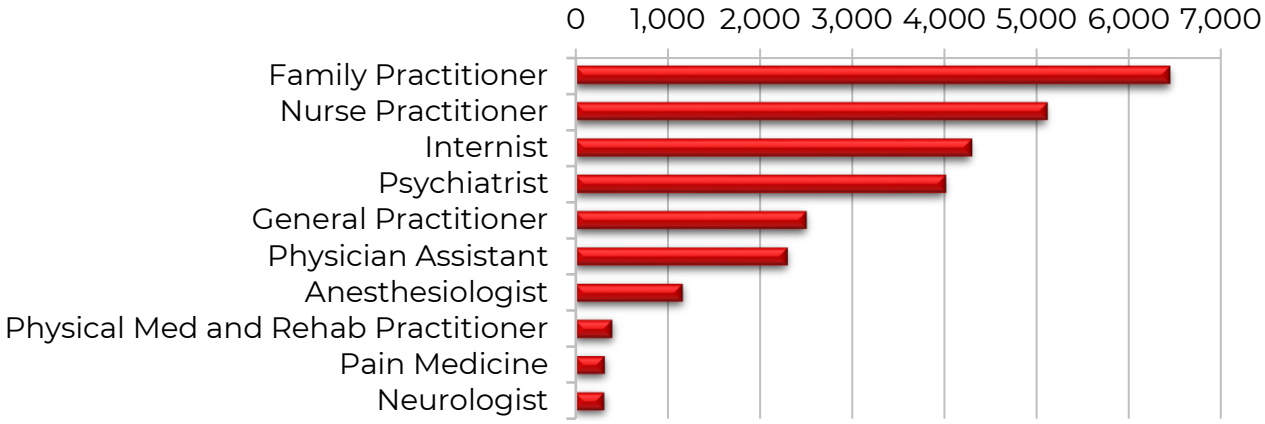
Demographics of Members Utilizing MAT Medications



Top Prescriber Specialties of Opioid Analgesics by Number of Claims



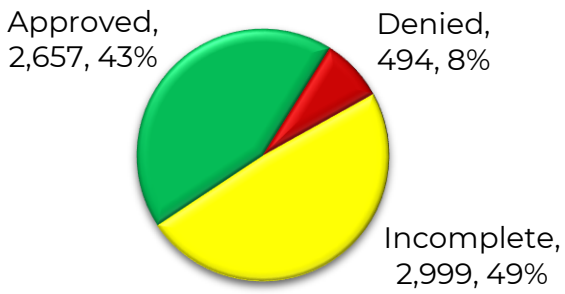
Top Prescriber Specialties of MAT Medications by Number of Claims



Prior Authorization of Opioid Analgesics and MAT Medications

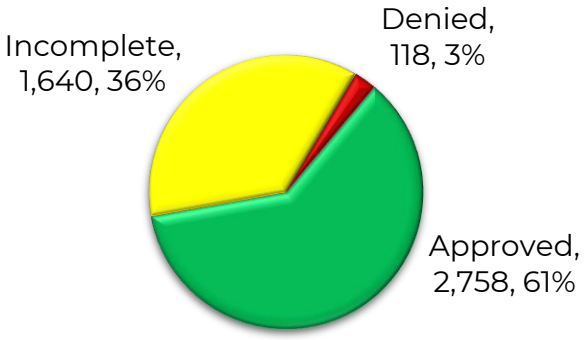
There were 6,150 prior authorization requests submitted for opioid analgesics during calendar year 2020. Computer edits are in place to detect diagnosis, quantity/day supply, and lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2020.

Status of Petitions: Opioid Analgesics



There were 4,516 prior authorizations submitted for MAT medications during calendar year 2020. 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 2020.

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
- Bunavail® (buprenorphine/naloxone buccal film): April 2035
- Sublocade® (buprenorphine ER injection): November 2035
- Xtampza® ER (oxycodone ER capsule): September 2036

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

- **August 2020:** The FDA approved Olinvyk® (oliceridine), an opioid agonist for the management of moderate-to-severe acute pain in adults, where the pain is severe enough to require an intravenous (IV) opioid and for whom alternative treatments are inadequate. Olinvyk® is indicated for short-term IV use in hospitals or other controlled clinical settings, such as during inpatient and outpatient procedures. It is not indicated for at-home use. A total of 1,535 patients with moderate-to-

severe acute pain were treated with Olinvyk® in controlled and open-label trials. The safety and efficacy were established by comparing Olinvyk® to placebo in randomized, controlled studies of patients who had undergone bunion surgery or abdominal surgery. Patients administered Olinvyk® reported decreased pain compared to placebo at the approved doses.

- **September 2020:** The FDA approved Qdolo™ (tramadol hydrochloride 5mg/mL oral solution), an opioid agonist indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

News:

- **July 2020:** In an interrupted time series analysis of 338,476 opioid poisonings among children younger than 20 years of age, state-level opioid-reduction policies were associated with immediate and sustained reductions in rates of opioid poisoning. This analysis used data from the National Poison Data System (NPDS), a database of poisoning information reported to poison control centers across the United States. Individuals younger than 20 years of age who experienced poisoning associated with ≥1 prescription opioid(s) from January 1, 2005 to November 30, 2017 were included. The analysis focused on 3 widespread policy interventions: the prescription drug monitoring program (PDMP), pain clinic legislation, and opioid prescribing guidelines. The implementation of a PDMP was associated with a reduction in the monthly rate of opioid poisoning in children and adolescents [-0.07 per million person-months; 95% confidence interval (CI): -0.09, -0.04] in the post implementation period. This reduction was observed for all age groups except for the 10- to 14-year-old age group (-0.03 per million person-months; 95% CI: -0.05, 0). Pain clinic legislation was associated with an immediate reduction in opioid poisoning (-6.22 per million person-months; 95% CI: -8.98, -3.47), which was statistically significant across all ages except for the 4 years of age or younger group. Analysis of the association of implementation of opioid prescribing guidelines was limited because of insufficient follow-up data, and it did not show an immediate or monthly change in the rate of opioid poisoning.
- **July 2020:** According to results of the Dutch ON-TIME 3 trial, swapping out IV fentanyl in favor of IV APAP in patients with ST-elevation myocardial infarction (STEMI) provides comparable pain relief but with desirably higher blood levels of ticagrelor both immediately after primary percutaneous intervention (PCI) and 1 hour post procedure. The synthetic opioid fentanyl impairs gastrointestinal absorption of oral P2Y12 receptor antagonists such as ticagrelor, whereas APAP does not. ON-TIME 3 was a multicenter, open-label, Phase 4 clinical trial in which

195 STEMI patients with a self-reported pain score of at least 4 on a 0-10 scale received crushed ticagrelor in the ambulance along with either 1,000mg IV APAP or 1-2mcg/kg IV fentanyl. Ticagrelor blood levels were significantly higher in the IV APAP group when measured just prior to primary PCI (151ng/mL vs. 60ng/mL), immediately after PCI (326ng/mL vs. 115ng/mL), and 1 hour post PCI (488ng/mL vs. 372ng/mL). A larger, longer-term trial is needed to determine whether the increased ticagrelor blood levels will translate into a measurable difference in clinical outcomes.

- **July 2020:** The Centers for Disease Control and Prevention (CDC) analyzed 2019 data from the pregnancy risk assessment monitoring system (PRAMS) survey in 32 jurisdictions and maternal and infant health surveys in 2 additional jurisdictions not participating in PRAMS to estimate self-reported prescription opioid pain reliever use during pregnancy, evaluating overall use and by maternal characteristics (i.e., maternal age, race/ethnicity, education, trimester of entry into prenatal care, health insurance at delivery, number of previous live births, cigarette use, depression during pregnancy) among women with a recent live birth. An estimated 6.6% of respondents reported prescription opioid use during pregnancy. Among these women, 21.2% reported misuse (a source other than a health care provider or a reason for use other than pain), 27.1% indicated wanting or needing to cut down or stop using, and 68.1% received counseling from a provider on how prescription opioid use during pregnancy could affect an infant. Among respondents reporting opioid use during pregnancy, most indicated receiving prescription opioids from a health care provider and using for pain reasons; however, answers from 1 in 5 women indicated misuse. Additionally, the prevalence of opioid use was statistically different across the following categories: health insurance at delivery, cigarette smoking during the last 3 months of pregnancy, and depression during pregnancy ($P<0.05$).
- **July 2020:** Despite widespread devastation caused by America's opioid epidemic, an investigation by National Public Radio (NPR) found that doctors and other health care providers still prescribe highly addictive pain medications at rates widely considered unsafe. Public data, including new government studies and reports in medical literature, shows enough opioid prescriptions are being written each year for half of all Americans to have 1 prescription. In 2018, more than 1 in 5 Americans had an opioid prescription filled, according to the CDC. A CDC study released in May 2020 found many physicians prescribe opioid medications even when better treatment options are available, which is inconsistent with federal guidelines. Studies of prescribing practices reviewed by NPR show that physicians regularly prescribe opioids even for relatively mild pain conditions, including lower back

pain, muscle strain, and headaches. A study published in 2020 found that between 1% and 4% of patients who are introduced to opioids develop opioid-use disorder. Studies show other medical professionals may be overprescribing opioids as well. Data released in 2020 by researchers at the University of Pittsburgh showed as many as half of the opioids prescribed by American dentists are unnecessary and inappropriate, and up to 10% of medical opioids distributed in the United States each year are now prescribed by dentists. Data shows prescription rates overall have declined significantly from their peak in 2012; however, medical experts warn that the total volume of opioid medications prescribed to patients nationwide remains perilously high. CDC data shows clinicians in some parts of the United States write opioid prescriptions at rates between 2 and 6 times the national average. Experts interviewed by NPR agree opioids are an important medication when used properly and that pain management is one of the most complicated and frustrating challenges physicians face.

- **August 2020:** The American College of Physicians (ACP) and the American Academy of Family Physicians (AAFP) released clinical guidelines in the *Annals of Internal Medicine* to address acute musculoskeletal pain as a complement to the 2017 ACP guideline for acute low back pain. The new joint ACP/AAFP guidelines are similar to the previous ACP guideline and recommend topical nonsteroidal anti-inflammatory drugs (NSAIDs) as first-line therapy for treating acute, non-low back pain from musculoskeletal injuries in outpatient settings. The guideline also suggests using oral NSAIDs, APAP, specific acupressure, or transcutaneous nerve stimulation to treat acute pain. Use of opioids, including tramadol, is only recommended in cases of severe injury or if first-line therapies aren't tolerated. The guideline recommendations are based on 2 studies: a systematic evidence review of 207 drug and nondrug trials for efficacy and safety and an analysis of predictors of prolonged opioid use after an acute musculoskeletal pain prescription that incorporated 13 observational studies.

Qdolo™ (Tramadol 5mg/mL Oral Solution) Product Summary[9,10]

Indication(s): Qdolo™ (tramadol 5mg/mL oral solution) is a schedule IV narcotic/opioid agonist indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, Qdolo™ should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) have not been tolerated or are not expected to be

tolerated and in whom alternative treatment options have not provided adequate analgesia or are not expected to provide adequate analgesia.

Boxed Warning:

- Risk of medication errors
- Addiction, abuse, and misuse
- Risk Evaluation and Mitigation Strategy (REMS)
- Life-threatening respiratory depression
- Accidental ingestion
- Ultra-rapid metabolism of tramadol and other risk factors for life-threatening respiratory depression in children
- Neonatal opioid withdrawal syndrome
- Interactions with drugs affecting cytochrome P450 isoenzymes
- Risks from concomitant use with benzodiazepines or other central nervous system (CNS) depressants

How Supplied: Tramadol hydrochloride 5mg/mL grape-flavored oral solution supplied in 473mL white, opaque plastic bottles

Dosing and Administration:

- The recommended starting dose is 25mg/day and may be titrated in 25mg increments as separate doses every 3 days up to 100mg/day (25mg 4 times a day).
- Thereafter, the total daily dose may be increased by 50mg as tolerated every 3 days up to 200mg/day (50mg 4 times a day).
- After titration, Qdolo™ 50mg to 100mg can be administered as needed for pain relief every 4 to 6 hours, not to exceed 400mg/day.
- Using the lowest effective dosage for the shortest duration consistent with individual patient treatment goals is recommended.
- Patients should be advised to always use a calibrated oral syringe or other oral dosing device with metric units of measurements (i.e., mL) to correctly measure the prescribed amount of medication.

Contraindication(s):

- Children younger than 12 years of age
- Postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy
- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Hypersensitivity to tramadol, any other component of this product, or opioids

- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days

Efficacy: The efficacy of Qdolo™ was established by performing pharmacokinetic studies compared to IR tramadol tablets and utilizing clinical studies performed with tramadol oral tablets.

Cost: The cost information for Qdolo™ is not yet available.

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 and with changes are listed):

1. Placement of Qdolo™ (tramadol 5mg/mL oral solution) into the Short-Acting Special PA category of the Opioid Analgesics Tier chart
2. Removal of Combunox™ (oxycodone/ibuprofen tablet), Embeda® (morphine/naltrexone ER capsule), Oxecta® (oxycodone tablet), Primlev™ (oxycodone/APAP tablet), Vantrela™ ER (hydrocodone ER tablet), and Xolox® (oxycodone/APAP tablet) due to product discontinuation

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
	~~**morphine/ naltrexone ER cap (Embeda®)**~~	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) **Brand Preferred**	~~**hydrocodone ER tab (Vantrela™ ER)**~~	
	tramadol ER tab (Ultram ER®, Ryzolt®)	hydromorphone ER tab (Exalgo®)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
		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)	oxymorphone IR tab (Opana®)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	tapentadol IR tab (Nucynta®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab
codeine tab		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/APAP tab (Primlev™, Xolox®)**~~	
hydrocodone/ APAP tab (Norco®)		oxycodone tab (Oxaydo®)	
hydrocodone/IBU tab (Vicoprofen®, Ibudone®, Reprexain™)		~~**oxycodone tab (Oxecta®)**~~	
hydromorphone tab (Dilaudid®)		oxycodone tab (RoxyBond™)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
morphine IR tab (MSIR®)			
oxycodone/APAP tab (Percocet®)			***Oncology Only:***
oxycodone/ASA tab (Percodan®)			fentanyl buccal film (Onsolis®)
~~**oxycodone/IBU tab (Combunox™)**~~			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

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Abstral®, Actiq®, Fentora®, Lazanda®, Onsolis®, and Subsys® are approved for oncology-related diagnoses only.
2. Unique Strengths of Hydrocodone/Acetaminophen (APAP) 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.
3. 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.
4. 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.

5. 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.
6. 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.
7. **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.

Additionally, the College of Pharmacy recommends 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 Cassipa® (buprenorphine/naloxone SL film) and Probuphine® (buprenorphine implant) based on product discontinuation

Bunavail® (Buprenorphine/Naloxone Buccal Film), ~~Cassipa®~~ ~~[Buprenorphine/Naloxone Sublingual (SL) Film]~~, Suboxone® (Buprenorphine/Naloxone 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®, ~~Cassipa®;~~ 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. For Cassipa®, the member must have been titrated to a dose of 16mg buprenorphine using another buprenorphine product prior to approval; and~~
4. 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
5. Member must have an FDA approved diagnosis of opioid abuse/ dependence; and
6. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
7. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
8. 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.
~~l. Cassipa® 16mg/4mg SL films: A quantity limit of 30 SL films per 30 days will apply.~~

~~**Probuphine® (Buprenorphine Implant) Approval Criteria:**~~

~~1. An FDA approved indication of maintenance treatment of opioid dependence; and~~
~~2. Member must be currently on a maintenance dose of ≤8mg per day of a Subutex® or Suboxone® sublingual tablet or its transmucosal buprenorphine product equivalent; and~~
~~3. Member must have been stable on current transmucosal buprenorphine dose (of ≤8mg per day) for 3 months or longer without any need for supplemental dosing or adjustments; and~~
~~4. Member must have had no positive urine toxicology results or paid claims for opioids within the last 3 months. Concomitant treatment with opioids (including tramadol) will be denied; and~~
~~5. Probuphine® 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~~
~~6. Prescribers must verify they have considered the following factors in determining clinical stability and suitability for Probuphine®:~~
~~a. Period free from illicit opioid drug use; and~~
~~b. Stability of living environment; and~~
~~c. Participation in a structured activity/job; and~~
~~d. Consistency in participation in recommended behavioral therapy/peer support program; and~~
~~e. Consistency in compliance with clinic visit requirements; and~~
~~f. Minimal to no desire or need to use illicit opioids; and~~
~~g. Period without episodes of hospitalizations (addiction or mental health issues), emergency room visits, or crisis interventions; and~~
~~h. Social support system; and~~
~~7. The prescriber must verify enrollment in the Probuphine® Risk Evaluation and Mitigation Strategy (REMS) program; and~~
~~8. Approvals will be for 1 kit (4 implants) per 6 months. Reauthorizations for an additional 6 months may be granted if the member does not~~

~~have ongoing use of supplemental dosing with transmucosal buprenorphine or opioid analgesics while utilizing Probuphine®.~~

Utilization Details of Opioid Analgesics: Calendar Year 2020

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	41,101	6,422	$664,730.95	$16.17	6.4
HYDROCOD/APAP TAB 7.5-325MG	29,190	13,187	$429,707.56	$14.72	2.21
HYDROCOD/APAP TAB 5-325MG	28,350	19,924	$351,281.19	$12.39	1.42
HYDROCOD/APAP SOL 7.5-325MG	4,119	3,757	$95,839.23	$23.27	1.1
HYDROCOD/IBU TAB 7.5-200MG	356	85	$8,990.07	$25.25	4.19
HYDROCOD/IBU TAB 10-200MG	56	11	$10,781.93	$192.53	5.09
LORCET HD TAB 10-325MG	21	16	$355.27	$16.92	1.31
LORCET TAB 5-325MG	5	5	$73.53	$14.71	1
HYDROCOD/IBU TAB 5-200MG	4	3	$429.86	$107.47	1.33
LORCET PLUS TAB 7.5-325	3	3	$46.40	$15.47	1
SUBTOTAL	**103,205**	**43,413**	**$1,562,235.99**	**$15.14**	**2.38**
IMMEDIATE-RELEASE OXYCODONE PRODUCTS					
OXYCOD/APAP TAB 10-325MG	15,839	2,750	$430,425.05	$27.18	5.76
OXYCOD/APAP TAB 5-325MG	11,631	8,624	$146,360.47	$12.58	1.35
OXYCOD/APAP TAB 7.5-325MG	7,400	2,934	$144,675.54	$19.55	2.52
OXYCODONE TAB 15MG	5,849	849	$121,111.88	$20.71	6.89
OXYCODONE TAB 10MG	4,594	942	$84,667.36	$18.43	4.88
OXYCODONE TAB 5MG	3,166	2,072	$40,639.69	$12.84	1.53
OXYCODONE TAB 20MG	1,638	260	$46,320.55	$28.28	6.3
OXYCODONE SOL 5MG/5ML	1,011	931	$18,285.49	$18.09	1.09
OXYCODONE TAB 30MG	641	115	$20,571.66	$32.09	5.57
ENDOCET TAB 10-325MG	43	9	$1,261.84	$29.35	4.78
OXYCODONE CAP 5MG	50	49	$1,455.13	$29.10	1.02
OXYCOD/APAP TAB 2.5-325MG	18	6	$2,161.43	$120.08	3
OXYCODONE CONC 100MG/5ML	11	5	$1,795.85	$163.26	2.2
ENDOCET TAB 7.5-325MG	4	1	$64.00	$16.00	4
ENDOCET TAB 5-325MG	1	1	$9.30	$9.30	1
SUBTOTAL	**51,896**	**19,548**	**$1,059,805.24**	**$20.42**	**2.65**
IMMEDIATE-RELEASE TRAMADOL PRODUCTS					
TRAMADOL TAB 50MG	22,332	7,561	$241,953.67	$10.83	2.95
TRAMADOL/APAP TAB 37.5-325MG	196	145	$2,918.52	$14.89	1.35
SUBTOTAL	**22,528**	**7,706**	**$244,872.19**	**$10.87**	**2.92**
CODEINE PRODUCTS					
APAP/CODEINE TAB 300-30MG	7,617	4,720	$93,051.39	$12.22	1.61
APAP/CODEINE TAB 300-60MG	4,651	1,204	$105,251.29	$22.63	3.86

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUT/APAP/CAF/COD 50/325/40/30MG	248	87	$12,352.61	$49.81	2.85
ASCOMP/COD CAP 30MG	87	23	$6,434.96	$73.97	3.78
APAP/CODEINE TAB 300-15MG	47	47	$532.99	$11.34	1
BUT/ASA/CAF/COD 50/325/40/30MG	72	26	$4,217.34	$58.57	2.77
APAP/CODEINE SOL 120-12MG/5ML	27	7	$587.12	$21.75	3.86
CODEINE SULF TAB 30MG	22	3	$686.00	$31.18	7.33
APAP/CAF/DIHYDROCO 320.5/30/16MG	6	1	$850.69	$141.78	6
CODEINE SULF TAB 60MG	1	1	$80.27	$80.27	1
SUBTOTAL	**12,778**	**6,119**	**$224,044.66**	**$17.53**	**2.09**
IMMEDIATE-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG	1,228	257	$41,450.78	$33.75	4.78
MORPHINE SULF TAB 30MG	343	56	$17,027.84	$49.64	6.13
MORPHINE SULF SOL 100MG/5ML	97	57	$3,133.89	$32.31	1.7
MORPHINE SULF SOL 10MG/5ML	94	22	$1,666.30	$17.73	4.27
MORPHINE SULF SOL 20MG/5ML	6	5	$103.62	$17.27	1.2
MORPHINE SULF INJ 4MG/ML	2	1	$213.20	$106.60	2
MORPHINE SULF INJ 8MG/ML	2	1	$542.05	$271.03	2
MORPHINE SULF SOL 10MG/0.5ML	1	1	$510.66	$510.66	1
MORPHINE SULF SOL 20MG/ML	1	1	$22.59	$22.59	1
SUBTOTAL	**1,774**	**401**	**$64,670.93**	**$36.45**	**4.42**
IMMEDIATE-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 4MG	656	126	$11,763.37	$17.93	5.21
HYDROMORPHONE TAB 2MG	349	199	$4,962.51	$14.22	1.75
HYDROMORPHONE TAB 8MG	109	24	$3,918.93	$35.95	4.54
HYDROMORPHONE LIQ 1MG/ML	20	3	$8,445.32	$422.27	6.67
SUBTOTAL	**1,134**	**352**	**$29,090.13**	**$25.65**	**3.22**
PENTAZOCINE PRODUCTS					
PENTAZ/NALOX TAB 50-0.5MG	357	77	$62,664.95	$175.53	4.64
SUBTOTAL	**357**	**77**	**$62,664.95**	**$175.53**	**4.64**
MEPERIDINE PRODUCTS					
MEPERIDINE SOL 50MG/5ML	148	120	$1,450.44	$9.80	1.23
MEPERIDINE TAB 50MG	6	6	$129.90	$21.65	1
MEPERIDINE INJ 100MG/ML	2	1	$12.00	$6.00	2
SUBTOTAL	**156**	**127**	**$1,592.34**	**$10.21**	**1.23**
IMMEDIATE-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG	51	4	$2,791.78	$54.74	12.75
OXYMORPHONE TAB 5MG	20	3	$870.92	$43.55	6.67
SUBTOTAL	**71**	**7**	**$3,662.70**	**$51.59**	**10.14**
IMMEDIATE-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA TAB 50MG	34	7	$19,717.08	$579.91	4.86
SUBTOTAL	**34**	**7**	**$19,717.08**	**$579.91**	**4.86**
SHORT-ACTING SUBTOTAL	**193,933**	**77,757**	**$3,272,356.21**	**$16.87**	**2.49**
LONG-ACTING OPIOID ANALGESICS					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
EXTENDED-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG ER	2,696	421	$56,939.14	$21.12	6.4
MORPHINE SULF TAB 30MG ER	1,779	272	$53,617.49	$30.14	6.54
MORPHINE SULF TAB 60MG ER	281	59	$15,189.53	$54.06	4.76
MORPHINE SULF CAP 30MG ER	44	6	$6,448.57	$146.56	7.33
MORPHINE SULF TAB 100MG ER	32	7	$2,145.87	$67.06	4.57
MORPHINE SULF CAP 50MG ER	22	2	$4,713.95	$214.27	11
MORPHINE SULF CAP 10MG ER	17	6	$1,715.19	$100.89	2.83
MORPHABOND TAB 15MG ER	7	1	$2,314.91	$330.70	7
MORPHINE SULF CAP 20MG ER	5	3	$572.23	$114.45	1.67
MORPHINE SULF CAP 60MG ER	4	1	$1,116.96	$279.24	4
MORPHABOND TAB 30MG ER	3	1	$145.29	$48.43	3
EMBEDA CAP 30-1.2MG	2	2	$1,173.08	$586.54	1
MORPHINE SULF CAP 100MG ER	1	1	$386.34	$386.34	1
MORPHINE SULF CAP 40MG ER	1	1	$431.95	$431.95	1
SUBTOTAL	**4,894**	**783**	**$146,910.50**	**$30.02**	**6.25**
EXTENDED-RELEASE OXYCODONE PRODUCTS					
OXYCONTIN TAB 10MG ER	1,679	281	$360,173.51	$214.52	5.98
OXYCONTIN TAB 20MG ER	1,012	181	$415,747.42	$410.82	5.59
OXYCONTIN TAB 15MG ER	788	137	$262,847.94	$333.56	5.75
OXYCONTIN TAB 30MG ER	491	77	$305,643.17	$622.49	6.38
OXYCONTIN TAB 40MG ER	245	36	$190,010.11	$775.55	6.81
OXYCONTIN TAB 60MG ER	177	31	$208,139.64	$1,175.93	5.71
OXYCONTIN TAB 80MG ER	104	18	$168,019.84	$1,615.58	5.78
XTAMPZA ER CAP 18MG	49	7	$23,062.01	$470.65	7
XTAMPZA ER CAP 13.5MG	35	10	$11,239.14	$321.12	3.5
XTAMPZA ER CAP 9MG	32	8	$8,668.96	$270.91	4
XTAMPZA ER CAP 36MG	22	3	$9,568.01	$434.91	7.33
XTAMPZA ER CAP 27MG	14	3	$10,356.73	$739.77	4.67
SUBTOTAL	**4,648**	**792**	**$1,973,476.48**	**$424.59**	**5.87**
BUPRENORPHINE PAIN PRODUCTS					
BUTRANS DIS 10MCG/HR	829	371	$375,763.42	$453.27	2.23
BUTRANS DIS 20MCG/HR	738	156	$579,974.95	$785.87	4.73
BUTRANS DIS 15MCG/HR	711	208	$461,222.20	$648.70	3.42
BUTRANS DIS 5MCG/HR	234	119	$70,701.13	$302.14	1.97
BELBUCA MIS 300MCG	209	63	$111,113.33	$531.64	3.32
BELBUCA MIS 600MCG	190	41	$145,330.63	$764.90	4.63
BELBUCA MIS 450MCG	142	39	$101,761.70	$716.63	3.64
BELBUCA MIS 900MCG	119	15	$99,093.21	$832.72	7.93
BELBUCA MIS 750MCG	115	22	$92,883.36	$807.68	5.23
BELBUCA MIS 150MCG	109	42	$36,639.86	$336.15	2.6
BUPRENORPHINE DIS 10MCG/HR	85	41	$19,865.55	$233.71	2.07
BUPRENORPHINE DIS 20MCG/HR	76	35	$30,880.53	$406.32	2.17

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUTRANS DIS 7.5MCG/HR	63	32	$26,522.86	$421.00	1.97
BUPRENORPHINE DIS 15MCG/HR	62	35	$21,068.70	$339.82	1.77
BELBUCA MIS 75MCG	32	20	$9,830.40	$307.20	1.6
BUPRENORPHINE DIS 5MCG/HR	12	9	$1,969.86	$164.16	1.33
BUPRENORPHINE DIS 7.5MCG/HR	1	1	$202.97	$202.97	1
SUBTOTAL	**3,727**	**1,249**	**$2,184,824.66**	**$586.22**	**2.98**
EXTENDED-RELEASE FENTANYL PRODUCTS					
FENTANYL DIS 25MCG/HR	595	133	$24,078.65	$40.47	4.47
FENTANYL DIS 12MCG/HR	379	86	$31,556.10	$83.26	4.41
FENTANYL DIS 50MCG/HR	239	70	$14,742.16	$61.68	3.41
FENTANYL DIS 75MCG/HR	175	44	$15,655.74	$89.46	3.98
FENTANYL DIS 100MCG/HR	143	36	$14,443.81	$101.01	3.97
FENTANYL DIS 37.5MCG/HR	78	14	$32,763.39	$420.04	5.57
SUBTOTAL	**1,609**	**383**	**$133,239.85**	**$82.81**	**4.2**
EXTENDED-RELEASE HYDROCODONE PRODUCTS					
HYSINGLA ER TAB 40MG	230	29	$128,080.42	$556.87	7.93
HYSINGLA ER TAB 20MG	226	34	$63,475.62	$280.87	6.65
HYSINGLA ER TAB 30MG	156	27	$61,963.60	$397.20	5.78
HYSINGLA ER TAB 60MG	72	9	$56,207.84	$780.66	8
HYSINGLA ER TAB 80MG	13	1	$13,679.75	$1,052.29	13
HYDROCODONE CAP 40MG ER	4	1	$1,620.09	$405.02	4
HYDROCODONE CAP 20MG ER	3	1	$1,421.40	$473.80	3
HYSINGLA ER TAB 100MG	1	1	$1,308.59	$1,308.59	1
SUBTOTAL	**705**	**103**	**$327,757.31**	**$464.90**	**6.84**
EXTENDED-RELEASE TRAMADOL PRODUCTS					
TRAMADOL TAB 100MG ER	215	41	$9,345.55	$43.47	5.24
TRAMADOL TAB 200MG ER	178	45	$11,447.46	$64.31	3.96
TRAMADOL TAB 300MG ER	107	27	$10,009.80	$93.55	3.96
TRAMADOL CAP 200MG ER	1	1	$312.29	$312.29	1
SUBTOTAL	**501**	**114**	**$31,115.10**	**$62.11**	**4.39**
METHADONE PRODUCTS					
METHADONE TAB 10MG	232	28	$4,518.91	$19.48	8.29
METHADONE TAB 5MG	82	14	$1,491.02	$18.18	5.86
METHADONE SOL 5MG/5ML	40	21	$579.41	$14.49	1.9
METHADONE SOL 10MG/5ML	2	1	$15.13	$7.57	2
SUBTOTAL	**356**	**64**	**$6,604.47**	**$18.55**	**5.56**
EXTENDED-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 20MG ER	13	1	$6,010.33	$462.33	13
OXYMORPHONE TAB 10MG ER	12	1	$3,036.83	$253.07	12
SUBTOTAL	**25**	**2**	**$9,047.16**	**$361.89**	**12.5**
EXTENDED-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 32MG ER	2	1	$2,457.62	$1,228.81	2
HYDROMORPHONE TAB 16MG ER	2	1	$697.84	$348.92	2

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
HYDROMORPHONE TAB 8MG ER	1	1	$469.32	$469.32	1
SUBTOTAL	**5**	**3**	**$3,624.78**	**$724.96**	**1.67**
LONG-ACTING SUBTOTAL	**16,470**	**3,493**	**$4,816,600.31**	**$292.45**	**4.72**
OPIOID TOTAL	**210,403**	**62,671***	**$8,088,956.52**	**$38.45**	**3.36**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
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 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUPRENORPHINE MAT PRODUCTS					
SUBOXONE MIS 8-2MG	11,387	1,421	$5,494,097.03	$482.49	8.01
BUPREN/NALOX SUB 8-2MG	6,743	1,005	$521,984.74	$77.41	6.71
BUPRENORPHINE SUB 8MG	3,730	562	$233,918.04	$62.71	6.64
BUPREN/NALOX SUB 2-0.5MG	359	92	$21,947.46	$61.13	3.9
BUPRENORPHINE SUB 2MG	316	86	$12,018.39	$38.03	3.67
SUBOXONE MIS 4-1MG	272	65	$117,705.64	$432.74	4.18
SUBOXONE MIS 2-0.5MG	246	59	$50,709.40	$206.14	4.17
ZUBSOLV SUB 5.7-1.4MG	120	13	$54,642.60	$455.36	9.23
SUBOXONE MIS 12-3MG	99	17	$77,786.12	$785.72	5.82
SUBLOCADE INJ 100MG/0.5ML	48	10	$80,179.68	$1,670.41	4.8
SUBLOCADE INJ 300MG/1.5ML	31	16	$51,782.71	$1,670.41	1.94
ZUBSOLV SUB 8.6-2.1MG	26	4	$26,859.50	$1,033.06	6.5
BUPREN/NALOX MIS 8-2MG	25	9	$5,551.88	$222.08	2.78
ZUBSOLV SUB 2.9-0.71MG	11	2	$3,259.07	$296.28	5.5
ZUBSOLV SUB 11.4-2.9MG	11	2	$17,399.46	$1,581.77	5.5
BUNAVAIL MIS 6.3-1MG	1	1	$1,006.44	$1,006.44	1
SUBTOTAL	**23,425**	**3,364**	**$6,770,848.16**	**$289.04**	**6.96**
NALTREXONE PRODUCTS					
NALTREXONE TAB 50MG	4,079	821	$161,346.43	$39.56	4.97
VIVITROL INJ 380MG	114	36	$150,615.39	$1,321.19	3.17
SUBTOTAL	**4,193**	**857**	**$311,961.82**	**$74.40**	**4.89**
MAT TOTAL	**27,618**	**3,546***	**$7,082,809.98**	**$256.46**	**7.79**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
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	2	2	$6.50	1	$3.25
TOTAL	**2**	**2**	**$6.50**	**1**	**$3.25**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 06/2021. Last accessed 06/15/2021.
[2] Trevena, Inc. FDA Approves New Opioid for Intravenous Use in Hospitals, Other Controlled Clinical Settings. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-new-opioid-for-intravenous-use-in-hospitals-other-controlled-clinical-settings-301108621.html. Issued 08/07/2020. Last accessed 06/17/2021.
[3] Athena Bioscience. U.S. FDA Approves Athena Bioscience's New Drug Application (NDA) for QDOLO™ (Tramadol Hydrochloride) Oral Solution. *BioSpace*. Available online at: https://www.biospace.com/article/releases/u-s-fda-approves-athena-bioscience-s-new-drug-application-nda-for-qdolo-tramadol-hydrochloride-oral-solution/. Issued 09/08/2020. Last accessed 06/17/2021.
[4] Toce MS, Michelson K, Hudgins J. Association of State-Level Opioid-Reduction Policies with Pediatric Opioid Poisoning. *JAMA Pediatr* 2020; 174(10):961-968.
[5] Jancin B. Acetaminophen Beats Fentanyl in STEMI. *Medscape*. Available online at: https://www.medscape.com/viewarticle/933944. Issued 07/15/2020. Last accessed 06/17/2021.
[6] Ko JY, D'Angelo DV, Haight SC, et al. Vital Signs: Prescription Opioid Pain Reliever Use During Pregnancy - 34 U.S. Jurisdictions, 2019. *MMWR Morb Mortal Wkly Rep* 2020; 69:897–903. doi: http://dx.doi.org/10.15585/mmwr.mm6928a1
[7] Mann B. Doctors and Dentists Still Flooding U.S. with Opioid Prescriptions. *NPR*. Available online at: https://www.npr.org/2020/07/17/887590699/doctors-and-dentists-still-flooding-u-s-with-opioid-prescriptions. Issued 07/17/2020. Last accessed 06/17/2021.
[8] George J. Treating Acute Musculoskeletal Pain: New Guidance. *MedPage Today*. Available online at: https://www.medpagetoday.com/painmanagement/painmanagement/88118. Issued 08/17/2020. Last accessed 06/17/2021.
[9] Qdolo™ Prescribing Information. Athena Bioscience, LLC. Available online at: https://qdolo.com/wp-content/uploads/2020/10/QDOLO-Prescribing-Information.pdf. Last revised 09/2020. Last accessed 06/15/2021.
[10] Qdolo™ (Tramadol) – New drug approval. *OptumRx*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_qdolo_2020-0904.pdf. Issued 2020. Last accessed 06/17/2021.

Appendix I

Calendar Year 2020 Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Impeklo® (Clobetasol Propionate 0.05% Lotion)

Oklahoma Health Care Authority
July 2021

Current Prior Authorization Criteria

Tier-1 products are covered with no prior authorization necessary.

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, a patient-specific, clinically significant reason for requesting a Tier-2 medication in the same potency instead of trying a higher potency medication must be provided; and
3. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage formulation of that medication in Tier-2 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other 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, a patient-specific, clinically significant reason for requesting a Tier-3 medication in the same potency instead of trying a higher potency medication must be provided; 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 formulation of that medication in Tier-3 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

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.

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% (**Temovate®**)	**C,L,O, So**	augmented betamethasone dipropionate 0.05% (**Diprolene®**)	**L,O**	clobetasol propionate 0.05% (**Olux®, Olux-E®, Tovet®**)	**F**
fluocinonide 0.05%	**C,O,So**	betamethasone dipropionate 0.05% (**Diprosone®**)	**C,O**	desoximetasone 0.25% (**Topicort®**)	**C,O,Spr**
halobetasol propionate 0.05% (**Ultravate®**)	**C**	clobetasol propionate 0.05% (**Clobex®**)	**L**	diflorasone diacetate 0.05% (**Apexicon®**)	**C,O**
		clobetasol propionate 0.05% (**Temovate®**)	**G**	diflorasone diacetate 0.05% (**Apexicon E®**)	**C**
		desoximetasone 0.05% (**Topicort®**)	**G**	halobetasol propionate 0.01% (**Bryhali®**)	**L**
		fluocinonide 0.05%	**G**	halobetasol propionate 0.05% (**Lexette®**)	**F**
		fluocinonide 0.1% (**Vanos®**)	**C**		
		flurandrenolide tape 0.05% (**Cordran®**)	**Tape**		
		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 dipropionate/ calcipotriene 0.064%/0.005% (**Enstilar® Foam**)	**F**		
fluticasone propionate 0.05% (**Cutivate®**)	**C,O**	betamethasone valerate 0.12% (**Luxiq®**)	**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,L,O**		
		fluticasone propionate 0.05% (**Cutivate®**)	**L**		
		hydrocortisone butyrate 0.1%	**C,L,O, So**		
		hydrocortisone probutate 0.1% (**Pandel®**)	**C**		
		prednicarbate 0.1% (**Dermatop®**)	**C,O**		
		triamcinolone acetonide 0.147mg/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**				

C = cream; F = foam; G = gel; L = lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension
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).

Utilization of Topical Corticosteroids: Calendar Year 2020

Comparison of Calendar Years

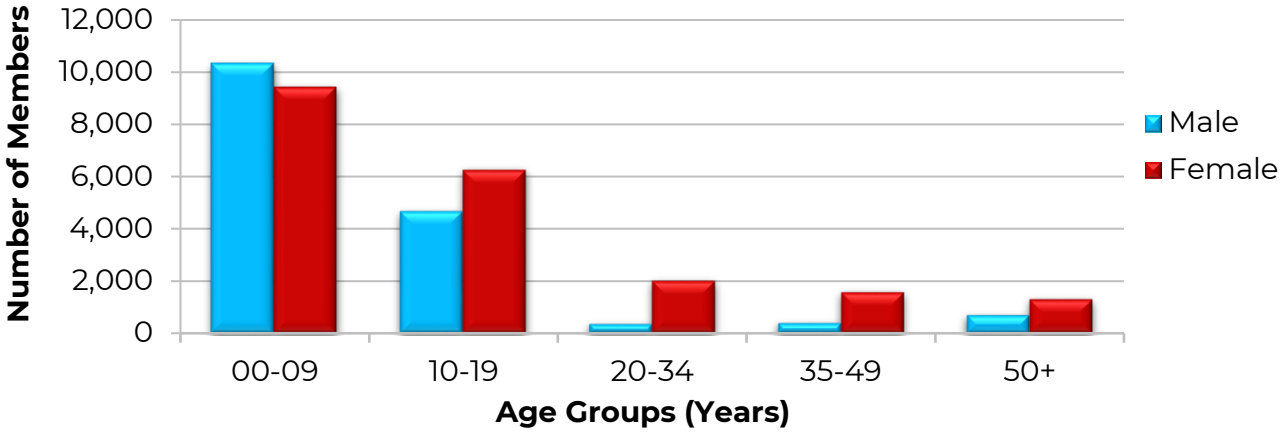
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	41,436	62,946	$1,335,376.65	$21.21	$1.27	4,102,864	1,051,055
2020	37,016	57,618	$1,108,202.32	$19.23	$1.10	3,974,887	1,006,562
% Change	**-10.70%**	**-8.50%**	**-17.00%**	**-9.30%**	**-13.40%**	**-3.10%**	**-4.20%**
Change	**-4,420**	**-5,328**	**-$227,174.33**	**-$1.98**	**-$0.17**	**-127,977**	**-44,493**

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

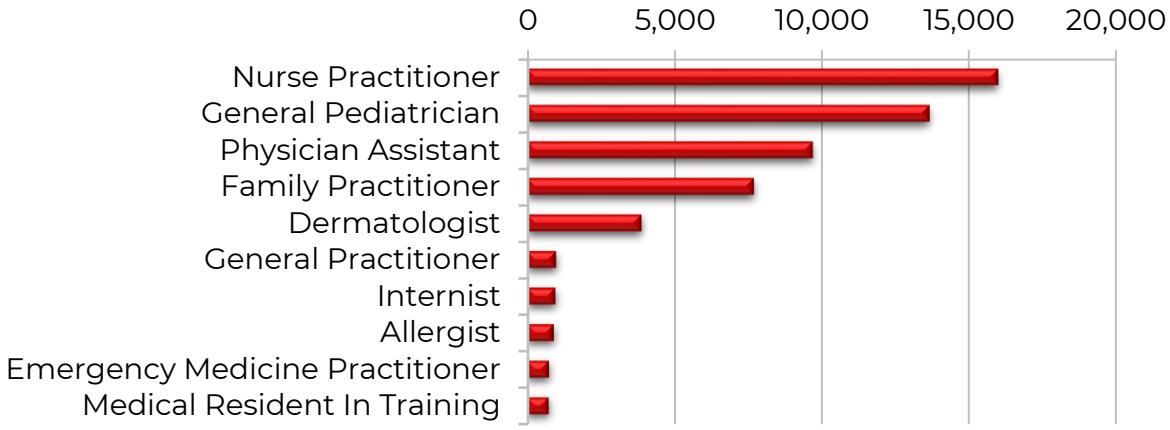
- Please note this category is heavily influenced by rebates and costs do not reflect rebated prices or net costs.
- Utilization of Eucrisa® may account for decreased topical corticosteroid utilization. Eucrisa® (crisaborole ointment) is a steroid-free, phosphodiesterase 4 inhibitor topical ointment indicated for the treatment of mild-to-moderate atopic dermatitis in patients 3 months of age and older. Eucrisa® requires prior authorization; however, claims will pay at the point of sale without prior authorization if the member

has a paid claim for Eucrisa® in the last 60 days, a paid claim for a Tier-1 topical corticosteroid in the previous 180 days for at least a 14-day supply, or if the prescription is written by a dermatologist.

Demographics of Members Utilizing Topical Corticosteroids



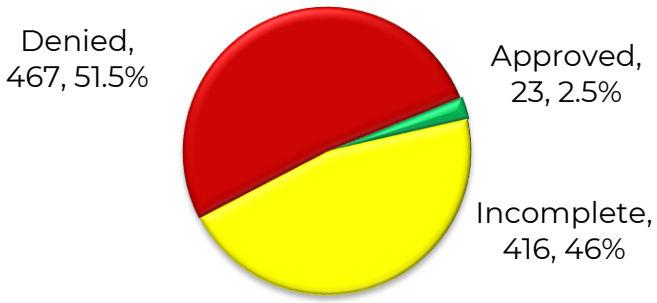
Top Prescriber Specialties of Topical Corticosteroids by Number of Claims



Prior Authorization of Topical Corticosteroids

There were 906 prior authorization requests submitted for topical corticosteroids during calendar year 2020. The following chart shows the status of the submitted petitions for calendar year 2020.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- 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
- 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

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

- **May 2020:** The FDA approved Impeklo® (clobetasol propionate 0.05% lotion) for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults 18 years of age and older. Impeklo® is the first and only metered-dose clobetasol lotion available. Clobetasol is generically available in various other formulations, including as a lotion (generic Clobex® lotion), cream, foam, gel, spray, ointment, shampoo, and solution.

Impeklo® (Clobetasol Propionate 0.05% Lotion) Product Summary[3]

- **Indication(s):** For relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older

- **Limitation(s) of Use:**
  - Impeklo® should not be used in the treatment of rosacea or perioral dermatitis.
  - Impeklo® should not be used in patients younger than 18 years of age due to numerically high rates of hypothalamic-pituitary-adrenal (HPA) axis suppression.
- **How Supplied:** Impeklo® is available as a 0.05% weight per weight (w/w) lotion in a 68g bottle with a metered-dose pump having an integral pump locking feature. Each pump actuation delivers on average 0.15mg of clobetasol propionate, USP in 0.30g of lotion.
- **Dosing and Administration:**
  - Impeklo® lotion is for topical use only and is not for ophthalmic, oral, or intravaginal use.
  - Impeklo® lotion should be applied to the affected skin areas twice daily and rubbed in gently and completely. Patients should avoid contact with eyes and wash hands after each application.
  - The total dosage should not exceed 50g per week because of the potential for the drug to suppress the HPA axis.
  - The maximum dose is 10 pump actuations per application twice daily or 20 pump actuations per day for 7 days; the maximum recommended dose should not be exceeded.
  - Impeklo® lotion contains a topical corticosteroid; therefore, treatment should be limited to 2 consecutive weeks for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and up to 2 additional weeks in localized lesions (<10% body surface area) of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment. Impeklo® should be discontinued when control is achieved.
  - Impeklo® should not be used with occlusive dressings unless directed by a physician.
- **Adverse Reactions:** The most common adverse reactions (incidence >1%) were skin atrophy, telangiectasia, discomfort of skin, and dry skin.
- **Cost Comparison:**

Medication	Cost Per Unit	Cost Per Package
Impeklo® (clobetasol propionate 0.05% lotion) with metered-dose pump	**$7.35/g**	**$499.80/68g**
clobetasol propionate 0.05% lotion (generic)	$0.58/mL	$68.44/118mL

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

Recommendations

The College of Pharmacy recommends adding Impeklo® (clobetasol propionate 0.05% lotion) to Tier-3 of the Ultra-High to High Potency Topical Corticosteroids Product Based Prior Authorization (PBPA) category; current Tier-3 criteria will apply (changes noted in red below):

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% (**Temovate®**)	**C,L,O, So**	augmented betamethasone dipropionate 0.05% (**Diprolene®**)	**L,O**	clobetasol propionate 0.05% (**Olux®, Olux-E®, Tovet®**)	**F**
fluocinonide 0.05%	**C,O,So**	betamethasone dipropionate 0.05% (**Diprosone®**)	**C,O**	**clobetasol propionate 0.05% (Impeklo®)**	**L**
halobetasol propionate 0.05% (**Ultravate®**)	**C**	clobetasol propionate 0.05% (**Clobex®**)	**L**	desoximetasone 0.25% (**Topicort®**)	**C,O,Spr**
		clobetasol propionate 0.05% (**Temovate®**)	**G**	diflorasone diacetate 0.05% (**Apexicon®**)	**C,O**
		desoximetasone 0.05% (**Topicort®**)	**G**	diflorasone diacetate 0.05% (**Apexicon E®**)	**C**
		fluocinonide 0.05%	**G**	halobetasol propionate 0.01% (**Bryhali®**)	**L**
		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**		

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 dipropionate/ calcipotriene 0.064%/0.005% (**Enstilar® Foam**)	**F**		
fluticasone propionate 0.05% (**Cutivate®**)	**C,O**	betamethasone valerate 0.12% (**Luxiq®**)	**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,L,O**		
		fluticasone propionate 0.05% (**Cutivate®**)	**L**		
		hydrocortisone butyrate 0.1%	**C,L,O, So**		
		hydrocortisone probutate 0.1% (**Pandel®**)	**C**		
		prednicarbate 0.1% (**Dermatop®**)	**C,O**		
		triamcinolone acetonide 0.147mg/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**				

C = cream; F = foam; G = gel; L = lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

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).

Utilization Details of Topical Corticosteroids: Calendar Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 MEDICATIONS						
LOW POTENCY PRODUCTS						
HYDROCORTISONE CR 2.5%	4,389	3,375	$58,396.68	$0.92	$13.31	5.27%
TRIAMCINOLONE CR 0.025%	4,088	3,183	$54,229.85	$0.86	$13.27	4.89%
HYDROCORTISONE OINT 2.5%	2,729	1,872	$43,425.48	$1.16	$15.91	3.92%
HYDROCORTISONE CR 1%	900	744	$10,681.99	$0.97	$11.87	0.96%
HYDROCORTISONE OINT 1%	476	410	$6,288.27	$1.17	$13.21	0.57%
TRIAMCINOLONE LOT 0.1%	344	255	$10,996.78	$1.58	$31.97	0.99%
HYDROCORTISONE LOT 2.5%	323	262	$8,425.64	$1.39	$26.09	0.76%
DESONATE GEL 0.05%	218	147	$132,588.84	$22.74	$608.21	11.96%
TRIAMCINOLONE LOT 0.025%	120	103	$3,756.89	$1.76	$31.31	0.34%
CAPEX SHAMPOO 0.01%	21	18	$8,259.16	$21.29	$393.29	0.75%
SUBTOTAL	**13,608**	**10,369**	**$337,049.58**	**$1.67**	**$24.77**	**30.41%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE CR 0.1%	19,381	14,704	14,704	$264,2	$0.77	$13.63
TRIAMCINOLONE OINT 0.1%	11,525	8,224	8,224	$182,73	$0.86	$15.86
TRIAMCINOLONE CR 0.025%	2,310	1,823	1,823	$35,204	$0.90	$15.24
TRIAMCINOLONE CR 0.5%	2,049	1,476	1,476	$35,106.	$1.21	$17.13
TRIAMCINOLONE OINT 0.5%	974	749	749	$18,781.	$1.33	$19.28
FLUTICASONE CR 0.05%	831	536	536	$20,979	$1.28	$25.25
MOMETASONE CR 0.1%	789	592	592	$17,951.	$1.30	$22.75
BETAMETHASONE VAL CR 0.1%	317	229	229	$11,424.	$2.18	$36.04
MOMETASONE OINT 0.1%	260	181	181	$5,160.5	$0.95	$19.85
BETAMETHASONE VAL OINT 0.1%	180	116	116	$7,052.1	$2.07	$39.18
FLUTICASONE OINT 0.005%	158	104	104	$4,715.	$1.47	$29.84
BETAMETH DIP LOT 0.05%	115	65	65	$4,426.	$1.71	$38.49
MOMETASONE SOL 0.1%	102	64	64	$2,599.	$1.08	$25.48
BETAMETHASONE VAL LOT 0.1%	54	43	43	$2,716.2	$2.37	$50.30
SUBTOTAL	**39,045**	**28,906**	**$613,098.95**	**$0.89**	**$15.70**	**55.33%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
AUG BETAMETH CR 0.05%	1,076	738	$19,138.78	$0.81	$17.79	1.73%
CLOBETASOL SOL 0.05%	963	567	$29,600.40	$1.00	$30.74	2.67%
CLOBETASOL CR 0.05%	936	610	$31,285.75	$1.73	$33.42	2.82%
CLOBETASOL OINT 0.05%	758	489	$22,391.17	$1.39	$29.54	2.02%
FLUOCINONIDE SOL 0.05%	496	302	$21,264.57	$1.80	$42.87	1.92%
FLUOCINONIDE OINT 0.05%	347	205	$12,615.55	$1.59	$36.36	1.14%
FLUOCINONIDE CR 0.05%	169	93	$9,113.52	$2.38	$53.93	0.82%
HALOBETASOL CR 0.05%	76	47	$3,375.28	$2.18	$44.41	0.30%
CLOBETASOL EMOL CR 0.05%	66	40	$2,654.95	$2.44	$40.23	0.24%
AUG BETAMETH GEL 0.05%	57	32	$5,228.95	$4.23	$91.74	0.47%
SUBTOTAL	**4,944**	**3,123**	**$156,668.92**	**$1.37**	**$31.69**	**14.13%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 TOTAL	**57,597**	**42,398**	**$1,106,817.45**	**$1.10**	**$19.22**	**99.87%**
TIER-2 MEDICATIONS						
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
FLUOCINOLONE ACT 0.01% SOL	12	11	$401.29	$2.15	$33.44	0.04%
TMC AER SPRAY 0.147MG/G	2	2	$534.78	$8.91	$267.39	0.05%
SUBTOTAL	**14**	**13**	**$936.07**	**$3.79**	**$66.86**	**0.09%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
BETAMETH DIP OINT 0.05%	1	1	$103.68	$4.15	$103.68	0.01%
BETAMETH DIP CR 0.05%	1	1	$26.12	$1.87	$26.12	0.00%
SUBTOTAL	**2**	**2**	**$129.80**	**$3.33**	**$64.90**	**0.01%**
TIER-2 TOTAL	**16**	**15**	**$1,065.87**	**$3.73**	**$66.62**	**0.10%**
TIER-3 MEDICATIONS						
LOW POTENCY PRODUCTS						
DESONIDE CR 0.05%	4	1	$225.60	$1.88	$56.40	0.02%
SUBTOTAL	**4**	**1**	**$225.60**	**$1.88**	**$56.40**	**0.02%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL PROP SHAM 0.05%	1	1	$93.40	$3.11	$93.40	0.01%
SUBTOTAL	**1**	**1**	**$93.40**	**$3.11**	**$93.40**	**0.01%**
TIER-3 TOTAL	**5**	**2**	**$319.00**	**$2.13**	**$63.80**	**0.03%**
TOTAL	**57,618**	**37,016***	**$1,108,202.32**	**$1.10**	**$19.23**	**100%**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
ACT = acetonide; AER = aerosol; AUG = augmented; BETAMETH = betamethasone; CR = cream; DIP= dipropionate; EMOL = emollient; HC = hydrocortisone; LOT = lotion; OINT = ointment; PROP = propionate; SHAM = shampoo; SOL = solution; TMC = triamcinolone; 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 06/2021. Last accessed 06/15/2021.
[2] Impeklo® (Clobetasol Propionate) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_impeklo_2020-0526.pdf. Issued 2020. Last accessed 06/16/2021.
[3] Impeklo® (Clobetasol Propionate*)* Prescribing Information. Mylan. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213691s000lbl.pdf. Last revised 05/2020. Last accessed 06/16/2021.

Appendix J

Calendar Year 2020 Annual Review of Ophthalmic Anti-Inflammatory Products

Oklahoma Health Care Authority
July 2021

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 0.5% gel (Lotemax®)
fluorometholone 0.1% sus (FML® Liquifilm®)	loteprednol 0.5% oint (Lotemax®)
loteprednol 0.5% sus (Lotemax®) – **Brand Preferred**	loteprednol 0.38% gel (Lotemax® SM)
prednisolone acetate 1% sus (Omnipred®)	prednisolone acetate 1% sus (Pred Forte®)
prednisolone acetate 0.12% sus (Pred Mild®)	
prednisolone sodium phosphate 1% sol	

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

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 of 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 of diagnosis 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 of 1 of the following:
    a. The treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); or
    b. The treatment of non-infectious uveitis affecting the posterior segment of the eye; or
    c. The 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.

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®)
nepafenac 0.3% sus (Ilevro®)	ketorolac 0.4% sol (Acular LS®)
	ketorolac 0.45% sol (Acuvail®)
	nepafenac 0.1% sus (Nevanac®)

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

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 2020

Comparison of Calendar Years: Ophthalmic Corticosteroids (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1,993	2,852	$244,863.25	$85.86	$3.29	19,035	74,367
2020	1,894	2,801	$221,414.74	$79.05	$3.05	18,746	72,600
% Change	**-5.0%**	**-1.8%**	**-9.6%**	**-7.9%**	**-7.3%**	**-1.5%**	**-2.4%**
Change	**-99**	**-51**	**-$23,448.51**	**-$6.81**	**-$0.24**	**-289**	**-1,767**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Please note: Some Tier-1 ophthalmic corticosteroid products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

Comparison of Calendar Years: Ophthalmic Corticosteroids (Medical Claims)

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2019	15	23	$45,455.69	$1,976.33	1.53
2020	24	34	$99,653.69	$2,930.99	1.42
% Change	**60%**	**47.8%**	**119.2%**	**48.3%**	**-7.2%**
Change	**9**	**11**	**$54,198.00**	**$954.66**	**-0.11**

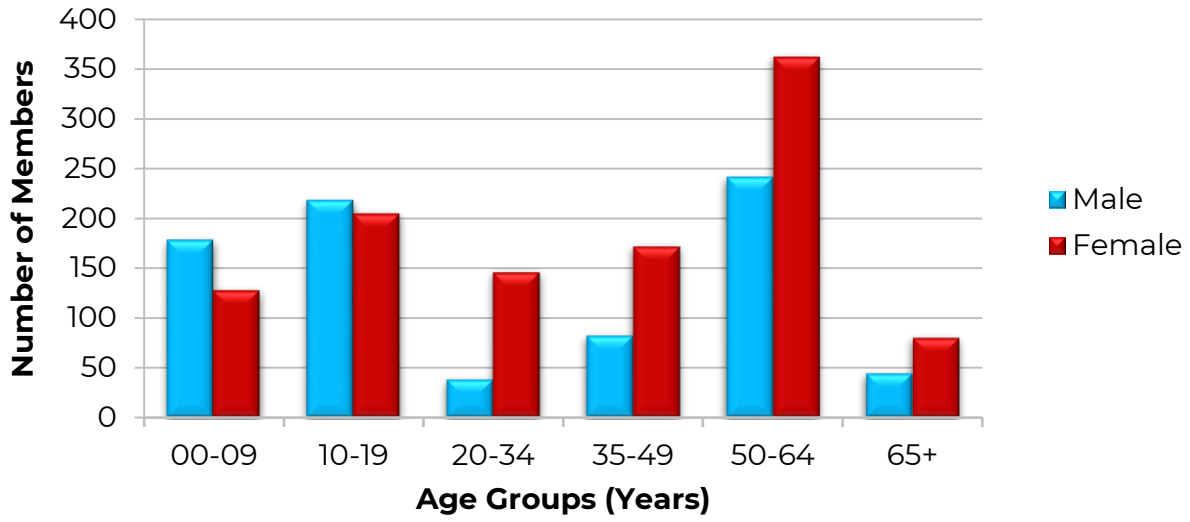
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.

Comparison of Calendar Years: Ophthalmic NSAIDs (Pharmacy Claims)

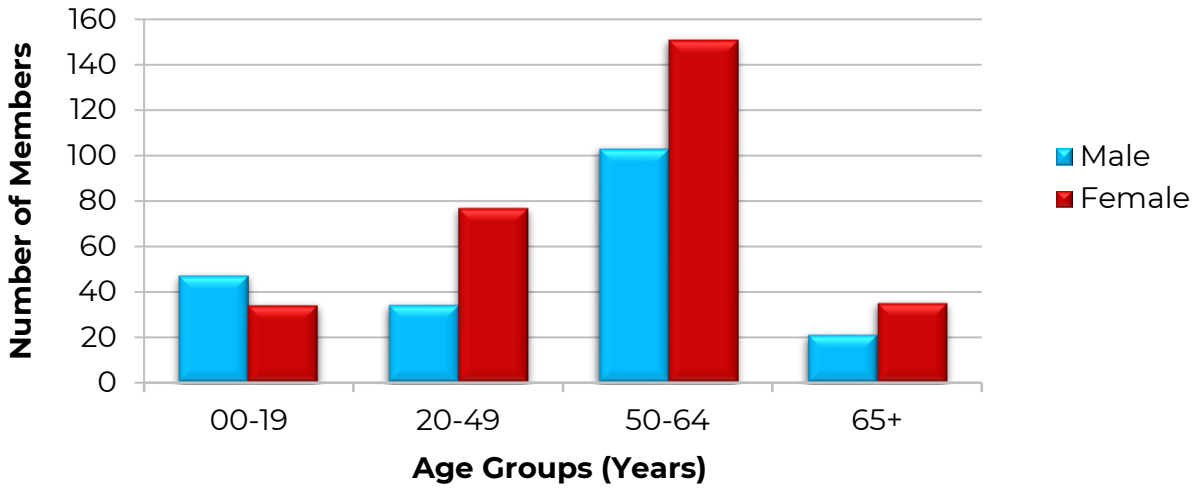
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	548	741	$44,606.74	$60.20	$2.52	3,744	17,687
2020	502	692	$38,137.42	$55.11	$2.28	3,588	16,762
% Change	**-8.4%**	**-6.6%**	**-14.5%**	**-8.5%**	**-9.5%**	**-4.2%**	**-5.2%**
Change	**-46**	**-49**	**-$6,469.32**	**-$5.09**	**-%0.24**	**-156**	**-925**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Please note: Some Tier-1 ophthalmic NSAID products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

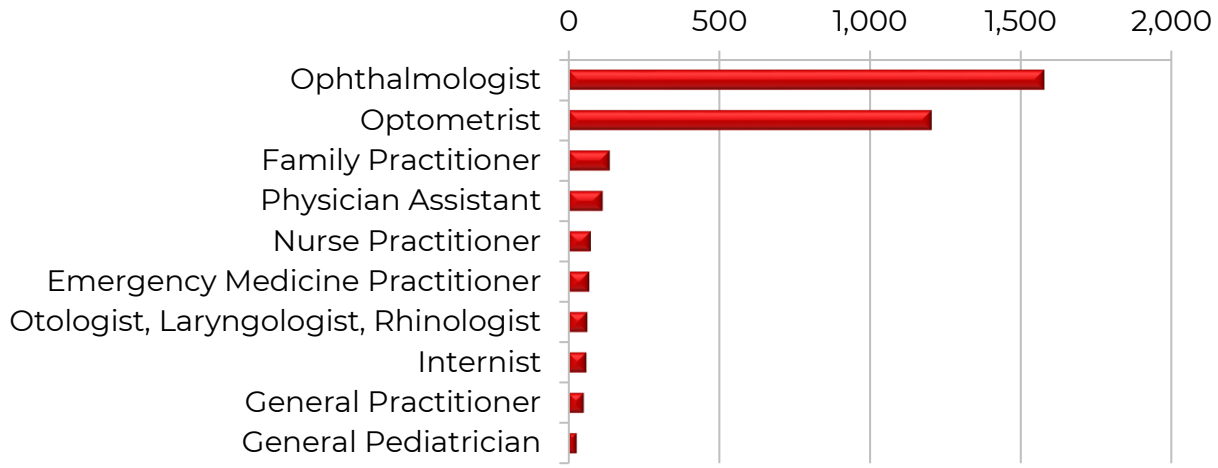
Demographics of Members Utilizing Ophthalmic Corticosteroids (Pharmacy Claims)



Demographics of Members Utilizing Ophthalmic NSAIDs (Pharmacy Claims)



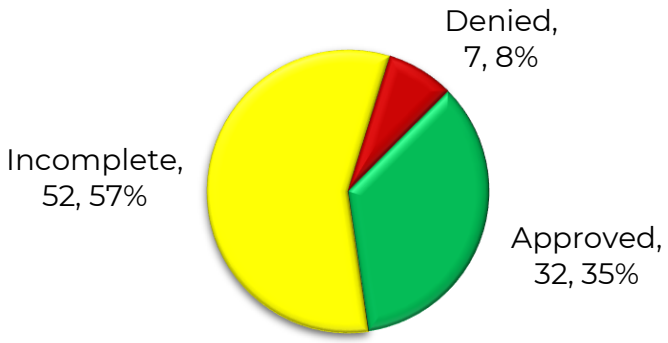
Top Prescriber Specialties of Ophthalmic Anti-Inflammatory Products by Number of Claims (Pharmacy Claims)



Prior Authorization of Ophthalmic Anti-Inflammatory Products

There were 91 prior authorization requests submitted for ophthalmic anti-inflammatory products during calendar year 2020. The following chart shows the status of the submitted petitions for calendar year 2020.

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
- Lotemax® SM (loteprednol 0.38% ophthalmic gel): December 2036

Recommendations

The College of Pharmacy recommends the following changes to the ophthalmic corticosteroids and ophthalmic NSAIDs Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier charts):

1. Moving brand name Lotemax® (loteprednol) 0.5% gel and 0.5% ointment from Tier-2 to Tier-1 in the Ophthalmic Corticosteroids PBPA Tier chart based on net costs
2. Moving Ilevro® (nepafenac) 0.3% suspension from Tier-1 to Tier-2 in the Ophthalmic NSAIDs PBPA Tier chart based on net costs; current Tier-2 criteria will apply

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 0.5% gel (Lotemax®)**~~
fluorometholone 0.1% sus (FML Liquifilm®)	~~**loteprednol 0.5% oint (Lotemax®)**~~
loteprednol 0.5% **gel, oint,** sus (Lotemax®) – **Brand Preferred**	loteprednol 0.38% gel (Lotemax® SM)
prednisolone acetate 1% sus (Omnipred®)	prednisolone acetate 1% sus (Pred Forte®)
prednisolone acetate 0.12% sus (Pred Mild®)	

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

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®)
~~**nepafenac 0.3% sus (Ilevro®)**~~	ketorolac 0.4% sol (Acular LS®)
	ketorolac 0.45% sol (Acuvail®)
	nepafenac 0.1% sus (Nevanac®)
	nepafenac 0.3% sus (Ilevro®)

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

Utilization Details of Ophthalmic Corticosteroids: Calendar Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
PREDNISOLONE PRODUCTS					
PREDNISOLONE SUS 1% OP	1,984	1,383	$98,652.92	$49.72	1.43
PRED MILD SUS 0.12% OP	5	4	$789.82	$157.96	1.25
PRED SOD PHO SOL 1% OP	1	1	$57.31	$57.31	1
SUBTOTAL	**1,990**	**1,388**	**$99,500.05**	**$50.00**	**1.43**
DIFLUPREDNATE PRODUCTS					
DUREZOL EMU 0.05%	251	156	$49,736.64	$198.15	1.61
SUBTOTAL	**251**	**156**	**$49,736.64**	**$198.15**	**1.61**
DEXAMETHASONE PRODUCTS					
DEXAMETHASONE SOL 0.1% OP	238	211	$14,940.79	$62.78	1.13
MAXIDEX SUS 0.1% OP	12	11	$998.88	$83.24	1.09
SUBTOTAL	**250**	**222**	**$15,939.67**	**$63.76**	**1.13**
FLUOROMETHOLONE PRODUCTS					
FLUOROMETHOLONE SUS 0.1% OP	120	83	$11,031.26	$91.93	1.45
FLAREX SUS 0.1% OP	29	22	$2,982.30	$102.84	1.32
FML LIQUIFLM SUS 0.1% OP	5	5	$836.55	$167.31	1
SUBTOTAL	**154**	**110**	**$14,850.11**	**$96.43**	**1.40**
LOTEPREDNOL PRODUCTS					
LOTEMAX SUS 0.5%	96	67	$29,032.39	$302.42	1.43
LOTEPREDNOL SUS 0.5%	50	38	$9,816.02	$196.32	1.32
SUBTOTAL	**146**	**105**	**$38,848.41**	**$266.09**	**1.39**
TIER-1 SUBTOTAL	**2,791**	**1,981**	**$218,874.88**	**$78.42**	**1.41**
TIER-2 UTILIZATION					
LOTEPREDNOL PRODUCTS					
LOTEMAX OIN 0.5%	7	2	$1,971.83	$281.69	3.5
LOTEMAX GEL 0.5%	2	1	$410.30	$205.15	2
SUBTOTAL	**9**	**3**	**$2,382.13**	**$264.68**	**3.00**
PREDNISOLONE PRODUCTS					
PRED FORTE SUS 1% OP	1	1	$157.73	$157.73	1
SUBTOTAL	**1**	**1**	**$157.73**	**$157.73**	**1**
TIER-2 SUBTOTAL	**10**	**4**	**$2,539.86**	**$253.99**	**2.50**
TOTAL	**2,801**	**1,894***	**$221,414.74**	**$79.05**	**1.48**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
OZURDEX® (J7312)	27	20	$35,360.65	$1,309.65
ILUVIEN® (J7313)	6	4	$55,953.10	$9,325.52
YUTIQ® (J7314)	1	1	$8,339.94	$8,339.94
TOTAL	**34⁺**	**24***	**$99,653.69**	**$2,930.99**

*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 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
KETOROLAC SOL 0.5%	539	404	$10,714.73	$19.88	1.33
ILEVRO DRO 0.3% OP	91	65	$25,770.51	$283.19	1.4
DICLOFENAC SOL 0.1% OP	59	40	$882.92	$14.96	1.48
TIER-1 SUBTOTAL	**689**	**509**	**$37,368.16**	**$54.24**	**1.35**
TIER-2 UTILIZATION					
BROMSITE DRO 0.075%	3	1	$769.26	$256.42	3
TIER-2 SUBTOTAL	**3**	**1**	**$769.26**	**$256.42**	**3**
TOTAL	**692**	**502***	**$38,137.42**	**$55.11**	**1.38**

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

[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 06/2021. Last accessed 06/10/2021.

Appendix K

30-Day Notice to Prior Authorize Nulibry™ (Fosdenopterin)

Oklahoma Health Care Authority
July 2021

Introduction[1,23]

Molybdenum cofactor deficiency (MoCD) Type A is a rare genetic disorder that is estimated to occur in 1 in 342,000 to 411,000 newborns worldwide. Most cases of MoCD are fatal in infancy or early childhood, and the prognosis may be more variable for later-onset cases. MoCD is categorized into 3 different types (A, B, and C) and is distinguished by the specific gene mutations. Patients with MoCD Type A have a genetic mutation in the molybdenum cofactor synthesis gene 1 (*MOCS1*) gene and experience severe and rapidly progressive neurologic damage due to the accumulation of toxic sulfite metabolites in the central nervous system (CNS). These patients often present with intractable seizures, feeding difficulties, and muscle weakness.

In February 2021, the U.S. Food and Drug Administration (FDA) approved Nulibry™ (fosdenopterin) to reduce the risk of death due to molybdenum cofactor deficiency (MoCD) Type A. Prior to the approval of Nulibry™, the only treatment options were supportive care and therapies directed towards the complications caused by the disease. Patients with MoCD Type A lack a substance known as cyclic pyranopterin monophosphate (cPMP). Nulibry™ is an intravenous (IV) replacement for the missing cPMP, and patients treated with Nulibry™ in clinical trials had a survival rate of 84% at 3 years, compared to 55% for untreated patients. The most common adverse reactions were catheter-related complications, fever, respiratory infections, vomiting, and diarrhea. Patients treated with Nulibry™ should avoid sunlight and wear sunscreen and protective clothing when exposed to the sun.

Nulibry™ (Fosdenopterin) Product Summary[4]

Indication(s): To reduce the risk of mortality in patients with MoCD Type A

How Supplied: 9.5mg of fosdenopterin as a lyophilized powder in a single-dose vial (SDV) for reconstitution

Dosing:

- 1 year of age or older: 0.9mg/kg given as an IV infusion once daily
- Younger than 1 year of age: See the following table for the recommended dosage given as an IV infusion once daily:

Titration Schedule	Preterm Neonates (GSA <37 weeks)	Term Neonates (GSA >37 weeks)
Initial Dosage	0.4mg/kg once daily	0.55mg/kg once daily
Dosage at Month 1	0.7mg/kg once daily	0.75mg/kg once daily
Dosage at Month 3 and Thereafter	0.9mg/kg once daily	0.9mg/kg once daily

GSA = gestational age

- Nulibry™ is intended for administration by a health care provider. If deemed appropriate by a health care provider, Nulibry™ may be administered at home by the patient's caregiver.
- Administration of Nulibry™ must be completed within 4 hours of reconstitution.

Mechanism of Action: Patients with MoCD Type A have a genetic mutation in the *MOCS1* gene that leads to a deficient synthesis of cPMP. Nulibry™ provides an exogenous source of cPMP, which is converted to molybdopterin. Molybdopterin is then converted to molybdenum cofactor, which is needed for the activation of molybdenum-dependent enzymes, including sulfite oxidase (*SOX*). *SOX* is an enzyme that reduces levels of neurotoxic sulfites.

Adverse Reactions: The most common adverse reactions (occurring in ≥25% of patients treated with fosdenopterin in clinical studies) were catheter-related complications, pyrexia, viral infection, pneumonia, otitis media, vomiting, cough/sneezing, viral upper respiratory infection, gastroenteritis, bacteremia, and diarrhea.

Efficacy: The efficacy of Nulibry™ was assessed in a combined analysis of 3 studies that included 13 patients with confirmed MoCD Type A and 18 patients from an untreated natural history cohort of patients with genetically confirmed MoCD Type A. Patients receiving Nulibry™ demonstrated significant improvement in overall survival when compared with the untreated genotype-matched historical controls [hazard ratio (HR): 0.18; 95% confidence interval (CI): 0.04, 0.72]. When looking at overall survival at 3 years, patients treated with Nulibry™ had a higher overall survival rate when compared to the untreated natural history cohort (84% vs. 55%).

Cost: The Wholesale Acquisition Cost (WAC) of Nulibry™ is $1,369.86 per SDV. The estimated annual cost for a patient 1 year of age or older weighing <10.5kg would be $499,998.90.

Recommendations

The College of Pharmacy recommends the prior authorization of Nulibry™ (fosdenopterin) with the following criteria:

Nulibry™ (Fosdenopterin) Approval Criteria:

1. An FDA approved indication to reduce the risk of mortality in members with molybdenum cofactor deficiency (MoCD) Type A; and
2. MoCD Type A must be confirmed by genetic testing; and
    a. If the member is presumed to have MoCD Type A, Nulibry™ can be approved for 1 month until genetic testing can be performed; and
    b. Nulibry™ will be discontinued if genetic testing results do not confirm MoCD Type A; and
3. Nulibry™ must be administered by a health care provider or the prescriber must verify the member or member's caregiver has been trained by a health care professional on proper storage, preparation, and intravenous (IV) administration of Nulibry™; and
4. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing according to package labeling; and
5. Approval quantities will be dependent on the member's age, weight, and dosing based on the Nulibry™ *Prescribing Information*.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Molybdenum Cofactor Deficiency Type A. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-molybdenum-cofactor-deficiency-type. Issued 02/26/2021. Last accessed 06/21/2021.

[2] Jethva R. Sulfite Oxidase Deficiency and Molybdenum Cofactor Deficiency. *Medscape*. Available online at: https://emedicine.medscape.com/article/949303-overview#a2. Last revised 02/18/2019. Last accessed 06/21/2021.

[3] BridgeBio Pharma and Affiliate Origin Biosciences Announce FDA Approval of NULIBRY™ (Fosdenopterin), the First and Only Approved Therapy to Reduce the Risk of Mortality in Patients with MoCD Type A. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2021/02/28/2183818/0/en/BridgeBio-Pharma-and-Affiliate-Origin-Biosciences-Announce-FDA-Approval-of-NULIBRY-fosdenopterin-the-First-and-Only-Approved-Therapy-to-Reduce-the-Risk-of-Mortality-in-Patients-wit.html. Issued 02/28/2021. Last accessed 07/01/2021.

[4] Nulibry™ Prescribing Information. Origin Biosciences, Inc. Available online at: https://www.nulibry.com/pdfs/nulibry-prescribing-information-v2.pdf. Last revised 02/2021. Last accessed 06/21/2021.

Appendix L

30-Day Notice to Prior Authorize Feraheme® (Ferumoxytol), Injectafer® (Ferric Carboxymaltose), and Monoferric® (Ferric Derisomaltose)

Oklahoma Health Care Authority
July 2021

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

Iron deficiency anemia (IDA) is defined as reduced red blood cell production due to low iron stores in the body. Iron deficiency can result from blood loss, decreased dietary iron intake, impaired iron absorption, or increased iron demand (e.g., during pregnancy). IDA is the most common form of anemia worldwide, accounting for approximately 50% of all anemias. In the United States, the rate of IDA is approximately 10% in women of childbearing age. Additionally, IDA is a frequent complication of chronic kidney disease (CKD), with increasing prevalence at higher stages of CKD. IDA in CKD can be related to either a true deficiency of iron stores or functional iron deficiency due to underlying inflammation which impairs the body's ability to utilize iron stored in the tissues. While many patients with IDA are asymptomatic, some patients experience symptoms such as fatigue, decreased ability to work, or shortness of breath. Additionally, untreated IDA in pregnant women can result in adverse fetal outcomes such as preterm delivery or low birth weight. IDA is diagnosed through laboratory evaluation demonstrating anemia in addition to reduced iron stores. Once identified, treatment of IDA should involve treatment of any underlying causes plus supplementation with oral iron therapy. For adults, the recommended oral dose for the treatment of IDA is 120mg of elemental iron per day for 3 months. For patients who cannot tolerate or have an inadequate response to oral iron therapy, intravenous (IV) iron products may be necessary. A variety of IV iron formulations have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of various forms of IDA and include iron dextran, sodium ferric gluconate, iron sucrose, ferumoxytol, ferric carboxymaltose, and ferric derisomaltose. Because of serious allergic reactions and toxicity associated with early forms of parenteral iron, currently available IV iron formulations consist of an iron core surrounded by a carbohydrate shell which helps to slow the release of elemental iron, allowing for larger doses to be administered safely.

IV iron products are reimbursed by SoonerCare through medical claims only. Previously, the IV iron products category has been managed through the medical department of the Oklahoma Health Care Authority (OHCA). IV iron products will now be managed through the Drug Utilization Review (DUR) Board process.

Utilization of IV Iron Products: Medical Claims

Calendar Year	Total Members*	Total Claims†	Total Cost	Cost/ Claim	Total Units
2020	404	820	$228,260.89	$278.37	121,007

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

Market News and Updates[6,7,8]

Anticipated Patent Expiration(s):

- Feraheme® (ferumoxytol injection): June 2023
- Injectafer® (ferric carboxymaltose injection): February 2028
- Monoferric® (ferric derisomaltose injection): August 2029

New FDA Approval(s):

- **January 2020:** The FDA approved Monoferric® (ferric derisomaltose injection) for the treatment of IDA in adult patients with an intolerance or unsatisfactory response to oral iron or with non-hemodialysis dependent CKD. Monoferric® was approved as a single-dose treatment option for IDA. The approval of Monoferric® was based on data from 2 randomized, open-label studies in 3,050 adults with IDA which demonstrated that Monoferric® was noninferior to iron sucrose for the primary efficacy endpoint, change in hemoglobin from baseline to week 8.
- **April 2021:** The FDA approved Injectafer® (ferric carboxymaltose injection) for a new single-dose regimen. Patients weighing ≥50kg may now receive a 15mg/kg dose, up to a maximum of 1,000mg, as a single-dose treatment course. The previous FDA approved regimen for Injectafer® for patients weighing ≥50kg was (2) 750mg doses separated by at least 7 days for a total of 1,500mg per treatment course. The approval of the new single-dose regimen was based on data from 2 randomized, open-label studies evaluating the safety and tolerability of Injectafer® as a single dose up to a maximum of 1,000mg in patients weighing at least 50kg. The manufacturer of Injectafer® plans to launch a new 1,000mg single-dose vial (SDV) for use with the new regimen.

Feraheme® (Ferumoxytol Injection) Product Summary[9]

Indication(s): Feraheme® (ferumoxytol injection) is indicated for the treatment of IDA in adult patients with:

- Intolerance or unsatisfactory response to oral iron; or
- CKD

Boxed Warning: Risk for Serious Hypersensitivity/Anaphylaxis Reactions

- Fatal and serious hypersensitivity reactions including anaphylaxis have occurred in patients receiving Feraheme®. Initial symptoms may include hypotension, syncope, unresponsiveness, and cardiac/ cardiorespiratory arrest.
  - Feraheme® should only be administered as an IV infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.
  - Patients should be observed for signs or symptoms of hypersensitivity reactions during and for at least 30 minutes following Feraheme® infusion including monitoring of blood pressure and pulse during and after administration.
  - Hypersensitivity reactions have occurred in patients in whom a previous Feraheme® dose was tolerated.

How Supplied: SDV containing 510mg/17mL (30mg/mL) of elemental iron

Dosing and Administration:

- (2) 510mg doses administered 3 to 8 days apart
- Should be administered as an IV infusion in 50-200mL 0.9% sodium chloride or 5% dextrose over at least 15 minutes
- Hematologic response (e.g., hemoglobin, ferritin, iron, transferrin saturation) should be evaluated at least 1 month after the second dose of Feraheme®
- May be readministered to patients with persistent or recurrent IDA
- For patients receiving hemodialysis, Feraheme® should be administered once the blood pressure is stable and after at least 1 hour of hemodialysis has been completed; signs and symptoms of hypotension should be monitored following each Feraheme® infusion

Contraindication(s):

- Known hypersensitivity to Feraheme® or any of its components
- History of allergic reaction to any IV iron product

Injectafer® (Ferric Carboxymaltose Injection) Product Summary[10]

Indication(s): Injectafer® (ferric carboxymaltose injection) is indicated for the treatment of IDA in adult patients with:

- Intolerance or unsatisfactory response to oral iron; or
- Non-dialysis dependent CKD

How Supplied: SDVs containing 750mg/15mL or 1,000mg/20mL (50mg/mL) of elemental iron

Dosing and Administration:

- Patients weighing ≥50kg:
  - (2) 750mg doses administered at least 7 days apart; or
  - 15mg/kg, up to a maximum of 1,000mg, as a single dose
- Patients weighing <50kg:
  - (2) 15mg/kg doses administered at least 7 days apart
- May be administered by IV infusion or as an undiluted slow IV push
- For IV infusion, up to 1,000mg of Injectafer® should be diluted in no more than 250mL 0.9% sodium chloride with a concentration not less than 2mg of iron per mL and should be administered over at least 15 minutes
- For IV push, Injectafer® 750mg should be administered at the rate of approximately 100mg (2mL) per minute and the 1,000mg dose should be administered slowly over 15 minutes; patients should be monitored for extravasation and use of the administration site should be discontinued if extravasation occurs
- May be repeated if IDA reoccurs

Contraindication(s):

- History of hypersensitivity to Injectafer® or any of its components

Monoferric® (Ferric Derisomaltose Injection) Product Summary[11]

Indication(s): Monoferric® (ferric derisomaltose injection) is indicated for the treatment of IDA in adult patients with:

- Intolerance or unsatisfactory response to oral iron; or
- Non-hemodialysis dependent CKD

How Supplied: SDV containing 1,000mg/10mL (100mg/mL) of elemental iron

Dosing and Administration:

- Patients weighing ≥50kg:
  - 1,000mg as a single dose
- Patients weighing <50kg:
  - 20mg/kg as a single dose
- Should be diluted in 100-500mL 0.9% sodium chloride to a final concentration >1mg of iron per mL and administered by IV infusion over at least 20 minutes
- May be repeated if IDA reoccurs

Contraindication(s):

- Serious hypersensitivity to Monoferric® or any of its components

Relative Risk of Serious Adverse Events (SAEs)[12,13]

A systematic review and meta-analysis of 103 randomized clinical studies comparing the occurrence of SAEs with IV iron formulations relative to non-IV iron controls was published in 2015 in *Mayo Clinic Proceedings*. Adverse event types included in the meta-analysis were infections, infusion reactions, cardiovascular reactions, neurologic reactions, respiratory reactions, gastrointestinal reactions, thromboembolic reactions, and severe constitutional reactions. SAEs were defined as grade 3 through 5 reactions, as defined by the Common Terminology Criteria for Adverse Events (CTCAE) grading system, for each adverse event type. In the CTCAE grading system, adverse events are assigned a grade of 1 through 5, with higher grades indicating increased severity. In general, grade 1 represents mild or asymptomatic events which do not require intervention, grade 2 represents moderate events, grade 3 represents severe or medically significant but not immediately life-threatening events, grade 4 represents life-threatening events, and grade 5 represents death related to the adverse event. In the included studies, a pooled total of 10,390 patients treated with IV iron were compared with control arms consisting of 4,044 patients treated with oral iron, 3,335 treated with placebo, 1,329 treated with no iron, and 155 treated with intramuscular (IM) iron. SAEs were reported in 95% of the included studies, but no overall increased risk of SAEs was seen with IV iron compared to controls [relative risk (RR): 1.04; 95% confidence interval (CI): 0.93, 1.17]. The overall risk of serious infusion reactions was higher for IV iron than for controls (RR: 2.47; 95% CI: 1.43, 4.28). Individually, however, iron dextran, iron sucrose, ferumoxytol, ferric carboxymaltose, and ferric derisomaltose were not associated with statistically significant increases in the risk of severe infusion reactions in the included studies.

Generic Name	SAEs	RR (95% CI)
ferric carboxymaltose	All SAEs	0.82 (0.64, 1.06)
	Serious infusion reactions	1.47 (0.40, 5.39)
ferric derisomaltose or iron polymaltose*	All SAEs	1.09 (0.43, 2.80)
	Serious infusion reactions	1.00 (0.99, 1.01)
ferumoxytol	All SAEs	1.04 (0.71, 1.53)
	Serious infusion reactions	2.26 (0.19, 26.22)
iron dextran	All SAEs	1.05 (0.77, 1.45)
	Serious infusion reactions	3.10 (0.86, 11.22)
iron sucrose	All SAEs	1.33 (0.96, 1.83)
	Serious infusion reactions	1.75 (0.69, 4.43)

CI = confidence interval; RR = relative risk; SAEs = serious adverse events

*The results for ferric derisomaltose and iron polymaltose were grouped together in the meta-analysis. Only 2 studies utilizing ferric derisomaltose and 3 studies utilizing iron polymaltose met inclusion criteria and were included in the meta-analysis. Iron polymaltose formulations are not available in the United States.

Cost Comparison

Product	Cost Per mg	Cost Per Treatment Course*
Monoferric® (ferric derisomaltose inj) 1,000mg/10mL	**$2.46**	**$2,460.00**
Injectafer® (ferric carboxymaltose inj) 750mg/15mL	**$1.11**	**$1,665.00**
Feraheme® (ferumoxytol inj) 510mg/17mL	**$0.97**	**$989.40**
Infed® (iron dextran inj) 100mg/2mL	$0.30	$300.00
Venofer® (iron sucrose inj) 200mg/2mL	$0.23	$230.00

inj = injection
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per treatment course based on 1,000mg for Monoferric®, (2) 750mg doses for Injectafer®, (2) 510mg doses for Feraheme®, 1,000mg for Infed®, and (5) 200mg doses for Venofer®

Recommendations

The College of Pharmacy recommends the prior authorization of Feraheme® (ferumoxytol injection), Injectafer® (ferric carboxymaltose injection), and Monoferric® (ferric derisomaltose injection) with the following 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 patients 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 patients 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 Details of IV Iron Products: Calendar Year 2020

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J1750 IRON DEXTRAN INJ 50MG (INFED)	606	320	$116,850.00	$192.82
J1439 FERRIC CARBOXYMALTOSE INJ 1MG (INJECTAFER)	101	50	$81,101.38	$802.98
Q0138 FERUMOXYTOL INJ 1MG (NON-ESRD) (FERAHEME)	60	30	$27,742.04	$462.37
J1756 IRON SUCROSE INJ 1MG (VENOFER)	53	13	$2,567.47	$48.44
TOTAL	**820**	**404**	**$228,260.89**	**$278.37**

ESRD = end-stage renal disease; INJ = injection
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.

[1] Warner MJ, Kamran MT. StatPearls: Iron Deficiency Anemia. Available online at: https://www.ncbi.nlm.nih.gov/books/NBK448065/. Last revised 08/10/2020. Last accessed 06/17/2021.
[2] Short MW, Domagalski JE. Iron Deficiency Anemia: Evaluation and Management. *Am Fam Physician* 2013; 87(2):98-104.
[3] Batchelor EK, Kapitsinou P, Pergola PE, et al. Iron Deficiency in Chronic Kidney Disease: Updates on Pathophysiology, Diagnosis, and Treatment. *J Am Soc Nephrol* 2020; 31(3):456-468.
[4] National Heart, Lung, and Blood Institute. Health Topics: Iron-Deficiency Anemia. Available online at: https://www.nhlbi.nih.gov/health-topics/iron-deficiency-anemia. Last accessed 06/17/2021.
[5] Auerbach M, Macdougall I. The Available Intravenous Iron Formulations: History, Efficacy, and Toxicology. *Hemodial Int* 2017; 21(1):S83-S92.
[6] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 06/2021. Last accessed 06/14/2021.
[7] Park B. Monoferric® Injection Approved for Iron Deficiency Anemia. *MPR*. Available online at: https://www.empr.com/home/news/monoferric-injection-approved-for-iron-deficiency-anemia/. Issued 01/30/2020. Last accessed 06/14/2021.
[8] Daiichi Sankyo, Inc. Injectafer® (Ferric Carboxymaltose Injection) Receives FDA Approval for Single Dose Option for the Treatment of Adult Patients with Iron Deficiency Anemia. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/injectafer-ferric-carboxymaltose-injection-receives-fda-approval-for-single-dose-option-for-the-treatment-of-adult-patients-with-iron-deficiency-anemia-301285079.html. Issued 05/06/2021. Last accessed 06/14/2021.
[9] Feraheme® (Ferumoxytol) Prescribing Information. AMAG Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022180s024lbl.pdf. Last revised 09/2020. Last accessed 06/14/2021.
[10] Injectafer® (Ferric Carboxymaltose) Prescribing Information. American Regent, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/203565s014lbl.pdf. Last revised 04/2021. Last accessed 06/14/2021.
[11] Monoferric® (Ferric Derisomaltose) Prescribing Information. Pharmacosmos Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208171s001lbl.pdf. Last revised 09/2020. Last accessed 06/14/2021.
[12] Avni T, Bieber A, Grossman A, et al. The Safety of Intravenous Iron Preparations: Systematic Review and Meta-analysis. *Mayo Clin Proc* 2015; 90(1):12-23.
[13] National Institutes of Health: National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE). Available online at: https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm. Last revised 09/21/2020. Last accessed 06/28/2021.

Appendix M

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: June 21, 2021

FDA Approves First Oral Blood Thinning Medication for Children

The FDA approved Pradaxa (dabigatran etexilate) oral pellets to treat children 3 months to younger than 12 years of age with venous thromboembolism (VTE) after they have been treated with an injectable blood thinner for at least 5 days. The FDA also approved Pradaxa oral pellets to prevent recurrent clots among patients 3 months to younger than 12 years of age who completed treatment for their first VTE.

In addition, Pradaxa was approved in capsule form to treat blood clots in patients 8 years of age and older with VTE after they have been treated with an injectable blood thinner for at least 5 days and to prevent recurrent clots in patients 8 years of age and older who completed treatment for their first VTE.

Pradaxa is the first FDA approved blood thinner that children can take by mouth; the only other FDA approved blood thinner for children is given by injection. Pradaxa was originally FDA approved in 2010 to reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation.

Children are most at risk for blood clots if they have cancer, congenital heart disease, a central venous catheter, or are admitted to an intensive care unit. VTE can lead to complications, including swelling and discomfort near the clot, chest pain, lung damage, and even death.

The safety and efficacy of Pradaxa for treating blood clots in patients younger than 18 years of age was evaluated in 1 study of 267 pediatric patients. In this open-label study, patients were randomly assigned to receive either Pradaxa or standard of care. The study compared the 2 groups for the number of patients who met the composite endpoint, which meant that they had not died from a blood clot, their blood clots had completely resolved, and they had no additional blood clots. Results showed that 81 (45.8%) of the 177 patients taking Pradaxa met the composite endpoint compared to 38 (42.2%) of the 90 patients who received standard of care.

The safety of Pradaxa to prevent recurrent blood clots in the same pediatric population was evaluated in an open-label, single-arm study in 214 patients with a history of blood clots. The primary endpoints of the study were recurrence of blood clots, major and minor bleeding events, and death (both overall and related to blood clots). The safety of Pradaxa with long-term use was similar to the previously discussed study. Recurrence of blood clots occurred in 3 patients (1.4%), which was comparable to prior standard of care treatments.

The most common side effects of Pradaxa include digestive system symptoms and bleeding. Pradaxa can cause serious and fatal bleeding. Pradaxa is not recommended for patients with bioprosthetic heart valves or triple-positive antiphospholipid syndrome. Pradaxa has a *Boxed Warning* cautioning that early treatment discontinuation may increase the risk of blood clots and that blood accumulation within parts of the spinal cord (spinal or epidural hematomas) in patients undergoing spinal procedures may cause

serious side effects. Pradaxa received Priority Review designation for this indication. The FDA granted the approval of Pradaxa to Boehringer Ingelheim Pharmaceuticals, Inc.

FDA NEWS RELEASE

For Immediate Release: June 17, 2021

FDA Approves a Nasal Antihistamine for Nonprescription Use

The FDA approved a nasal antihistamine for nonprescription use through a process called a partial prescription to nonprescription switch. The FDA approved Astepro (azelastine hydrochloride 0.15% nasal spray) for seasonal and perennial allergic rhinitis for adults and children 6 years of age and older.

For a drug to switch from prescription to nonprescription status, the data provided must demonstrate that the drug is safe and effective for use in self-medication as directed in proposed labeling. The manufacturer must show that consumers can understand how to use the drug safely and effectively without the supervision of a health care professional. This approval is a first-in-class switch for a nasal antihistamine and is considered a partial switch because the 0.1% strength, which includes the perennial allergy indication for children 6 months to 6 years of age and seasonal allergy indication for children 2 to 6 years of age, will remain prescription based.

Azelastine can cause drowsiness. The label warns that consumers using this product should avoid alcoholic drinks and be careful when driving a motor vehicle or operating machinery. Using azelastine nasal spray with alcohol, sedatives, or tranquilizers may increase drowsiness. The FDA granted the approval of nonprescription Astepro to Bayer Healthcare, LLC.

FDA NEWS RELEASE

For Immediate Release: June 11, 2021

FDA Takes Steps to Increase Availability of COVID-19 Vaccine

Following careful review and deliberation, the FDA is taking important steps that will allow a critically needed supply of the Janssen (Johnson & Johnson) COVID-19 vaccine to be made available.

The FDA announced that it authorized for use, under the emergency use authorization (EUA) for the Janssen COVID-19 vaccine, 2 batches of vaccine drug substance manufactured at the Emergent BioSolutions facility in Baltimore. Before making this decision, the FDA conducted a thorough review of facility records and the results of quality testing performed by the manufacturer. Based on this review and considering the current COVID-19 public health emergency, the FDA concluded these batches are suitable for use. While the FDA is not yet ready to include the Emergent BioSolutions plant in the Janssen EUA as an authorized manufacturing facility, the FDA continues to work through issues there with Janssen and Emergent BioSolutions management.

The FDA's decision to include these 2 batches of vaccine drug substance in the EUA for the Janssen COVID-19 vaccine means that Janssen vaccine made with this drug substance can be used in the United States or exported to other countries. A condition on any export of these batches, or of vaccine manufactured from these batches, is that Janssen and Emergent agree that the FDA may share relevant information about the manufacturer of the batches under an appropriate confidentiality agreement, with the regulatory authorities of the countries in which the vaccine may be used.

The FDA has also revised the letter of authorization for the Janssen vaccine to help facilitate potential export to other countries. Under the revised letter of authorization, the

distribution and administration of exported vaccines must comply with the laws of the recipient countries.

The FDA has determined several other batches are not suitable for use, but additional batches are still under review and the agency will keep the public informed as those reviews are completed.

Additionally, the FDA has extended the expiration dating for the refrigerated Janssen COVID-19 vaccine after reviewing information submitted by Janssen and determining that the vaccine can be stored at 2-8°C for 4.5 months instead of 3 months.

The FDA has indicated they will keep the public and their global partners informed as they continue to work expeditiously on this issue and will share information when they are able.

FDA NEWS RELEASE

For Immediate Release: June 07, 2021

FDA Grants Accelerated Approval for Alzheimer's Drug

The FDA approved Aduhelm (aducanumab) for the treatment of Alzheimer's disease, a debilitating disease affecting 6.2 million Americans. Aduhelm was approved using the accelerated approval pathway, which can be used for a drug for a serious or life-threatening illness that provides a meaningful therapeutic advantage over existing treatments. Accelerated approval can be based on the drug's effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients, with a required post-approval trial to verify that the drug provides the expected clinical benefit.

Alzheimer's disease is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually, the ability to carry out simple tasks. While the specific causes of Alzheimer's disease are not fully known, it is characterized by changes in the brain – including amyloid plaques and neurofibrillary, or tau, tangles – that result in loss of neurons and their connections. These changes affect a person's ability to remember and think.

Aduhelm represents a first-of-its-kind treatment approved for Alzheimer's disease. It is the first new treatment approved for Alzheimer's disease since 2003 and is the first therapy that targets the fundamental pathophysiology of the disease.

Researchers evaluated Aduhelm's efficacy in 3 separate studies representing a total of 3,482 patients. The studies consisted of double-blind, randomized, placebo-controlled dose-ranging studies in patients with Alzheimer's disease. Patients receiving the treatment had significant dose- and time-dependent reduction of amyloid beta plaque, while patients in the control arm of the studies had no reduction of amyloid beta plaque.

These results support the accelerated approval of Aduhelm, which is based on the surrogate endpoint of reduction of amyloid beta plaque in the brain – a hallmark of Alzheimer's disease. Amyloid beta plaque was quantified using positron emission tomography (PET) imaging to estimate the brain levels of amyloid beta plaque in a composite of brain regions expected to be widely affected by Alzheimer's disease pathology compared to a brain region expected to be spared of such pathology.

The P*rescribing Information* for Aduhelm includes a warning for amyloid-related imaging abnormalities (ARIA), which most commonly presents as temporary swelling in areas of the brain that usually resolves over time and does not cause symptoms, though some people may have other symptoms such as headache, confusion, dizziness, vision changes, or nausea. Another warning for Aduhelm is for a risk of hypersensitivity reactions, including angioedema and urticaria. The most common side effects of

Aduhelm were ARIA, headache, fall, diarrhea, and confusion/delirium/altered mental status/disorientation.

Under the accelerated approval provisions, which provide patients suffering from the disease earlier access to the treatment, the FDA is requiring Biogen to conduct a new randomized, controlled clinical trial to verify the drug's clinical benefit. If the study fails to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

Aduhelm was granted Fast Track designation, which seeks to expedite the development and review of drugs that are intended to treat serious conditions where initial evidence showed the potential to address an unmet medical need. The FDA granted approval of Aduhelm to Biogen.

FDA NEWS RELEASE

For Immediate Release: June 04, 2021

FDA Approves First Treatment for Patients with Plasminogen Deficiency, a Rare Genetic Disorder

The FDA approved Ryplazim (plasminogen, human-tvmh) for the treatment of patients with plasminogen deficiency type 1, also referred to as hypoplasminogenemia, a disorder that can impair normal tissue and organ function and may lead to blindness.

Individuals with this disease lack a protein called plasminogen, which is responsible for the ability of the body to break down fibrin clots. Plasminogen deficiency leads to an accumulation of fibrin, causing the development of lesions that can impair normal tissue and organ function and may lead to blindness when these lesions affect the eyes.

The active ingredient in Ryplazim is plasminogen, purified from human plasma. Treatment with Ryplazim helps to increase the plasma level of plasminogen, enabling a temporary correction of the plasminogen deficiency and reduction or resolution of the lesions.

The efficacy and safety of Ryplazim are primarily based on 1 single-arm, open-label clinical study enrolling 15 adult and pediatric patients with plasminogen deficiency type 1. All patients received Ryplazim administered every 2 to 4 days for 48 weeks. The effectiveness of Ryplazim was demonstrated by at least 50% improvement of lesions in all 11 patients who had lesions at baseline, and absence of recurrent or new lesions in any of the 15 patients through the 48 weeks of treatment.

The most common side effects reported by patients who received Ryplazim were abdominal pain, bloating, nausea, bleeding, limb pain, fatigue, constipation, dry mouth, headache, dizziness, joint pain, and back pain.

The FDA granted Ryplazim Orphan Drug, Fast Track, and Priority Review designations as well as a Rare Pediatric Disease Priority Review Voucher. The FDA's rare pediatric disease priority review voucher program is intended to encourage development of new drugs and biologics to prevent and/or treat rare diseases in children.

Patients with plasminogen deficiency type 1 may bleed from active disease-related lesions. The use of Ryplazim may prolong or worsen active bleeding. Tissue sloughing has also been observed. Because Ryplazim is derived from human plasma, it carries a risk of transmitting infectious agents. Based on effective donor screening procedures and product manufacturing processes, the risk of infectious disease transmission is remote. The FDA granted approval of Ryplazim to ProMetic Biotherapeutics, Inc.

FDA NEWS RELEASE

For Immediate Release: May 28, 2021

FDA Approves First Targeted Therapy for Lung Cancer Mutation Previously Considered Resistant to Drug Therapy

The FDA approved Lumakras (sotorasib) as the first treatment for adult patients with non-small cell lung cancer (NSCLC) whose tumors have a specific type of genetic mutation called KRAS G12C and who have received at least 1 prior systemic therapy. This is the first approved targeted therapy for tumors with any KRAS mutation, which accounts for approximately 25% of mutations in NSCLC. KRAS G12C mutations represent about 13% of mutations in NSCLC.

Lung cancer, the most common cancer type with the highest mortality, can largely be categorized by the genetic mutations that cause it. KRAS is a type of mutation in a group of genes that help regulate cell growth and division.

Researchers evaluated the efficacy of Lumakras in a study of 124 patients with locally advanced or metastatic KRAS G12C-mutated NSCLC with disease progression after receiving an immune checkpoint inhibitor and/or platinum-based chemotherapy. The major outcomes measured were objective response rate (proportion of patients whose tumor is destroyed or reduced) and duration of response. The objective response rate was 36% and 58% of those patients had a duration of response of 6 months or longer.

The approved 960mg dose is based on available clinical data, as well as pharmacokinetic and pharmacodynamic modeling that support the approved dose. As part of the evaluation for this accelerated approval, the agency is requiring a postmarketing study to investigate whether a lower dose will have a similar clinical effect.

The most common side effects of Lumakras include diarrhea, musculoskeletal pain, nausea, fatigue, liver damage, and cough. Lumakras should be withheld if patients develop symptoms of interstitial lung disease and permanently discontinued if interstitial lung disease is confirmed. Health care professionals should monitor a patient's liver function tests prior to starting and when taking Lumakras. If a patient develops liver damage, Lumakras should be withheld, dose reduced, or permanently discontinued. Patients should avoid taking acid-reducing agents, drugs that induce or are substrates for certain enzymes in the liver, and drugs that are substrates of P-glycoprotein while taking Lumakras.

Lumakras was approved using the accelerated approval pathway. Further study is required to verify and describe anticipated clinical benefits of Lumakras. The FDA granted this application Orphan Drug, Fast Track, Priority Review, and Breakthrough Therapy designations. This review was conducted under Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among international partners. For this review, FDA collaborated with the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Regulatory Agency (ANVISA), Health Canada and Medicines and Healthcare products Regulatory Agency (MHRA; United Kingdom). The application reviews are ongoing at the other regulatory agencies. The FDA granted approval of Lumakras to Amgen, Inc.

Along with Lumakras, the FDA also approved the QIAGEN therascreen KRAS RGQ PCR kit (approval granted to QIAGEN GmbH) and the Guardant360 CDx (approval granted to Guardant Health, Inc.) as companion diagnostics for Lumakras. The QIAGEN GmbH test analyzes tumor tissue and the Guardant Health, Inc. test analyzes plasma specimens to determine if Lumakras is an appropriate treatment for patients. If no mutation is detected in a plasma specimen, the patient's tumor should be tested.

FDA NEWS RELEASE

For Immediate Release: May 26, 2021

FDA Authorizes Additional Monoclonal Antibody for Treatment of COVID-19

The FDA issued an EUA for the investigational monoclonal antibody therapy sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40kg) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death. This includes, for example, individuals who are 65 years of age and older or individuals who have certain medical conditions.

The safety and efficacy of this investigational therapy continue to be evaluated for treatment of COVID-19. Sotrovimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. This treatment has not shown benefit in patients hospitalized due to COVID-19 and monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation.

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful antigens such as viruses. Sotrovimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2 and is designed to block the virus' attachment and entry into human cells.

The issuance of an EUA is different than FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency. Based on the FDA's review of the totality of the scientific evidence available, the agency determined that it is reasonable to believe that sotrovimab may be effective in treating adults and certain pediatric patients with mild-to-moderate COVID-19. And, when used to treat COVID-19 for the authorized population, the known and potential benefits outweigh the known and potential risks for the drug. There are no adequate, approved, and available alternative treatments to sotrovimab.

The data supporting this EUA for sotrovimab are based on an interim analysis from a Phase 1/2/3 randomized, double-blind, placebo-controlled clinical study in 583 non-hospitalized adults with mild-to-moderate COVID-19 symptoms and a positive SARS-CoV-2 test result. Of these patients, 291 received sotrovimab and 292 received a placebo within 5 days of onset of COVID-19 symptoms. The primary endpoint was progression of COVID-19 (defined as hospitalization for greater than 24 hours for acute management of any illness or death from any cause) through day 29. Hospitalization or death occurred in 21 (7%) patients who received placebo compared to 3 (1%) patients treated with sotrovimab, an 85% reduction.

The FDA is carefully monitoring circulating viral variants and their sensitivity to monoclonal antibodies authorized to treat COVID-19, including sotrovimab. Laboratory testing showed that sotrovimab retains activity against the current circulating variants first reported in the United Kingdom, South Africa, Brazil, California, New York, and India.

The EUA allows for sotrovimab to be distributed and administered intravenously by health care providers as a 500mg single dose. The EUA requires that fact sheets that provide important information about using sotrovimab in treating COVID-19 be made available to health care providers and to patients, parents, and caregivers, including dosing instructions, potential side effects and drug interactions. Potential side effects of sotrovimab include anaphylaxis and infusion-related reactions, rash, and diarrhea. The EUA was issued to GlaxoSmithKline.

Current Drug Shortages Index (as of June 25, 2021):

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

Acetazolamide Injection	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Anagrelide Hydrochloride Capsules	***Currently in Shortage***
Asparaginase Erwinia Chrysanthemi (Erwinaze)	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Atropine Sulfate Ophthalmic Ointment	***Currently in Shortage***
Azacitidine 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***
Calcitriol Injection 1MCG/ML	***Currently in Shortage***
Calcium Disodium Versenate Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cefoxitin for Injection	***Currently in Shortage***
Ceftazidime and Avibactam (AVYCAZ) for Injection, 2g/0.5g	***Currently in Shortage***
Ceftolozane and Tazobactam (Zerbaxa) Injection	***Currently in Shortage***
Chlordiazepoxide Hydrochloride Capsules	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Cisatracurium Besylate Injection	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Cortisone Acetate Tablets	***Currently in Shortage***
Crisantapase (Erwinase)	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cysteamine Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol (Bal in Oil) 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, 0.1mg/mL	***Currently in Shortage***
Epinephrine Injection, Auto-Injector	***Currently in Shortage***
Famotidine Injection	***Currently in Shortage***
Famotidine Tablets	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Floxuridine for Injection	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gemifloxacin Mesylate (Factive) Tablets	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Histreline Acetate Implant	***Currently in Shortage***
Hydralazine Hydrochloride Injection	***Currently in Shortage***
Hydrocortisone Tablets	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Imipenem and Cilastatin for 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***
Letermovir (Prevymis) 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***
Lithium Oral Solution	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Loxapine Capsules	***Currently in Shortage***
Methohexital Sodium (Brevital) Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Misoprostol Tablets	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nalbuphine Hydrochloride Injection	***Currently in Shortage***

Nefazodone Hydrochloride Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Ondansetron Hydrochloride Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Pindolol Tablets	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Promethazine (Phenergan) Injection	***Currently in Shortage***
Propofol Injectable Emulsion	***Currently in Shortage***
Protamine Sulfate Injection	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sclerosol Intrapleural Aerosol	***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 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection USP, 0.9% Vials and Syringes	***Currently in Shortage***
Succimer (Chemet) Capsules	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Tacrolimus Capsules	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Teprotumumab-trbw	***Currently in Shortage***
Thiothixene Capsules	***Currently in Shortage***
Timolol Maleate Ophthalmic Gel Forming Solution	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Varenicline Tartrate (Chantix) Tablets	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***