OKLAHOMA
Health Care Authority

Drug Utilization Review Board

OHCA Webinar
Wednesday,
July 8, 2020
4:00pm

OHCA Webinar

Register for the meeting using the following website address:
https://odot.webex.com/odot/onstage/g.php?MTID=e9d464f216e5800f073f4c346d55f26c8

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Wendi Chandler, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – July 8, 2020

DATE: June 23, 2020

NOTE: In response to COVID-19, the July 2020 meeting will be held via OHCA webinar at 4:00pm. Please register for the meeting using the following website address: https://odot.webex.com/odot/onstage/g.php?MTID=e9d464f216e5800f073f4c346d55f26c8

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 Program Update – Appendix B

Action Item – Vote to Prior Authorize Wakix® (Pitolisant) – Appendix C

Action Item – Vote to Prior Authorize Secuado® (Asenapine Transdermal Patch) and Caplyta™ (Lumateperone Capsule) – Appendix D

Action Item – Vote to Prior Authorize Absorica LD™ (Isotretinoin Capsule), Amzeeq™ (Minocycline 4% Topical Foam), Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit), Caldolor® (Ibuprofen Injection), Exservan™ (Riluzole Oral Film), Metronidazole 1% Gel, Noritate® (Metronidazole 1% Cream), Procysbi® [Cysteamine Delayed-Release (DR) Granule], Pyridostigmine 30mg Tablet, Quzyttir™ (Cetirizine Injection), Relafen™ DS (Nabumetone Tablet), Slynd™ (Drospirenone Tablet), Talicia® (Omeprazole/ Amoxicillin/Rifabutin Capsule), and Tirosint® (Levothyroxine Capsule) – Appendix E

Action Item – Vote to Prior Authorize Iluvien® (Fluocinolone Intravitreal Implant), Ozurdex® (Dexamethasone Intravitreal Implant), and Retisert® (Fluocinolone Intravitreal Implant) – Appendix F

Action Item – Vote to Prior Authorize Isturisa® (Osilodrostat) – Appendix G

30-Day Notice to Prior Authorize Koselugo™ (Selumetinib), Pemazyre™ (Pemigatinib), and Qinlock™ (Ripretinib) – Appendix H

Action Item – Annual Review of Topical Corticosteroids – Appendix I

Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Tramadol 100mg Tablet – Appendix J

Annual Review of Amyloidosis Medications – Appendix K

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 8, 2020 @ 4:00pm

OHCA Webinar
Register for the meeting here:
https://odot.webex.com/odot/onstage/g.php?MTID=e9d464f216e5800f073f4c346d55f26c8

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. Call to Order

A. Roll Call – Dr. Skrepnek

Telephone Conference Participants

DUR Board Members:

Dr. Stephen Anderson –	participating via Webex Teleconference
Dr. Jennifer de los Angeles –	participating via Webex Teleconference
Ms. Jennifer Boyett –	participating via Webex Teleconference
Dr. Markita Broyles –	participating via Webex Teleconference
Dr. Theresa Garton –	participating via Webex Teleconference
Dr. Megan Hanner –	participating via Webex Teleconference
Dr. Lynn Mitchell –	participating via Webex Teleconference
Dr. John Muchmore –	participating via Webex Teleconference
Dr. Lee Muñoz –	participating via Webex Teleconference
Dr. James Osborne –	participating via Webex Teleconference

Public Access to Meeting via Webex:

Register at:
https://odot.webex.com/odot/onstage/g.php?MTID=e9d464f216e5800f073f4c346d55f26c8

Or join by phone:

Dial: +1-415-655-0002

Event number: 133 269 7414
Event password: 20200608

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 www.okhca.org/DUR 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.

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 10, 2020 DUR Minutes – Vote
B. June 10, 2020 DUR Recommendations Memorandum

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

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

A. Pharmacy Helpdesk Activity for June 2020
B. Medication Coverage Activity for June 2020
C. Chronic Medication Adherence Program Update

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

5. Action Item – Vote to Prior Authorize Wakix® (Pitolisant) – See Appendix C

A. Introduction
B. College of Pharmacy Recommendations

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

6. Action Item – Vote to Prior Authorize Secuado® (Asenapine Transdermal Patch) and Caplyta™ (Lumateperone Capsule) – See Appendix D

A. Introduction
B. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Absorica LD™ (Isotretinoin Capsule), Amzeeq™ (Minocycline 4% Topical Foam), Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit), Caldolor® (Ibuprofen Injection), Exservan™ (Riluzole Oral Film), Metronidazole 1% Gel, Noritate® (Metronidazole 1% Cream), Procysbi® [Cysteamine Delayed-Release (DR) Granule], Pyridostigmine 30mg Tablet, Quzyttir™ (Cetirizine Injection), Relafen™ DS (Nabumetone Tablet), Slynd™ (Drospirenone Tablet), Talicia® (Omeprazole/ Amoxicillin/ Rifabutin Capsule), and Tirosint® (Levothyroxine Capsule) – See Appendix E

A. Introduction
B. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Iluvien® (Fluocinolone Intravitreal Implant), Ozurdex® (Dexamethasone Intravitreal Implant), and Retisert® (Fluocinolone Intravitreal Implant) – See Appendix F

A. Introduction
B. Cost Comparison
C. College of Pharmacy Recommendations

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

9. Action Item – Vote to Prior Authorize Isturisa® (Osilodrostat) – See Appendix G

A. Introduction
B. College of Pharmacy Recommendations

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

10. 30-Day Notice to Prior Authorize Koselugo™ (Selumetinib), Pemazyre™ (Pemigatinib), and Qinlock™ (Ripretinib) – See Appendix H

A. Introduction
B. Market News and Updates
C. Product Summaries
D. Recommendations

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

11. Action Item – Annual Review of Topical Corticosteroids – 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. College of Pharmacy Recommendations
F. Utilization Details of Topical Corticosteroids

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

12. Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Tramadol 100mg Tablet – See Appendix J

A. Current Prior Authorization Criteria
B. Medicaid Drug Rebate Program
C. Utilization of Opioid Analgesics and MAT Medications
D. Prior Authorization of Opioid Analgesics and MAT Medications
E. Market News and Updates
F. College of Pharmacy Recommendations
G. Utilization Details of Opioid Analgesics
H. Utilization Details of MAT Medications

Non-Presentation Item; Questions Only:

13. Annual Review of Amyloidosis Medications – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Amyloidosis Medications
C. Prior Authorization of Amyloidosis Medications
D. Market News and Updates
E. College of Pharmacy Recommendations

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

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

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

15. Future Business* (Upcoming Product and Class Reviews)
No meeting scheduled for August 2020.

A. Synagis® (Palivizumab)
B. Sickle Cell Medications and Beta Thalassemia Medications
C. Breast Cancer Medications
D. Prostate Cancer Medications

**Future business subject to change.*

16. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF JUNE 10, 2020

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.; Clinical Pharmacist	x	
Rebekah Bargewell; Administrative Assistant		x
Wendi Chandler, Pharm.D.; Clinical Pharmacist	x	
Andrew Craig; Database Analyst	x	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Erin Ford, Pharm.D.; Clinical Pharmacist		x
Mark Fuelling; Client Support 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; Interim Director	x	
Regan Smith, Pharm.D.; Clinical Pharmacist	x	
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Brian Thomas, Pharm.D.; Clinical Pharmacist		x
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	x	
Tri Van, Pharm.D.; Pharmacy Resident	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): Stephanie Tompkins, Brandon McLaughlin	x	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony, Chief State Medicaid Director; Chief Operating Officer		x

Ellen Buettner, Chief of Staff		x
Kevin Corbett, C.P.A.; Chief Executive Officer		x
Terry Cothran, D.Ph.; Pharmacy Director	x	
Susan Eads, J.D.; Director of Litigation	x	
Stacey Hale; Drug Rebate Manager		x
Michael Herndon, D.O.; Chief Medical Officer		x
Paula Root, M.D.; Medical Director	x	
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Nathan Valentine, M.D.; Senior Medical Director	x	
Kerri Wade; Pharmacy Operations Manager	x	

OTHERS PRESENT:	
John Brunson, Amneal	Doug Pierce, GenenTech
Shelley Thompson, Alkermes	Brian Maves, Pfizer
Lee Stout, Chiesi	Marc Parker, Sunovion
Bradford Loo, Intra-Cellular Therapies	Nima Nabavi, Amgen
Shellie Keast, Mercer	Thomas Nunn, OMES
Burl Beasley, OMES	Jeff Knappen, Spark Therapeutics
Mohan Bikkina, Sandoz	Lorien Stringer, Avanir
Chris Voyiatt, ITCI	Tim Hambacher, Coherus
Rhonda Clark, Indivior	Jomy Joseph, Sanofi
Terry McCurren, Otsuka	Tom Telly, Ascendis
Dave Poskey, UCB	Kristi Kemp, Allergan
Ronald Cain, Pfizer	Jim Dunlap, PhRmA
D.R. McCale, Akcea Therapeutics	John Omick, GBT
Janie Huff, Tricida	Jim Chapman, Abbvie
Aaron Shaw, Boehringer Ingelheim	Jeff Mussack, Otuska
Audrey Rattan, Alkermes	Mark Kaiser, Otsuka
Lori Howarth, Bayer	Tara McKinley, Otsuka
Bethany Holderread, Mercer	Amanda Chancey, Aimmune Therapeutics
Brent Hildebrand, Gilead Sciences	Gibby Rodriguez, Indivior
Brett McCabe, Aimmune Therapeutics	David Large, Biohaven Pharmaceuticals
Doug Wood, ViiV Health Care	Dave Miley, Teva
Brian Lehman, Sandoz	Evie Knisley, Novartis
Dan Joy, Boehringer Ingelheim	Seth Bernstein, Allergan
Karen Hoyt	Gina Heinen, Novo Nordisk
Emily Oliphant, OUHSC	

PRESENT FOR PUBLIC COMMENT:	
Amanda Chancey	Aimmune Therapeutics
Bradford Loo	Intra-Cellular Therapies
Tara McKinley	Otsuka
Shelley Thompson	Alkermes

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

1A: ROLL CALL

Dr. Mitchell called the meeting to order. Roll call by Dr. Skrepnek established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

2A: AGENDA ITEM NO. 6 AMANDA CHANCEY

2B: AGENDA ITEM NO. 8 BRADFORD LOO
2C: AGENDA ITEM NO. 8 TARA MCKINLEY
2D: AGENDA ITEM NO. 8 SHELLEY THOMPSON
ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MEETING MINUTES
3A: MAY 13, 2020 DUR MINUTES – VOTE
3B: MAY 13, 2020 DUR RECOMMENDATIONS MEMORANDUM
Materials included in agenda packet; presented by Dr. Mitchell
Dr. Anderson moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/USE OF ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ACEI)/ANGIOTENSIN RECEPTOR BLOCKER (ARB)/ANGIOTENSIN RECEPTOR-NEPRILYSIN INHIBITOR (ARNI) THERAPY IN PATIENTS WITH CHRONIC HEART FAILURE (HF) MAILING UPDATE
4A: PHARMACY HELPDESK ACTIVITY FOR MAY 2020
4B: MEDICATION COVERAGE ACTIVITY FOR MAY 2020
4C: USE OF ACEI/ARB/ARNI THERAPY IN PATIENTS WITH CHRONIC HF MAILING SUMMARY
Materials included in agenda packet; presented by Dr. Nawaz, Dr. Van
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE ZIEXTENZO® (PEGFILGRASTIM-BMEZ)
5A: INTRODUCTION
5B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Adams
Dr. Garton moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE PALFORZIA™ (PEANUT ALLERGEN POWDER-DNFP)
6A: INTRODUCTION
6B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
Dr. Broyles moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE NOURIANZ™ (ISTRADEFYLLINE TABLET)
7A: INTRODUCTION
7B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Nawaz
Dr. Anderson moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE SECUADO® (ASENAPINE TRANSDERMAL SYSTEM) AND CAPLYTA™ (LUMATEPERONE CAPSULE)
8A: CURRENT PRIOR AUTHORIZATION CRITERIA

8B: MEDICAID DRUG REBATE PROGRAM
8C: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
8D: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
8E: MARKET NEWS AND UPDATES
8F: SECUADO® (ASENAPINE TRANSDERMAL SYSTEM) PRODUCT SUMMARY
8G: CAPLYTA™ (LUMATEPERONE CAPSULE) PRODUCT SUMMARY
8H: COLLEGE OF PHARMACY RECOMMENDATIONS
8I: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIED

<u>AGENDA ITEM NO. 9:</u> ANNUAL REVIEW OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE WAKIX® (PITOLISANT)
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: MEDICAID DRUG REBATE PROGRAM
9C: UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
9D: PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
9E: MARKET NEWS AND UPDATES
9F: WAKIX® (PITOLISANT) PRODUCT SUMMARY
9G: COST COMPARISON
9H: COLLEGE OF PHARMACY RECOMMENDATIONS
9I: UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 10:</u> ANNUAL REVIEW OF VARIOUS SPECIAL FORMULATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ABSORICA LD™ (ISOTRETINOIN CAPSULE), AMZEEQ™ (MINOCYCLINE 4% TOPICAL FOAM), APRIZIO PAK™ (LIDOCAINE/PRILOCAINE 2.5%/2.5% KIT), CALDOLOR® (IBUPROFEN INJECTION), EXSERVAN™ (RILUZOLE ORAL FILM), METRONIDAZOLE 1% GEL, NORITATE® (METRONIDAZOLE 1% CREAM), PROCYSBI® [CYSTEAMINE DELAYED-RELEASE (DR) GRANULE], PYRIDOSTIGMINE 30MG TABLET, QUZYTTIR™ (CETIRIZINE INJECTION), RELAFEN™ DS (NABUMETONE TABLET), SLYND™ (DROSPIRENONE TABLET), TALICIA® (OMEPRAZOLE/AMOXICILLIN/ RIFABUTIN CAPSULE), AND TIROSINT® (LEVOTHYROXINE CAPSULE)
10A: INTRODUCTION
10B: CURRENT PRIOR AUTHORIZATION CRITERIA
10C: UTILIZATION OF VARIOUS SPECIAL FORMULATIONS
10D: PRIOR AUTHORIZATION OF VARIOUS SPECIAL FORMULATIONS
10E: PRODUCT SUMMARIES
10F: COLLEGE OF PHARMACY RECOMMENDATIONS
10G: UTILIZATION DETAILS OF VARIOUS SPECIAL FORMULATIONS
Materials included in agenda packet; presented by Dr. Chandler
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF OPHTHALMIC ANTI-INFLAMMATORIES AND 30-DAY NOTICE TO PRIOR AUTHORIZE ILUVIEN® (FLUOCINOLONE INTRAVITREAL IMPLANT), OZURDEX® (DEXAMETHASONE INTRAVITREAL IMPLANT), AND RETISERT® (FLUOCINOLONE INTRAVITREAL IMPLANT)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF OPHTHALMIC ANTI-INFLAMMATORIES

11C: PRIOR AUTHORIZATION OF OPHTHALMIC ANTI-INFLAMMATORIES
11D: MARKET NEWS AND UPDATES
11E: ILUVIEN® (FLUOCINOLONE INTRAVITREAL IMPLANT) PRODUCT SUMMARY
11F: OZURDEX® (DEXAMETHASONE INTRAVITREAL IMPLANT) PRODUCT SUMMARY
11G: RETISERT® (FLUOCINOLONE INTRAVITREAL IMPLANT) PRODUCT SUMMARY
11H: OTHER FORMULATIONS AND COST COMPARISON
11I: COLLEGE OF PHARMACY RECOMMENDATIONS
11J: UTILIZATION DETAILS OF OPHTHALMIC NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)
11K: UTILIZATION DETAILS OF OPHTHALMIC CORTICOSTEROIDS
Materials included in agenda packet; presented by Dr. Van
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: 30-DAY NOTICE TO PRIOR AUTHORIZE ISTURISA® (OSILODROSTAT)
12A: MARKET NEWS AND UPDATES
12B: ISTURISA® (OSILODROSTAT) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Van
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: 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. 14: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
14A: TOPICAL CORTICOSTEROIDS
14B: OPIOID ANALGESIC AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
14C: AMYLOIDOSIS MEDICATIONS
14D: KOSELUGO™ (SELUMETINIB) AND PEMAZYRE™ (PEMIGATINIB)
**Future business subject to change.*
Materials included in agenda packet; Non-presentation; Questions only
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ADJOURNMENT
The meeting was adjourned at 5:21pm.

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

Memorandum

Date: June 11, 2020

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

From: Michyla Adams, Pharm.D.
Clinical Pharmacist
Pharmacy Management Consultants

Subject: Drug Utilization Review (DUR) Board Recommendations from Meeting of June 10, 2020

Recommendation 1: Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB)/ Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy in Patients with Chronic Heart Failure (HF) Mailing Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Ziextenzo® (Pegfilgrastim-bmez)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Ziextenzo® (pegfilgrastim-bmez) with the following criteria (changes are shown in red):

Fulphila® (Pegfilgrastim-jmdb), Udenyca™ (Pegfilgrastim-cbqv), and Ziextenzo® (Pegfilgrastim-bmez) Approval Criteria:

1. An FDA approved diagnosis; and

2. A patient-specific, clinically significant reason why the member cannot use Neulasta® (pegfilgrastim) or Neupogen® (filgrastim) must be provided.

Recommendation 3: Vote to Prior Authorize Palforzia™ (Peanut Allergen Powder-dnfp)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Palforzia™ (peanut allergen powder-dnfp) with the following criteria (additions to clarify approval duration are shown in red):

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

1. Member must be 4 to 17 years of age to initiate initial dose escalation (maintenance dosing may be continued for members 4 years of age and older); and
2. Member must have a diagnosis of peanut allergy confirmed by a positive skin test, positive *in vitro* test for peanut-specific IgE, or positive clinician-supervised oral food challenge; and
3. Prescriber must confirm member will use Palforzia™ with a peanut-avoidant diet; and
4. Member must not have severe uncontrolled asthma; and
5. Member must not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
6. Member must not have had severe or life-threatening anaphylaxis within the previous 60 days; and
7. Member or caregiver must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist; and
9. Prescriber, health care setting, and pharmacy must be certified in the Palforzia™ Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Palforzia™ REMS program; and
11. Palforzia™ must be administered under the direct observation of a health care provider in a REMS certified health care setting with an observation duration in accordance with the prescribing information; and
12. After successful completion of initial dose escalation and all levels of up-dosing as documented by the prescriber, initial approvals of maintenance dosing will be for 6 months. For continued approval, the member must be compliant and prescriber must verify the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the current Allergen Immunotherapies approval criteria to remove the montelukast trial requirement based on the recent FDA *Boxed Warning* (changes are shown in red):

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

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

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

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific IgE antibodies to 1 of the 5 grass pollens contained in Oralair®; and

3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    ~~b. **Montelukast:** (1) 14-day trial during a previous season in combination with an antihistamine; and~~
    c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥16 weeks prior to the start of the grass pollen season (October 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 16 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist.

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

1. Member must be 18 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific IgE antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    ~~b. **Montelukast:** (1) 14-day trial during a previous season in combination with an antihistamine; and~~
    c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and

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

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

1. Member must be 18 to 65 years of age; and
2. Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each; and
    ~~b. **Montelukast:** (1) 14-day trial in combination with an antihistamine; and~~
    c. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each; and
6. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
7. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
8. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
9. Prescriber must be an allergist, immunologist, or be an advanced care practitioner with a supervising physician that is an allergist or immunologist; and

10. A quantity limit of 1 tablet daily will apply; and
11. Initial approvals will be for the duration of 6 months of therapy, at which time the prescriber must verify the patient is responding well to Odactra® therapy. Additionally, compliance will be evaluated for continued approval.

*Current prior authorization criteria is only applicable to allergen immunotherapies with a current federal drug rebate agreement. All criteria, regardless of coverage, are provided in this report for informational purposes.

Recommendation 4: Vote to Prior Authorize Nourianz™ (Istradefylline Tablet)

MOTION CARRIED by unanimous approval.

Nourianz™ (Istradefylline Tablet) Approval Criteria:

1. An FDA approved diagnosis of Parkinson's disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with istradefylline (istradefylline has not been shown to be effective as monotherapy for the treatment of PD); and
3. Prescriber must verify that the dose is appropriate for the member based on degree of hepatic impairment, concomitant strong CYP3A4 inhibitors, and smoking status of the member; and
4. Member must be experiencing at least 2 hours of "off" time per day; and
5. A quantity limit of 1 tablet per day will apply.

Recommendation 5: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Secuado® (Asenapine Transdermal System) and Caplyta™ (Lumateperone Capsule)

NO ACTION REQUIRED.

Recommendation 6: Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Wakix® (Pitolisant)

NO ACTION REQUIRED.

Recommendation 7: Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Absorica LD™ (Isotretinoin Capsule), Amzeeq™ (Minocycline 4% Topical Foam), Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit), Caldolor® (Ibuprofen Injection), Exservan™ (Riluzole Oral Film),

Metronidazole 1% Gel, Noritate® (Metronidazole 1% Cream), Procysbi® [Cysteamine Delayed-Release (DR) Granule], Pyridostigmine 30mg Tablet, Quzyttir™ (Cetirizine Injection), Relafen™ DS (Nabumetone Tablet), Slynd™ (Drospirenone Tablet), Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule), and Tirosint® (Levothyroxine Capsule)

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Iluvien® (Fluocinolone Intravitreal Implant), Ozurdex® (Dexamethasone Intravitreal Implant), and Retisert® (Fluocinolone Intravitreal Implant)

NO ACTION REQUIRED.

Recommendation 9: 30-Day Notice to Prior Authorize Isturisa® (Osilodrostat)

NO ACTION REQUIRED.

Recommendation 10: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

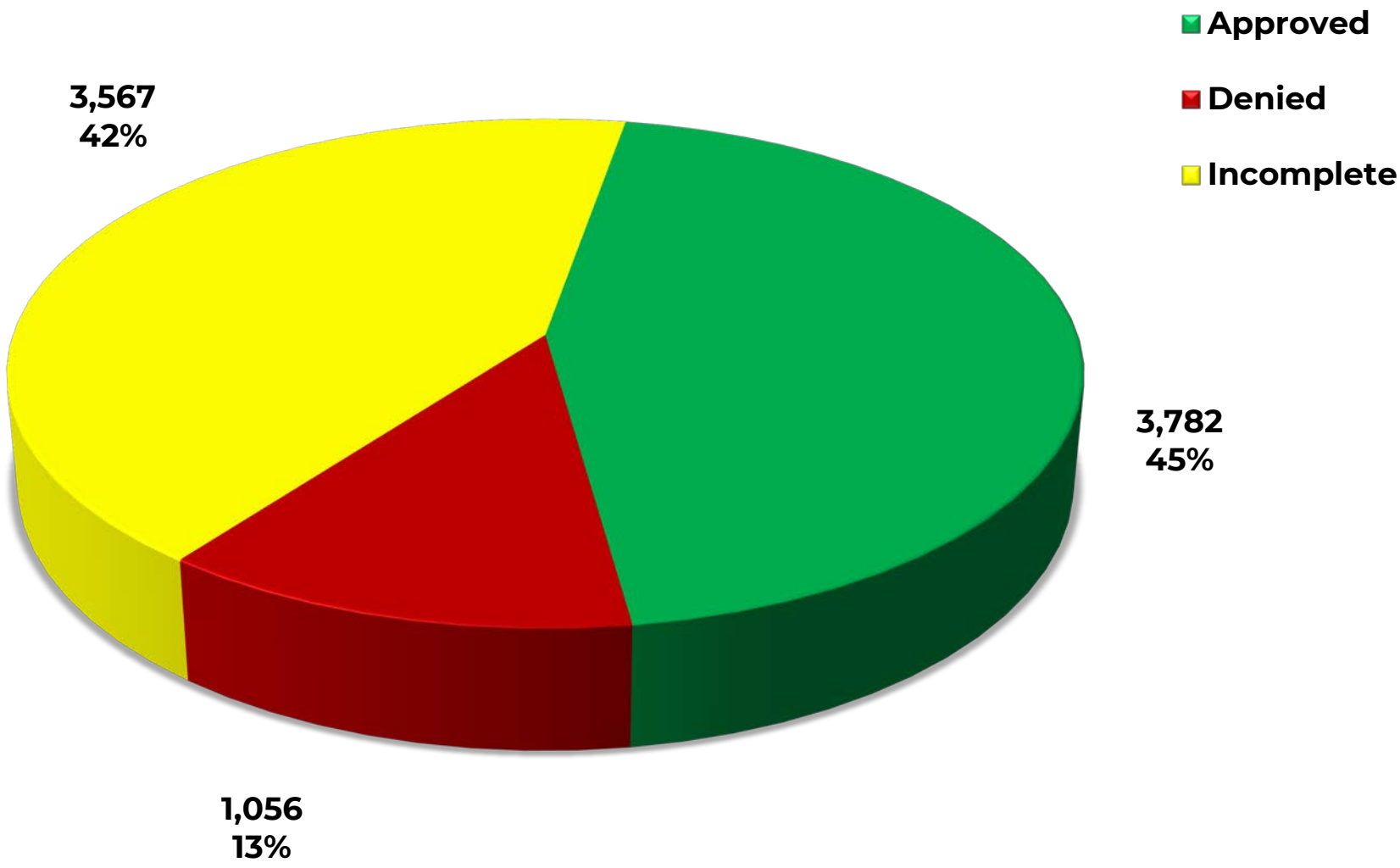
NO ACTION REQUIRED.

Recommendation 11: Future Business

NO ACTION REQUIRED.

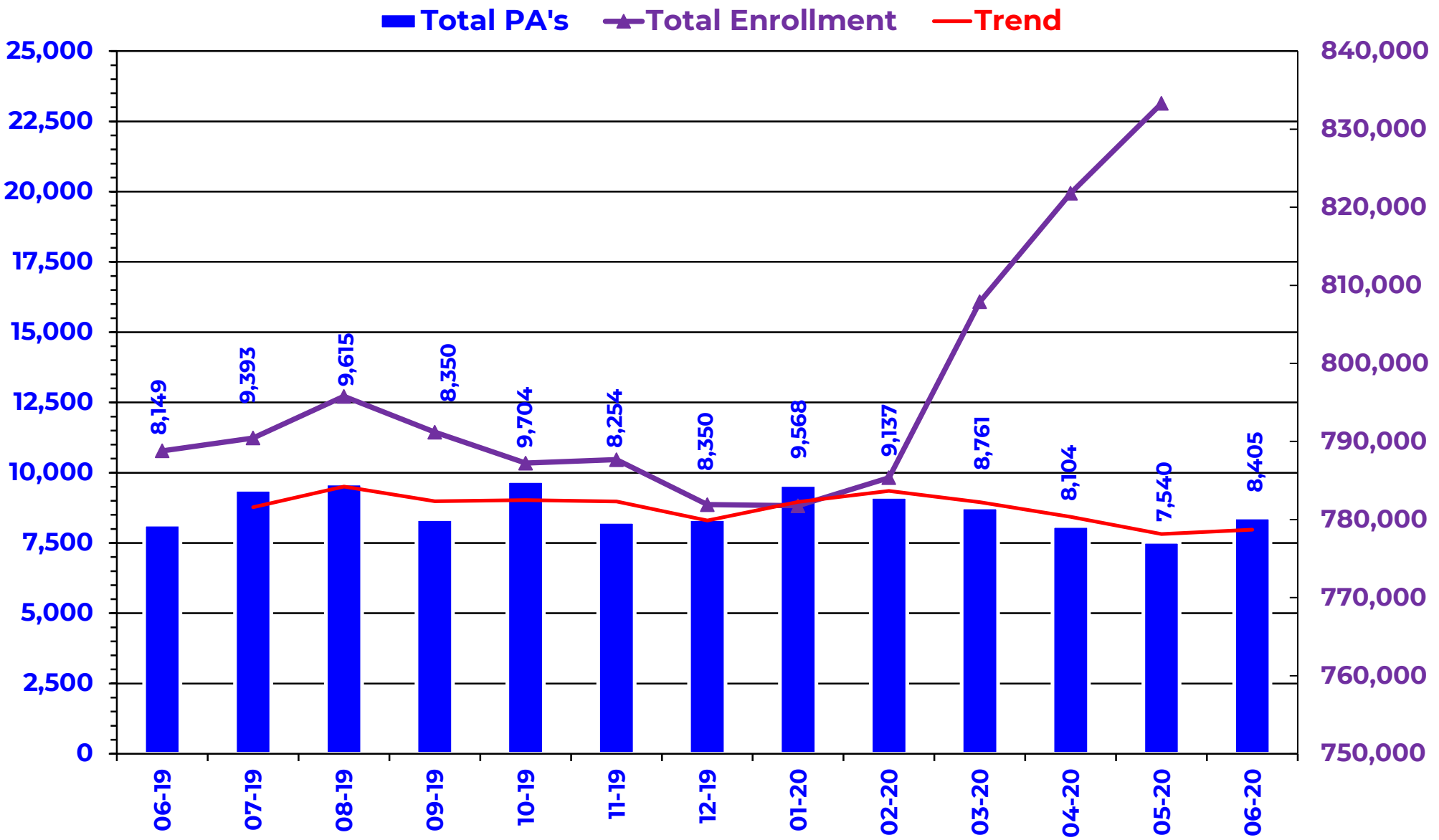
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JUNE 2020



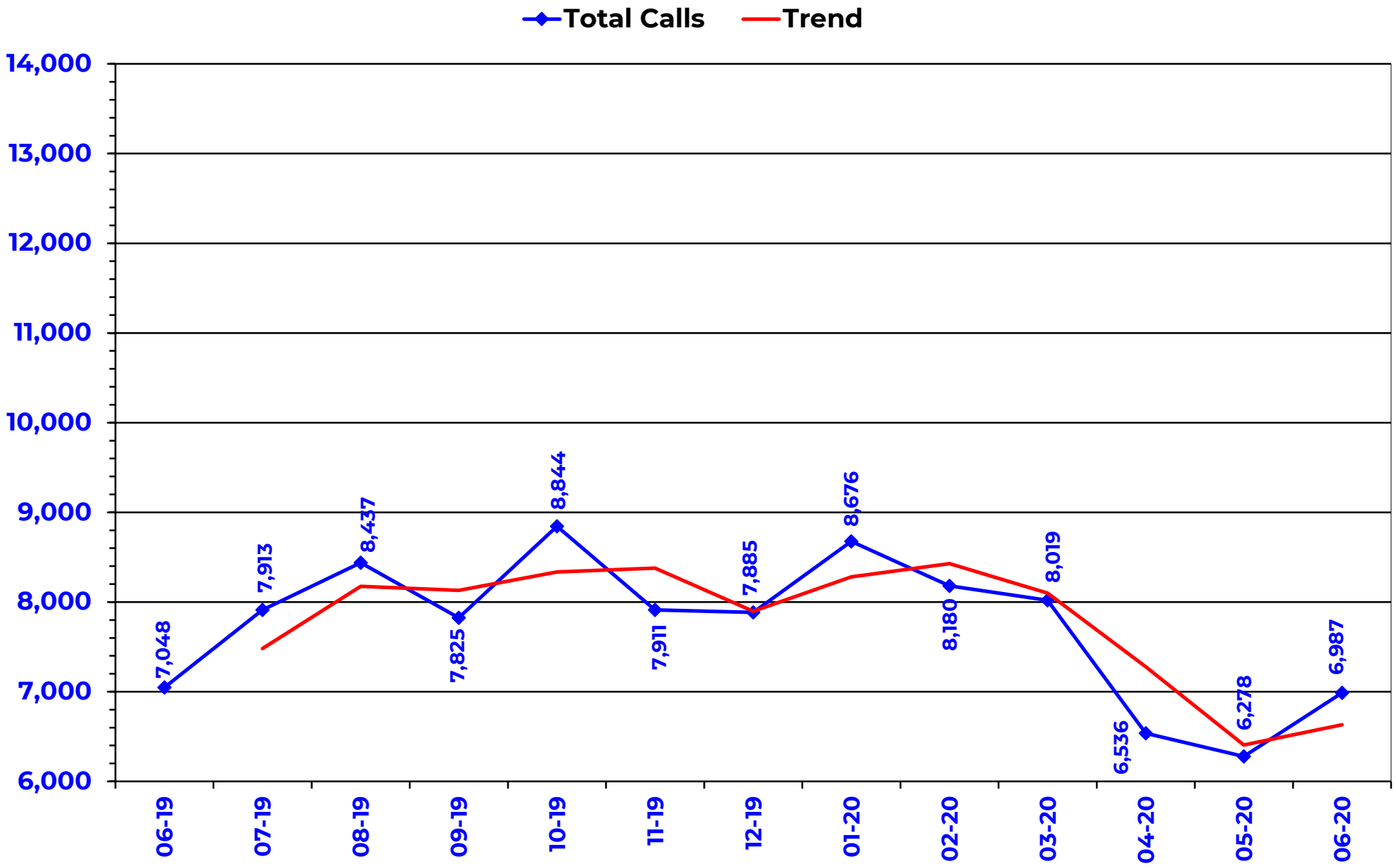
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JUNE 2019 – JUNE 2020



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JUNE 2019 – JUNE 2020



Prior Authorization Activity
6/1/2020 Through 6/30/2020

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	90	13	12	65	359
Analgesic - NonNarcotic	25	0	3	22	0
Analgesic, Narcotic	297	110	29	158	165
Antiasthma	49	18	9	22	287
Antibiotic	32	17	1	14	198
Anticonvulsant	158	65	14	79	329
Antidepressant	174	38	24	112	328
Antidiabetic	288	94	57	137	355
Antihemophilic Factor	13	8	0	5	160
Antihistamine	28	7	8	13	254
Antimalarial Agent	76	45	7	24	350
Antimigraine	162	34	58	70	220
Antineoplastic	145	91	13	41	181
Antiparasitic	16	4	1	11	9
Antiulcers	105	15	21	69	114
Anxiolytic	13	1	3	9	358
Atypical Antipsychotics	241	111	25	105	349
Biologics	186	108	17	61	292
Bladder Control	42	5	16	21	358
Blood Thinners	261	133	15	113	330
Botox	66	37	18	11	284
Buprenorphine Medications	67	8	2	57	80
Calcium Channel Blockers	19	5	3	11	182
Cardiovascular	87	23	13	51	295
Chronic Obstructive Pulmonary Disease	157	17	44	96	306
Constipation/Diarrhea Medications	166	22	59	85	254
Contraceptive	41	21	5	15	357
Dermatological	371	111	84	176	127
Diabetic Supplies	756	389	58	309	214
Diuretic	16	12	0	4	306
Endocrine & Metabolic Drugs	95	56	7	32	144
Erythropoietin Stimulating Agents	16	11	0	5	108
Fibromyalgia	20	1	2	17	358
Fish Oils	31	1	11	19	360
Gastrointestinal Agents	132	39	26	67	165
Genitourinary Agents	19	13	1	5	124
Glaucoma	14	2	2	10	190
Growth Hormones	121	80	9	32	114
Hematopoietic Agents	43	23	3	17	180
Hepatitis C	126	83	8	35	11
HFA Rescue Inhalers	21	1	0	20	77
Insomnia	34	2	7	25	132
Insulin	144	45	14	85	324
Miscellaneous Antibiotics	10	1	1	8	25
Multiple Sclerosis	34	14	6	14	228
Muscle Relaxant	40	12	9	19	98
Nasal Allergy	68	7	20	41	216
Neurological Agents	90	26	20	44	276
NSAIDs	40	1	7	32	10
Ocular Allergy	34	5	6	23	85
Other*	255	65	37	153	296

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Otic Antibiotic	31	5	2	24	10
Pediculicide	24	6	2	16	17
Respiratory Agents	42	28	0	14	247
Statins	19	4	2	13	312
Stimulant	575	290	52	233	347
Testosterone	44	10	9	25	351
Topical Antifungal	27	5	6	16	38
Topical Corticosteroids	84	0	35	49	0
Vitamin	73	27	29	17	200
Pharmacotherapy	138	125	1	12	210
Emergency PAs	0	0	0	0	
Total	**6,591**	**2,550**	**953**	**3,088**	
Overrides					
Brand	23	10	3	10	236
Compound	14	12	0	2	71
Diabetic Supplies	6	5	0	1	63
Dosage Change	345	327	1	17	14
High Dose	3	2	0	1	190
Ingredient Duplication	6	4	0	2	18
Lost/Broken Rx	97	90	2	5	18
MAT Override	235	150	4	81	67
NDC vs Age	283	160	37	86	232
NDC vs Sex	8	7	0	1	81
Nursing Home Issue	29	25	0	4	10
Opioid MME Limit	101	49	5	47	129
Opioid Quantity	38	27	1	10	177
Other*	71	57	7	7	12
Quantity vs. Days Supply	495	269	40	186	218
STBS/STBSM	23	13	3	7	71
Stolen	4	2	0	2	20
Third Brand Request	33	23	0	10	16
Overrides Total	**1,814**	**1,232**	**103**	**479**	
Total Regular PAs + Overrides	**8,405**	**3,782**	**1,056**	**3,567**	

Denial Reasons	
Unable to verify required trials.	2,873
Does not meet established criteria.	1,096
Lack required information to process request.	646
Other PA Activity	
Duplicate Requests	825
Letters	14,802
No Process	8
Changes to existing PAs	647
Helpdesk Initiated Prior Authorizations	703
PAs Missing Information	36

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

Chronic Medication Adherence Program Update

Oklahoma Health Care Authority
July 2020

Prescriber Mailing: Maintenance Diabetes and Cardiovascular Medications

The Chronic Medication Adherence (CMA) educational mailing is processed quarterly and sent to prescribers with members on chronic maintenance medications for diabetes mellitus (DM), blood pressure (BP), or cholesterol. The purpose of the CMA mailings is to encourage medication adherence and improve the quality of care for SoonerCare members on these medications.

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 patients using maintenance medications and to make their patients' adherence more convenient to track 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, and inclusion criteria required the prescriber to have at least 7 SoonerCare patients taking DM, BP, and cholesterol medications. The review period for each mailing is 1 year, and patients are assigned to prescribers if they are the last prescriber of record for a maintenance medication on SoonerCare paid pharmacy claims.

Each mailing includes a prescriber summary report with a "star rating" based on the prescriber's overall percentage of patients considered adherent to chronic maintenance medications. Adherence is estimated by measuring the proportion of days covered (PDC), or percent of days in the past year covered by prescription claims. A patient is considered adherent if their PDC is ≥80%. A patient is considered non-adherent if their PDC is <80%. A higher percentage (and corresponding star rating) is better and indicates that more of their patients are adherent to their maintenance medications. 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 only outlines CMA mailings that have included both CV and DM modules in 1 mailing.

Date Letter Processed	Total Letters Mailed	Total Members Included
February 2018*	278	7,190
May 2018	274	7,038
August 2018	272	6,900
November 2018	259	6,411
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

*CMA prescriber list updated

Star Ratings[1]

The star ratings for the percentage of patients that are adherent to CV or DM medications are based on the 2020 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.

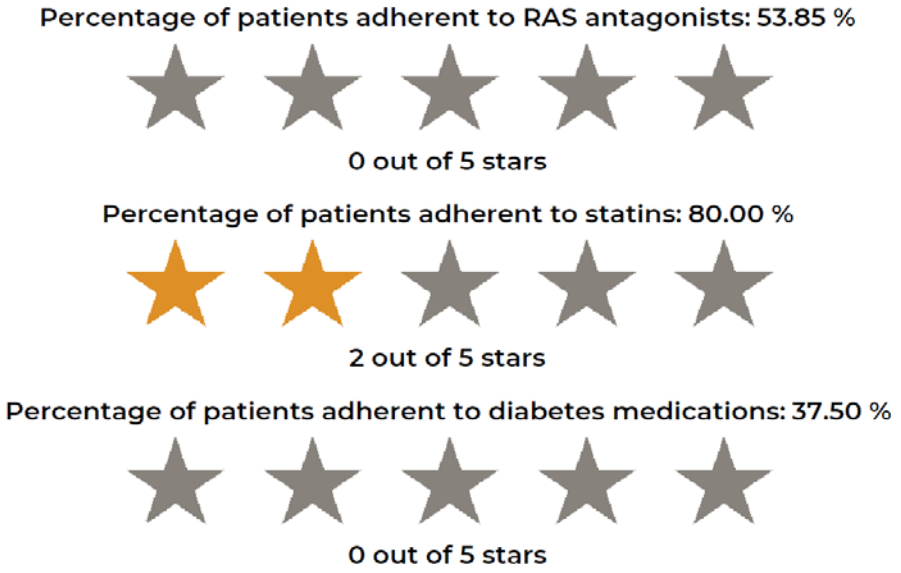
- **CV Star Ratings:** CV star ratings address adherence to maintenance renin angiotensin system (RAS) antagonists [i.e., angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), direct renin inhibitors] and HMG-CoA reductase inhibitors (i.e., statins). Adherence is shown 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 (excluding insulin and Symlin®).

Star Ratings	RAS Antagonists	Statins	Diabetes Meds
★★★★★ **5 Stars: Excellent**	≥90%	≥88%	≥88%
★★★★☆ **4 Stars: Above Average**	≥88% to <90%	≥86% to <88%	≥85% to <88%
★★★☆☆ **3 Stars: Average**	≥85% to <88%	≥83% to <86%	≥83% to <85%
★★☆☆☆ **2 Stars: Below Average**	≥83% to <85%	≥79% to <83%	≥79% to <83%
★☆☆☆☆ **1 Star: Poor**	≥60% to <83%	≥60% to <79%	≥60% to <79%
☆☆☆☆☆ **0 Stars: Very Poor**	<60%	<60%	<60%

RAS = renin angiotensin system; meds = medications

Example Star Rating

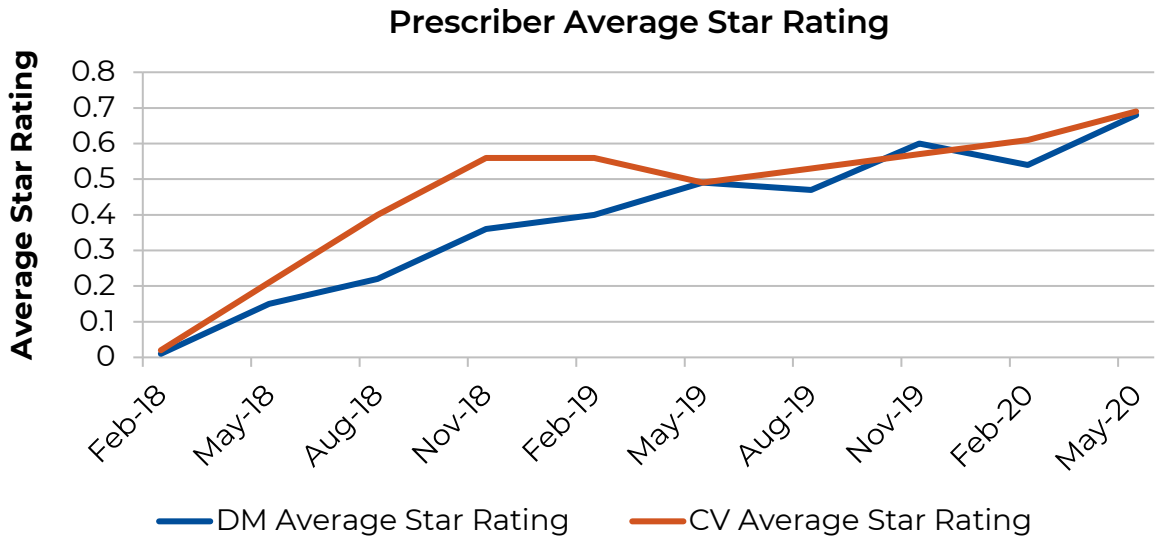
Report date: <Report Date>
Provider: <Provider Name>
NPI: <Prescriber NPI>
SoonerCare Provider ID: <Provider ID>



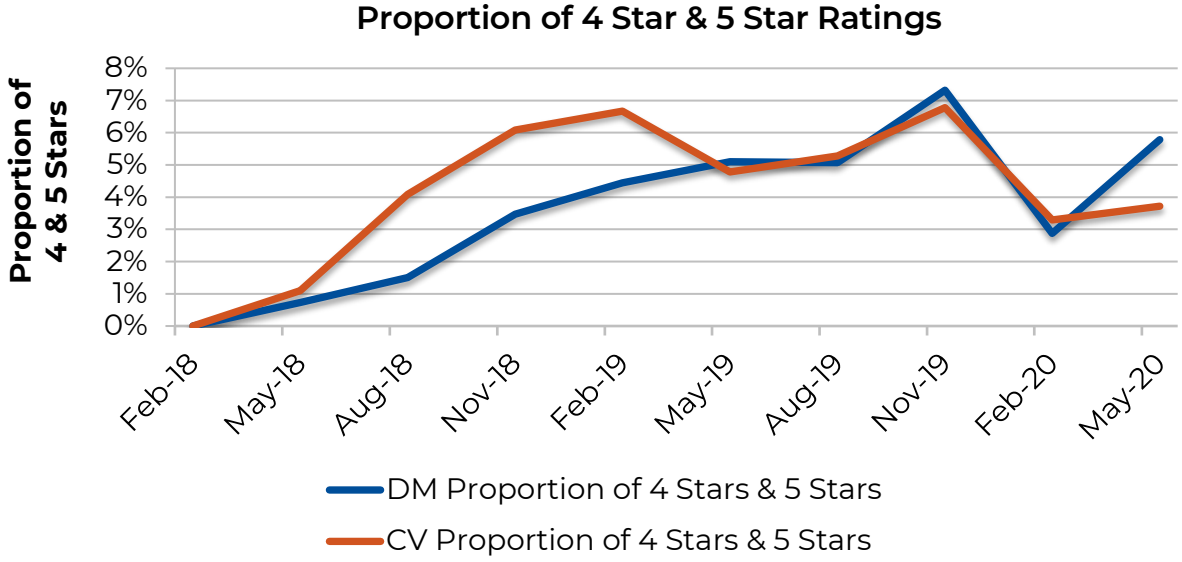
Chronic Medication Adherence Trends

The following line graph shows trends in the average star rating for prescribers included in the CMA mailing since February 2018. 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

2018 to include a larger number of prescribers as well as prescribers who were not previously receiving a mailing and was again updated in February 2020. 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.

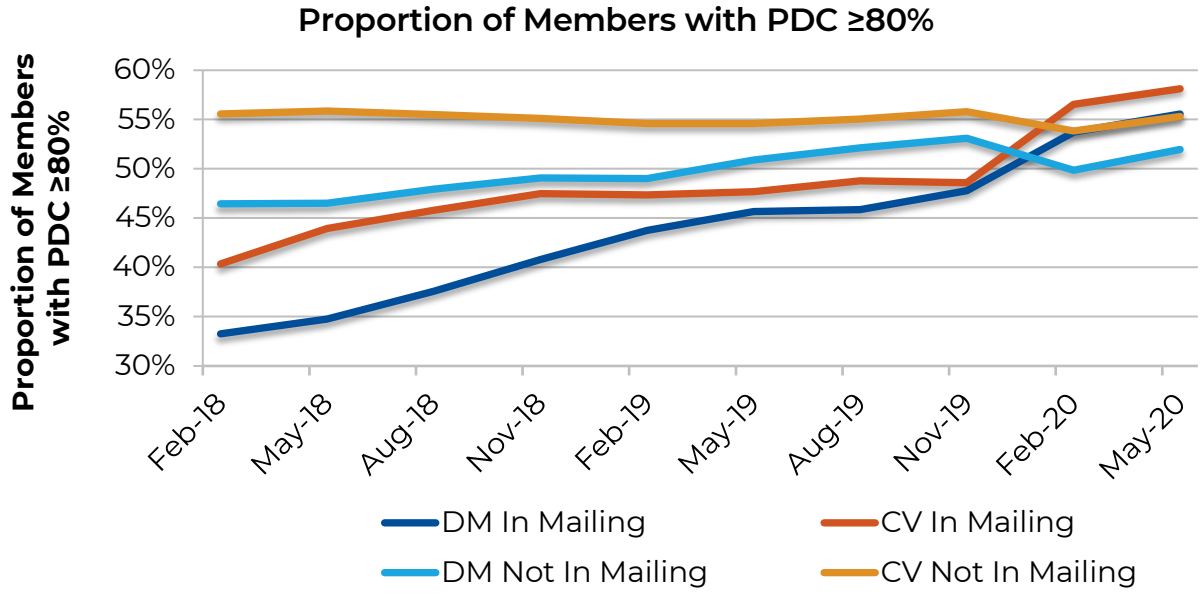


The following line graph shows trends in the proportion of prescribers with 4 star and 5 star ratings included in the CMA mailing since February 2018. An overall increase in the proportion of 4 star and 5 star ratings was seen for both mailing modules. Similar to the average star rating, while favorable 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 for both

modules since February 2018. A member is considered adherent if their PDC is ≥80%. Please note, the vertical axis starts at 30% 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 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 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 2020 Part C & D Star Rating Technical Notes*. Available online at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData. Last revised 10/01/2019. Last accessed 06/19/2020.

Appendix C

Vote to Prior Authorize Wakix® (Pitolisant)

Oklahoma Health Care Authority
July 2020

Introduction[1,2]

In August 2019, the U.S. Food and Drug Administration (FDA) approved Wakix® (pitolisant), a first-in-class medication, for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. Pitolisant is a selective histamine 3 (H_3) receptor antagonist/inverse agonist that works through a novel mechanism of action to increase the synthesis and release of histamine, a wake-promoting neurotransmitter in the brain. Pitolisant binds to the H_3 receptor with a high affinity and has no appreciable binding to other histamine receptors. Pitolisant is the first and only treatment approved by the FDA for patients with narcolepsy that is not classified as a controlled substance by the U.S. Drug Enforcement Administration (DEA).

Wakix® is supplied as 4.45mg and 17.8mg oral tablets, and following dose titration, the recommended dosage range for pitolisant is 17.8mg to 35.6mg administered once daily in the morning upon awakening. Dosage may be adjusted based on tolerability. It may take up to 8 weeks for some patients to achieve a clinical response. Dosage adjustment is recommended for concomitant use of pitolisant with strong CYP2D6 inhibitors or strong CYP3A4 inducers, in patients known to be poor CYP2D6 metabolizers, and in patients with moderate (Child-Pugh class B) hepatic impairment or with moderate [estimated glomerular filtration rate (eGFR) 30 to 59mL/min/1.73m^2] or severe (eGFR 15 to 29mL/min/1.73m^2) renal impairment (*refer to Wakix® Prescribing Information for specific dosing recommendations*). Pitolisant is contraindicated in patients with severe (Child-Pugh class C) hepatic impairment and is not recommended in patients with end stage renal disease (ESRD; eGFR <15mL/min/1.73m^2).

The efficacy of pitolisant for the treatment of EDS in adult patients with narcolepsy was evaluated in 2 multicenter, randomized, double-blind, placebo-controlled clinical studies. EDS was assessed using the Epworth Sleepiness Scale (ESS), an 8-item questionnaire by which patients rate their perceived likelihood of falling asleep during usual daily life activities. In both studies, pitolisant demonstrated statistically significantly greater improvement in the least square mean final ESS score compared to placebo. The Wholesale Acquisition Cost (WAC) of Wakix® (pitolisant) is $94.75 per 4.45mg tablet and $189.50 per 17.8mg tablet, resulting in an annual cost of $136,440.00 at the maximum dose of 35.6mg [(2) 17.8mg tablets] once daily.

Cost Comparison

Medication	Current Tier Placement	Cost Per Unit	Cost Per Month*
methylphenidate 5mg chewable tablet	Special PA	$1.98	$118.80
methylphenidate 5mg/5mL oral solution	Special PA	$0.13	$39.00
methylphenidate 5mg tablet	Tier-1	$0.10	$6.00
dexmethylphenidate 5mg tablet	Tier-1	$0.16	$9.60
methylphenidate 10mg chewable tablet	Special PA	$4.92	$295.20
methylphenidate 10mg/5mL oral solution	Special PA	$0.09	$27.00
methylphenidate 10mg tablet	Tier-1	$0.13	$7.80
dexmethylphenidate 10mg tablet	Tier-1	$0.30	$18.00

PA = prior authorization; Unit = chewable tablet, milliliter, or tablet
*Cost per month is based on twice daily (BID) dosing (5mg BID for the 5mg strengths and 10mg BID for the 10mg strengths).
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Recommendations

The College of Pharmacy recommends following changes to the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following Tier chart and approval criteria; only criteria and Tier chart with changes are listed):

1. The prior authorization of Wakix® (pitolisant) in the Narcolepsy Medications category
    a. Criteria similar to the current approval criteria for Sunosi™ (solriamfetol) and Xyrem® (sodium oxybate) will apply
2. Moving methylphenidate oral solution to Tier-1 in the ADHD Medications Tier chart based on cost
    a. The brand formulation of Methylin® oral solution will no longer be preferred over the generic formulation
    b. 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			
Methylphenidate Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Short-Acting			
dexmethylphenidate tab (Focalin®)			methylphenidate ~~**soln and**~~ chew tab (Methylin®)
methylphenidate tab **and soln** (Methylin®)			
methylphenidate tab (Ritalin®)			
Long-Acting			
dexmethylphenidate ER cap (Focalin XR®) brand name only	dexmethylphenidate ER cap (generic Focalin XR®)	methylphenidate ER cap (Adhansia XR™)	methylphenidate ER ODT (Cotempla XR-ODT®)
methylphenidate ER cap (Aptensio XR®)	methylphenidate ER susp (Quillivant XR®)	methylphenidate ER cap (Jornay PM®)	methylphenidate ER patch (Daytrana®)
methylphenidate ER cap (Metadate CD®)		methylphenidate 72mg ER tab	
methylphenidate ER cap (Ritalin LA®)		methylphenidate ER tab (Concerta®)	
methylphenidate ER chew tab (QuilliChew ER®)		methylphenidate ER tab (Metadate ER®)	
		methylphenidate ER tab (Methylin ER®)	
		methylphenidate ER tab (Ritalin SR®)	

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable. Placement of products shown in blue is based on net cost after rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ADHD = attention-deficit/hyperactivity disorder; PA = prior authorization; ER = extended-release; cap = capsule; tab = tablet; ODT = orally disintegrating tablet; chew tab = chewable tablet; soln = solution; susp = suspension

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. 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.
2. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Daytrana®, 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.

3. Methylin® Chewable Tablets ~~and Solution~~ 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. Use of Methylin® chewable tablets or generic Methylin® solution will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of Methylin® solution (brand name Methylin® solution is the preferred product); and~~
   d. 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 Methylin® oral solution, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
   a. An FDA approved diagnosis of moderate-to-severe BED; and
   b. Member must be 18 years of age or older; and
   c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and

d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
e. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
   a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
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; and
4. Use of Sunosi™ (solriamfetol), Wakix® (pitolisant), or Xyrem® (sodium oxybate) 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. The diagnosis of obstructive sleep apnea requires concurrent treatment for the obstructive sleep apnea; and
6. 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] Harmony Biosciences. Harmony Biosciences Announces FDA Approval of Wakix® (Pitolisant). *Narcolepsy Network*. Available online at: https://narcolepsynetwork.org/pitolisant-fda-approval/. Issued 08/16/2019. Last accessed 06/16/2020.

[2] Wakix® (Pitolisant) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8daa5562-824e-476c-9652-26ceef3d4b0e. Last revised 11/06/2019. Last accessed 06/16/2020.

Appendix D

Vote to Prior Authorize Secuado® (Asenapine Transdermal System) and Caplyta™ (Lumateperone Capsule)

Oklahoma Health Care Authority
July 2020

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

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

- **Secuado® (Asenapine Transdermal System):** In October 2019, the FDA approved Secuado® (asenapine transdermal system), the first and only transdermal patch formulation for the treatment of adult patients with schizophrenia. Secuado® is supplied as a once daily transdermal system that provides sustained concentrations of asenapine over 24 hours in 3 strengths: 3.8mg/24 hours, 5.7mg/24 hours, and 7.6mg/24 hours. The recommended regimen is 1 transdermal system applied every 24 hours, and Secuado® may be applied to 1 of the following sites: hip, abdomen, upper arm, or upper back area. The recommended starting dose of Secuado® is 3.8mg/24 hours. The strength may be increased to 5.7mg/24 hours or 7.6mg/24 hours after 1 week. Asenapine is also available as a sublingual (SL) tablet, Saphris®, which was first FDA approved in 2009. Based on the average exposure [area under the curve (AUC)] of asenapine, Secuado® 3.8mg/24 hours corresponds to 5mg twice daily of SL asenapine and Secuado® 7.6mg/24 hours corresponds to 10mg twice daily of SL asenapine. The systemic safety profile of Secuado® was consistent with what is known for SL asenapine. Secuado® has a *Boxed Warning* for increased mortality in elderly patients with dementia-related psychosis treated with antipsychotic drugs. Secuado® is not approved for the treatment of patients with dementia-related psychosis. The efficacy of Secuado® was established, in part, on the basis of efficacy data from studies with the SL formulation of asenapine (Saphris®). In addition, the efficacy of Secuado® was evaluated in a 6-week, fixed-dose, randomized, double-blind, placebo-controlled study of 607 adult patients with schizophrenia. The Positive and Negative Syndrome Scale (PANSS) rating scale was used as the primary efficacy measure. The placebo-subtracted difference in the change from baseline in the PANSS total score was -6.6 [95% confidence interval (CI): -9.81, -3.40] for Secuado® 3.8mg/24 hours and -4.8 (95% CI: -8.06, -1.64) for Secuado® 7.6mg/24 hours. The Wholesale Acquisition Cost (WAC) of Secuado® for all strengths is $14,400 per year, compared to the National Average Drug

Acquisition Cost (NADAC) of Saphris® 10mg twice daily at $13,795.20 per year.

- **Caplyta™ (Lumateperone Capsule):** In December 2019, the FDA approved once daily Caplyta™ (lumateperone capsule) for the treatment of schizophrenia in adult patients. Caplyta™ is available as a 42mg oral capsule, and the recommended regimen is 42mg once daily with food. The exact mechanism of action of Caplyta™ in the treatment of schizophrenia is unknown; however, it may be mediated through a combination of antagonist activity at central serotonin 2A ($5\text{-}HT_{2A}$) receptors and postsynaptic antagonist activity at central dopamine 2 (D_2) receptors. Caplyta™ has a *Boxed Warning* for increased mortality in elderly patients with dementia-related psychosis treated with antipsychotic drugs. Caplyta™ is not approved for the treatment of patients with dementia-related psychosis. In pooled data from short-term studies, mean changes from baseline in weight gain, fasting glucose, triglycerides, and total cholesterol were similar between Caplyta™ and placebo. The incidence of extrapyramidal symptoms was 6.7% for Caplyta™ and 6.3% for placebo. Caplyta™ is also being developed for the treatment of bipolar depression, behavioral disturbances in patients with dementia (including Alzheimer's disease), depression, and other neuropsychiatric and neurological disorders. In March 2020, Intra-Cellular Therapies announced that Caplyta™ is now available to pharmacies. The annual WAC of Caplyta™ is $15,840 compared to risperidone 3mg twice daily, another FDA approved treatment option for schizophrenia, with a NADAC of $50.40 per year.

Recommendations

The College of Pharmacy recommends the placement of Secuado® (asenapine transdermal system) and Caplyta™ (lumateperone capsule) into Tier-3 of the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) Tier chart. Current Tier-3 criteria will apply, and Secuado® will also require additional criteria (changes shown in red in the following Tier chart and Tier-3 Approval Criteria):

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®)

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole lauroxil IM inj (Aristada Initio®)		cariprazine (Vraylar®)
clozapine (Clozaril®)◊		clozapine (Fazaclo®)+
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®)		paliperidone (Invega®)
risperidone (Risperdal®)		
risperidone IM inj (Risperdal Consta®)		
risperidone ER sub-Q inj (Perseris™)		
ziprasidone (Geodon®)		

ER = extended-release; IM = intramuscular; inj = injection; susp = suspension; sub-Q = subcutaneous
*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable. Placement of products shown in blue is based on net cost after 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.
^In addition to the Tier-3 criteria requirements, approval of olanzapine/fluoxetine (Symbyax®) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

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) and 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.

[1] Secuado® Prescribing Information. Noven Therapeutics. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=685eaf44-5944-4f38-afba-0a4fc0b3462b. Last revised 10/2019. Last accessed 06/17/2020.
[2] Noven Pharmaceuticals. U.S. FDA Approves Secuado® (Asenapine) Transdermal System, the First-and-Only Transdermal Patch, for the Treatment of Adults with Schizophrenia. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20191015005668/en/U.S.-FDA-Approves-SECUADO%C2%AE-asenapine-Transdermal-System. Issued 10/15/2019. Last accessed 06/17/2020.
[3] Intra-Cellular Therapies. FDA Approves Intra-Cellular Therapies' Novel Antipsychotic, Caplyta™ (Lumateperone) for the Treatment of Schizophrenia in Adults. *Globe Newswire*. Available online at: https://ir.intracellulartherapies.com/node/10691/pdf. Issued 12/23/2019. Last accessed 06/17/2020.
[4] Intra-Cellular Therapies. Intra-Cellular Therapies Announces Availability of Caplyta™ (Lumateperone) for Adult Patients with Schizophrenia. *Globe Newswire*. Available online at: https://ir.intracellulartherapies.com/news-releases/news-release-details/intra-cellular-therapies-announces-availability-caplytatm. Issued 03/23/2020. Last accessed 06/17/2020.
[5] Caplyta™ Prescribing Information. Intra-Cellular Therapies. Available online at: https://www.intracellulartherapies.com/docs/caplyta_pi.pdf. Last revised 12/2019. Last accessed 06/17/2020.

Appendix E

Vote to Prior Authorize Absorica LD™ (Isotretinoin Capsule), Amzeeq™ (Minocycline 4% Topical Foam), Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit), Caldolor® (Ibuprofen Injection), Exservan™ (Riluzole Oral Film), Metronidazole 1% Gel, Noritate® (Metronidazole 1% Cream), Procysbi® [Cysteamine Delayed-Release (DR) Granule], Pyridostigmine 30mg Tablet, Quzyttir™ (Cetirizine Injection), Relafen™ DS (Nabumetone Tablet), Slynd™ (Drospirenone Tablet), Talicia® (Omeprazole/ Amoxicillin/Rifabutin Capsule), and Tirosint® (Levothyroxine Capsule)

Oklahoma Health Care Authority
July 2020

Introduction[1,2,3,4,5,6,7,8,9,10,11,12,13,14]

Absorica LD™ (isotretinoin capsule) is a retinoid indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater. Absorica LD™ is supplied as liquid-filled, oral capsules containing micronized isotretinoin in suspension available in 6 strengths: 8mg, 16mg, 20mg, 24mg, 28mg, and 32mg. The recommended dose is 0.4 to 0.8mg/kg/day given in 2 divided doses for 15 to 20 weeks and may be taken with or without a meal. Absorica LD™ is not substitutable with Absorica® because of different bioavailability and recommended dosages. Lipid abnormalities and hepatoxicity have been reported with isotretinoin use. Due to these risks, a fasting lipid profile and liver function tests are recommended prior initiating treatment with Absorica LD™ and at regular intervals during treatment. Additionally, Absorica LD™ has a *Boxed Warning* for its contraindication in pregnancy and is only available through a Risk Evaluation and Mitigation Strategy (REMS) program called the iPLEDGE REMS.

- Other Formulation(s) Available: generic isotretinoin capsules

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days	Cost Per 20 Weeks
Absorica LD™ (isotretinoin) 24mg capsule	**$38.13**	**$4,270.56**	**$21,352.80**
isotretinoin 30mg capsule (generic)	$5.12	$573.44	$2,867.20

Unit = capsule
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
Cost for both products based on maximum FDA recommended dose for a 60kg patient.

Amzeeq™ (minocycline 4% topical foam) is a tetracycline-class drug indicated to treat inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older. Amzeeq™ is supplied as a 4% topical foam available in a 30g aluminum can. The recommended dosing is to apply a small amount of topical foam onto the fingertips of the hand and then onto acne-affected area(s) once daily. Amzeeq™ should be applied at approximately the same time each day at least 1 hour before bedtime.

- Other Formulation(s) Available: erythromycin 2% topical solution and clindamycin 1% topical solution

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Amzeeq™ (minocycline) 4% topical foam	**$15.59**	**$467.70**
erythromycin 2% topical solution (generic)	$0.46	$27.60
clindamycin 1% topical solution (generic)	$0.23	$13.80

Unit = gram or milliliter (mL)
*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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Aprizio Pak™ (lidocaine/prilocaine 2.5%/2.5% kit) is indicated as a topical anesthetic for use on normal intact skin for local analgesia and genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia. Aprizio Pak™ is supplied as a kit containing (3) 30g tubes of lidocaine/prilocaine 2.5%/2.5% cream, (20) 6x7cm frame style transparent dressings, and 1 pair of disposable medical scissors. The recommended dosing is based on the procedure, location of the procedure, and patient age (patient weight is also considered for pediatric patients).

- Other Formulation(s) Available: lidocaine/prilocaine 2.5%/2.5% cream

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Aprizio Pak™ (lidocaine/prilocaine) 2.5%/2.5% kit	**$1,350.86**	**$1,350.86**
lidocaine/prilocaine 2.5%/2.5% cream (generic)	$0.25	$22.50

Unit = gram
*Cost per package for lidocaine/prilocaine 2.5%/2.5% cream (generic) based on (3) 30g tubes as supplied in Aprizio Pak™.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Caldolor® [ibuprofen (IBU) injection] is a non-steroidal anti-inflammatory drug (NSAID) indicated in adult and pediatric patients 6 months of age and older for the management of mild-to-moderate pain, the management of

moderate-to-severe pain as an adjunct to opioid analgesics, and the reduction of fever. Caldolor® is supplied as an injection for intravenous (IV) use and is available in 800mg/8mL single-dose vials (SDV), which require dilution before use, and 800mg/200mL single-dose, ready-to-use, polypropylene flexible bags. The recommended dose varies based on patient age and indication and ranges from 100mg every 4 hours as needed to 800mg every 6 hours as needed.

- Other Formulation(s) Available: IBU oral formulations [prescription (Rx) and over-the-counter (OTC) strengths]

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Day*
Caldolor® (IBU) injection 800mg/8mL SDV	**$17.36**	**$69.44**
IBU 800mg tablet (Rx)	$0.09	$0.36
IBU 400mg tablet (Rx)	$0.05	$0.40
IBU 200mg tablet (OTC)	$0.06⁺	$0.96⁺

IBU = ibuprofen; SDV = single-dose vial; Unit = SDV or tablet; Rx = prescription strength; OTC = over-the-counter strength
*Cost per day based on maximum recommended adult dose of 3,200mg.
⁺Cost for ibuprofen 200mg tablet (OTC) based on price available as of 05/15/2020 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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Exservan™ (riluzole oral film) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) and is supplied as a rectangular-shaped, orally-dissolving film containing 50mg of riluzole. The recommended dose is 50mg twice daily, 1 hour before or 2 hours after a meal. Exservan™ should be applied to the top of the tongue to adhere and dissolve; films should not be cut or split.

- Other Formulation(s) Available: riluzole tablets and Tiglutik® (riluzole oral suspension)

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Exservan™ (riluzole) 50mg oral film	**Unavailable**	**Unavailable**
Tiglutik® (riluzole) 50mg/10mL oral suspension	$5.41	$3,246.00
riluzole 50mg tablet (generic)	$1.40	$84.00

Unit = film, mL, tablet
*Cost per 30 days based on recommended dosing of 50mg twice daily.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Metronidazole 1% gel is indicated for the topical treatment of inflammatory lesions of rosacea and is supplied as a clear, colorless to pale yellow gel containing 10mg of metronidazole per gram. Metronidazole 1% gel is available in a 60g tube and a 55g pump, and both the 60g tube and 55g pump are available as generics. The recommended dosing is to apply a thin layer to the affected area(s) once daily.

- Other Formulation(s) Available: metronidazole 0.75% gel

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
metronidazole 1% gel (generic)	**$1.70**	**$102.00**
metronidazole 0.75% gel (generic)	$0.96	$43.20

Unit = gram
*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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Noritate® (metronidazole 1% cream) is indicated for the topical treatment of inflammatory lesions and erythema of rosacea. Noritate® is an emollient cream with each gram containing 10mg of micronized metronidazole and is supplied in a 60g tube. The recommended dosing is to apply and rub in a thin layer to the affected area(s) once daily.

- Other Formulation(s) Available: metronidazole 0.75% cream

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Package*
Noritate® (metronidazole) 1% cream	**$32.61**	**$1,956.60**
metronidazole 0.75% cream (generic)	$1.12	$50.40

Unit = gram
*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) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Procysbi® (cysteamine DR granule) is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older. Procysbi® granules are supplied in single-use packets available in 2 strengths: 75mg and 300mg. The recommended maintenance dose is 1.3g/m^2/day in 2 divided doses given every 12 hours with a maximum recommended dose of 1.95g/m^2/day. Prior to administration, the granules should be sprinkled onto applesauce, berry jelly, or fruit juice (except grapefruit juice), and mixed. For patients with a gastrostomy tube, the oral granules can be mixed in applesauce and administered via a gastrostomy tube. The entire contents should be consumed within 30 minutes of mixing, and the granules should not be crushed or chewed.

- Other Formulation(s) Available: Procysbi® DR capsules and Cystagon® immediate-release (IR) capsules

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Procysbi® (cysteamine) 300mg DR granule	**$405.28**	**$48,633.60**
Procysbi® (cysteamine) 75mg DR capsule	$101.32	$48,633.60
Cystagon® (cysteamine) 150mg IR capsule	$1.28	$307.20

Unit = granule packet or capsule; DR = delayed-release; IR = immediate-release
*Cost per 30 days based on recommended maintenance dose from dosing charts in the *Prescribing Information* for a 23kg patient.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Pyridostigmine 30mg tablet is indicated for the treatment of myasthenia gravis. The recommended dose is 600mg/day [(20) 30mg tablets] spaced throughout the day to provide maximum relief. Severe cases may require a dose of 1,500mg/day [(50) 30mg tablets], while mild cases may be treated with 60mg to 360mg/day.

- Other Formulation(s) Available: pyridostigmine 60mg tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
pyridostigmine 30mg tablet (generic)	**$6.96**	**$4,176.00**
pyridostigmine 60mg tablet (generic)	$0.37	$111.00

Unit = tablet
*Cost per 30 days based on the recommended dose of 600mg per day.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Quzyttir™ (cetirizine injection) is a histamine-1 (H_1) receptor antagonist indicated for the treatment of acute urticaria in adults and children 6 months of age and older. Quzyttir™ is supplied as 10mg/mL aqueous solution for IV administration (via IV push over 1 to 2 minutes) and is available in 2mL SDVs. The recommended dose is once every 24 hours as needed and ranges from 2.5mg to 10mg depending on the patient's age.

- Other Formulation(s) Available: cetirizine 5mg and 10mg tablets and cetirizine 1mg/mL oral solution

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Dose*
Quzyttir™ (cetirizine) 10mg/mL injection	**$300.00**	**$300.00**
cetirizine 10mg tablet (generic)	$0.07	$0.28
cetirizine 5mg tablet (generic)	$0.06	$0.48
cetirizine 1mg/mL oral solution (generic)	$0.04	$1.60

Unit = mL or tablet
*Cost per dose based on maximum recommended adult dose for acute urticaria (per guidelines for generic tablets and solution; per *Prescribing Information* for Quzyttir™).
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Relafen™ DS (nabumetone tablet) is an NSAID indicated for the relief of signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA) in adults and is supplied as 1,000mg white, coated, modified capsule-shaped tablets that are scored on 1 side. The recommended starting dose is 1,000mg taken as a single dose with or without food. The dose may be increased to 1,500mg per day or to a maximum recommended dose of 2,000mg per day as either a once or twice daily dose.

- Other Formulation(s) Available: nabumetone 500mg and 750mg tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Relafen™ DS (nabumetone) 1,000mg tablet	**$40.32**	**$1,814.40**
nabumetone 750mg tablet (generic)	$0.34	$20.40
nabumetone 500mg tablet (generic)	$0.24	$21.60

Unit = tablet
*Cost per 30 days based on dose of 1,500mg per day.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Slynd™ (drospirenone tablet) is a progestin-only oral contraceptive indicated for use by females of reproductive potential to prevent pregnancy. Slynd™ is supplied as white round, active film-coated tablets, each containing 4mg of drospirenone and green round, inert film-coated tablets that do not contain drospirenone. The tablets are available in blister cards that contain 24 active tablets and 4 inactive tablets. The recommended dose is to take 1 tablet daily for 28 consecutive days at the same time each day.

- Other Formulation(s) Available: norethindrone 0.35mg tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days
Slynd™ (drospirenone) 0.4mg tablet	**$6.61**	**$185.08**
norethindrone 0.35mg tablet (generic)	$0.22	$6.16

Unit = tablet
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Talicia® (omeprazole/amoxicillin/rifabutin capsule) is a 3-drug combination of omeprazole (a proton pump inhibitor), amoxicillin (a penicillin-class antibacterial), and rifabutin (a rifamycin antibacterial) indicated for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults. Talicia® is supplied as DR capsules containing omeprazole 10mg, amoxicillin 250mg, and rifabutin 12.5mg. The recommended dosing is 4 capsules every 8 hours for 14 days with food. Each dose (4 capsules) includes omeprazole 40mg, amoxicillin 1,000mg, and rifabutin 50mg.

- Other Formulation(s) Available: omeprazole 20mg DR capsules, amoxicillin 500mg capsules, and clarithromycin 500mg tablets†

†Clarithromycin 500mg tablet is being reviewed in place of rifabutin as rifabutin alone is only available as a 150mg capsule which is not currently indicated for the treatment of *H. pylori* infection.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Regimen*
Talicia® (omeprazole/amoxicillin/rifabutin) capsule	**$3.87**	**$650.16**
omeprazole 20mg capsule (generic)	$0.04	$0.80
amoxicillin 500mg capsule (generic)	$0.06	$2.40
clarithromycin 500mg tablet (generic)	$0.54	$10.80

Unit = capsule or tablet
*Cost per regimen based on recommended dosing and duration for *H. Pylori* treatment for product listed.
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Tirosint® (levothyroxine capsule) is L-thyroxine (T_4) indicated for hypothyroidism and pituitary thyrotropin (thyroid-stimulating hormone, TSH) suppression and is supplied as amber-colored, round/biconvex capsules that contain a viscous, amber-colored liquid. Tirosint® is available in 12 strengths ranging from 13mcg to 200mcg and the capsules are imprinted with a dosage strength specific letter on 1 side. The recommended dosing is once daily, on an empty stomach, 1/2 to 1 hour before breakfast. Tirosint® 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.

- Other Formulation(s) Available: levothyroxine tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Tirosint® (levothyroxine) capsule	**$4.24 - $4.44**	**$127.20 - $133.20**
levothyroxine tablet (generic)	$0.23 - $0.52	$6.90 - $15.60

Unit = capsule or tablet
Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Recommendations

The College of Pharmacy recommends the following changes to current Various Special Formulations approval criteria based on cost and product availability (changes shown in red):

1. Adding erythromycin 2% swabs to the current erythromycin 2% topical gel approval criteria based on Wholesale Acquisition Cost (WAC); and
2. Removing the potassium chloride 25mEq packet (Klor-Con®, Epiklor®) approval criteria based on product discontinuation.

~~**Erythromycin 2% Swabs Approval Criteria:**~~

~~1. Approval consideration requires a trial of erythromycin 2% topical solution or gel.~~

Erythromycin 2% Swabs and 2% Topical Gel Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution must be provided.

~~**Potassium Chloride 25mEq Packet (Klor-Con®, Epiklor®) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason why the member cannot use other non-prior authorized formulations of potassium chloride must be provided.~~

Additionally, the College of Pharmacy recommends the prior authorization of Absorica LD™ (isotretinoin capsule) with the addition of an upper age limit shown in red to be consistent with other acne products, Amzeeq™ (minocycline 4% topical foam), and Aprizio Pak™ (lidocaine/prilocaine 2.5%/2.5% kit) with the following criteria:

Absorica LD™ (Isotretinoin Capsule) Approval Criteria:

1. An FDA approved diagnosis of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater; and

2. Absorica LD™ is not covered for members older than 20 years of age; and
3. Prescriber must verify member is enrolled in the iPLEDGE REMS program; and
4. Prescriber must verify lipid profile and liver function tests will be monitored prior to initiation of Absorica LD™ and at regular intervals during treatment in accordance with the prescribing information; and
5. A patient-specific, clinically significant reason why the member cannot use other isotretinoin capsules available without prior authorization must be provided; and
6. A recent patient weight must be provided on the prior authorization request in order to authorize the appropriate amount of medication according to drug labeling.

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, which are available without prior authorization, must be provided; and
5. A quantity limit of 30 grams per 30 days will apply.

Aprizio Pak™ (Lidocaine/Prilocaine 2.5%/2.5% Kit) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the standard formulation of lidocaine/prilocaine 2.5%/2.5% cream, which is available without prior authorization, must be provided.

Additionally, the College of Pharmacy recommends the placement of Caldolor® (ibuprofen injection) and Relafen™ DS (nabumetone tablet) into the Special Prior Authorization (PA) Tier of the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Product Based Prior Authorization (PBPA) category. Current Special PA criteria will apply. The proposed changes are shown in red in the following NSAIDs Tier Chart:

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) 50mg, 100mg, & 200mg caps	diclofenac potassium (Cataflam®)	celecoxib (Celebrex®) 400mg caps
diclofenac epolamine (Flector® Patch) - brand name preferred	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac (Zorvolex®)
diclofenac ER (Voltaren® XR)	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac potassium (Cambia®) powder pack

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	etodolac (Lodine®) 200mg & 300mg caps	diclofenac potassium (Zipsor®) caps
diclofenac sodium 1% (Voltaren® Gel)	etodolac ER (Lodine® XL)	diclofenac sodium (Dyloject™)
etodolac (Lodine®) 400mg & 500mg tabs	naproxen sodium (Anaprox®) 275mg & 550mg tabs	diclofenac sodium (Pennsaid®) topical drops
flurbiprofen (Ansaid®)	oxaprozin (Daypro®)	fenoprofen (Nalfon®)
ibuprofen (Motrin®)	piroxicam (Feldene®)	**ibuprofen injection (Caldolor®)**
indomethacin IR capsules (Indocin® 25 & 50mg only)	tolmetin (Tolectin®)	ibuprofen/famotidine (Duexis®)
ketoprofen (Orudis®)		indomethacin (Indocin®) susp & ER caps
meloxicam (Mobic®)		indomethacin (Tivorbex®)
nabumetone (Relafen®)		ketoprofen ER (Oruvail®)
naproxen (Naprosyn®)		ketorolac tromethamine (Sprix®) nasal spray
naproxen EC (Naprosyn®)		meclofenamate (Meclomen®)
sulindac (Clinoril®)		mefenamic acid (Ponstel®)
		meloxicam (Vivlodex®) caps
		meloxicam orally disintegrating tablet (Qmiiz ODT™)
		nabumetone 1,000mg (Relafen™ DS)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

ER = extended-release; EC = enteric coated; caps = capsules; tabs = tablets; susp = suspension; IR = immediate-release; PA = prior authorization
Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

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

4. Additionally, use of Tivorbex™ will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.
5. Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose.

The College of Pharmacy also recommends the addition of Exservan™ (riluzole oral film) to the current Tiglutik® (riluzole oral suspension) approval criteria and the addition of Procysbi® (cysteamine DR granule) to the current Procysbi® (cysteamine DR capsule) approval criteria (proposed changes shown in red):

Exservan™ (Riluzole Oral Film) and Tiglutik® (Riluzole Oral Suspension) Approval Criteria:

1. An FDA approved indication for the treatment of amyotrophic lateral sclerosis (ALS); and
2. A patient-specific, clinically significant reason why the member cannot use riluzole tablets, even when tablets are crushed, must be provided; and
3. A quantity limit of 20mL per day or 600mL per 30 days will apply for Tiglutik®; and
4. A quantity limit of 2 films per day or 60 films per 30 days will apply for Exservan™.

Procysbi® (Cysteamine Bitartrate) Delayed-Release Capsule and Granule Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation Cystagon® (cysteamine bitartrate) must be provided; and
3. Use of Procysbi® granules will require a patient-specific, clinically significant reason why the member cannot use the capsule formulation of Procysbi®.

Further, the College of Pharmacy recommends the prior authorization of metronidazole 1% gel and Noritate® (metronidazole 1% cream) with the addition of an upper age limit shown in red to be consistent with other rosacea products with the following criteria:

Metronidazole 1% Gel Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% gel, which is available without prior authorization, must be provided; and

2. Metronidazole 1% gel is not covered for members older than 20 years of age.

Noritate® (Metronidazole 1% Cream) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% cream, which is available without prior authorization, must be provided; and
2. Noritate® is not covered for members older than 20 years of age.

The College of Pharmacy also recommends the prior authorization of pyridostigmine 30mg tablet, Quzyttir™ (cetirizine injection), Slynd™ (drospirenone tablet), and Talicia® (omeprazole/amoxicillin/rifabutin capsule) with the following criteria:

Pyridostigmine 30mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use pyridostigmine 60mg tablets, which are available without prior authorization, must be provided.

Quzyttir™ (Cetirizine Injection) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an oral formulation of cetirizine (e.g., tablets, oral solution) must be provided.

Slynd™ (Drospirenone Tablet) Approval Criteria:

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

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy treatments approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
3. A quantity limit of 168 capsules per 14 days will apply.

Finally, the College of Pharmacy recommends adding Tirosint® (levothyroxine capsule) to the current Tirosint®-SOL (levothyroxine oral solution) approval criteria (proposed changes are shown in red):

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 solution, a reason why the member cannot use the levothyroxine tablet formulation, even when the tablets are crushed, must be provided.

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Appendix F

Vote to Prior Authorize Iluvien® (Fluocinolone Intravitreal Implant), Ozurdex® (Dexamethasone Intravitreal Implant), and Retisert® (Fluocinolone Intravitreal Implant)

Oklahoma Health Care Authority
July 2020

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

- In June 2019, the U.S. Food and Drug Administration (FDA) approved a supplemental New Drug Application (sNDA) for **Dextenza® (dexamethasone ophthalmic insert)** to include the treatment of ocular inflammation following ophthalmic surgery as an additional indication. Dextenza® is the first FDA-approved intracanalicular insert and was originally FDA approved in 2018 for the treatment of ocular pain following ophthalmic surgery. Dextenza® is supplied as an ophthalmic intracanalicular insert containing 0.4mg dexamethasone in a polyethylene glycol-based hydrogel conjugated with fluorescein, and is designed to release a 0.4mg dose of dexamethasone for up to 30 days following insertion. Following the insertion, patients should be monitored for changes in intraocular pressure (IOP).
- **Iluvien® (fluocinolone intravitreal implant)** was FDA approved in 2014 and is indicated for the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in IOP. Iluvien® is supplied as a non-bioerodable intravitreal implant in a drug delivery system containing 0.19mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25mcg/day and lasting 36 months. Following the intravitreal injection, patients should be monitored for elevation in IOP, endophthalmitis, and cataract development.
- **Ozurdex® (dexamethasone intravitreal implant)** was FDA approved in 2009 and is indicated for the treatment of non-infectious uveitis affecting the posterior segment of the eye, DME, and macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO). Ozurdex® is supplied as an intravitreal implant containing 0.7mg dexamethasone in a solid polymer drug delivery system and lasting 3 to 4 months. Following the intravitreal injection, patients should be monitored for elevation in IOP, endophthalmitis, and cataract development.
- **Retisert® (fluocinolone intravitreal implant)** was FDA approved in 2004 and is indicated for the treatment of chronic, non-infectious

uveitis affecting the posterior segment of the eye. Retisert® is supplied as an intravitreal implant containing a 0.59mg fluocinolone acetonide tablet encased in a silicone elastomer cup containing a release orifice, and is designed to release fluocinolone acetonide at an initial rate of 0.6mcg/day, decreasing over the first month to a steady state between 0.3-0.4mcg/day over approximately 30 months. Following the intravitreal injection, patients should be monitored for elevation in IOP, endophthalmitis, and cataract development.

- **Yutiq™ (fluocinolone intravitreal implant)** was FDA approved in 2018 and is indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye. Yutiq™ is supplied as a non-bioerodible intravitreal implant in a drug delivery system containing 0.18mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25mcg/day and last 36 months. Following the intravitreal injection, patients should be monitored for change in IOP and for endophthalmitis.

Cost Comparison

Product	Cost Per Unit	Relative Cost Per 30 Days*
Iluvien® (fluocinolone) 0.19mg intravitreal implant	**$8,800.00**	**$244.44**
Ozurdex® (dexamethasone) 0.7mg intravitreal implant	**$1,333.00**	**$333.25-$444.33**
Retisert® (fluocinolone) 0.59mg intravitreal implant	**$19,025.00**	**$634.17**
Dextenza® (dexamethasone) 0.4mg ophthalmic insert	$538.83	$538.83
Yutiq™ (fluocinolone) 0.18mg intravitreal implant	$8,340.00	$231.67

Unit = intravitreal implant or ophthalmic insert

*Please note: The duration of treatments vary. Iluvien® and Yutiq™ are intended to last 36 months per implant, Retisert® 30 months per implant, Ozurdex® 3 to 4 months per implant, and Dextenza® 30 days per insert.

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Recommendations

The College of Pharmacy recommends the prior authorization of Iluvien® (fluocinolone intravitreal implant), Ozurdex® (dexamethasone intravitreal implant), and Retisert® (fluocinolone intravitreal implant) with the following criteria:

Iluvien® (Fluocinolone Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of diabetic macular edema (DME) in patients 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.

Ozurdex® (Dexamethasone Intravitreal Implant) Approval Criteria:

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:

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.

Additionally, the College of Pharmacy recommends the following changes to the current Dextenza® (dexamethasone ophthalmic insert) and Yutiq™ (fluocinolone intravitreal implant) approval criteria based on the new FDA approved indication(s) for Dextenza® and based on the net cost of Yutiq™ (changes shown in red):

Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria:

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.

Yutiq™ (Fluocinolone Intravitreal Implant) Approval Criteria:

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 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.

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[1] Ocular Therapeutix, Inc. Ocular Therapeutix Announces FDA Approval of Supplemental New Drug Application (sNDA) for Dextenza® (0.4mg Dexamethasone Intracanalicular Insert for Ophthalmic Use) for the Treatment of Ocular Inflammation Following Ophthalmic Surgery. *BioSpace*. Available online at: https://www.biospace.com/article/releases/ocular-therapeutix-announces-fda-approval-of-supplemental-new-drug-application-snda-for-dextenza-0-4-dexamethasone-intracanalicular-insert-for-ophthalmic-use-for-the-treatment-of-ocular-inflammation-following-ophthalmic-surgery/. Issued 06/21/2019. Last accessed 06/17/2020.

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Appendix G

Vote to Prior Authorize Isturisa® (Osilodrostat)

Oklahoma Health Care Authority
July 2020

Introduction[1,2]

In March 2020, the U.S. Food and Drug Administration (FDA) approved Isturisa® (osilodrostat), a cortisol synthesis inhibitor, for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Osilodrostat inhibits 11 beta-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. Osilodrostat lowers cortisol levels and can lead to hypocortisolism and sometimes life-threatening adrenal insufficiency. Prescribers should monitor 24-hour urine free cortisol (UFC), serum cortisol, or plasma cortisol and the patient's signs and symptoms periodically during osilodrostat treatment. Osilodrostat is associated with a dose-dependent QT interval prolongation. Prescribers should perform an electrocardiogram (ECG) to obtain a baseline QTc interval measurement prior to initiating therapy with osilodrostat and should monitor for an effect on the QTc interval thereafter. Hypokalemia and hypomagnesemia should be corrected prior to osilodrostat initiation, and patients should be monitored periodically during treatment with osilodrostat. Because of the potential for serious adverse reactions in the breastfed infant, such as adrenal insufficiency, patients should be advised that breastfeeding is not recommended during treatment with osilodrostat and for 1 week after the final dose.

Isturisa® is available in 1mg, 5mg, and 10mg oral tablets. The initial recommended dosage of osilodrostat is 2mg twice daily. The dosage of osilodrostat should be titrated by 1 to 2mg twice daily no more frequently than every 2 weeks based on the rate of cortisol changes, individual tolerability, and improvement in signs and symptoms, up to a maximum recommended dosage of 30mg twice daily (*refer to Isturisa® Prescribing Information for specific dosing recommendations*).

The Wholesale Acquisition Cost (WAC) of Isturisa® (osilodrostat) is $110, $400, and $475 per 1mg, 5mg, and 10 mg tablet, respectively. Treatment costs will vary depending on the maintenance dosage. The maintenance dosage varied between 2mg and 7mg twice daily in clinical trials, which would result in an annual cost of $158,400 for 2mg twice daily or $446,400 for 7mg twice daily. The annual cost of treatment with Isturisa® at the maximum recommended dosage of 30mg twice daily is $1,026,000.

Recommendations

The College of Pharmacy recommends the prior authorization of Isturisa® (osilodrostat) with the following criteria:

Isturisa® (Osilodrostat) Approval Criteria:

1. An FDA approved indication for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative; and
2. Member must be 18 years of age or older; and
3. Prescriber must document that the member has had an inadequate response to pituitary surgery or is not a candidate for pituitary surgery; and
4. Prescriber must verify that hypokalemia and hypomagnesemia are corrected prior to starting Isturisa®; and
5. Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline, 1 week after treatment initiation, and as clinically indicated thereafter; and
6. Prescriber must verify that dose titration will be followed according to package labeling; and
7. For female members, prescriber must verify that the member is not breastfeeding; and
8. Isturisa® must be prescribed by, or in consultation with, an endocrinologist (or be an advanced care practitioner with a supervising physician who is an endocrinologist); and
9. Initial authorizations will be for the duration of 3 months after which time, compliance and 24-hour urine free cortisol levels within the normal range (to demonstrate the effectiveness of this medication) will be required for continued approval. Subsequent approvals will be for the duration of 1 year and will require the prescriber to verify the member is still not a candidate for pituitary surgery.

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[2] Isturisa® (Osilodrostat) Prescribing Information. Recordati Rare Diseases Inc. Available online at: https://www.recordatirarediseases.com/sites/www.recordatirarediseases.com/files/inline-files/Isturisa-Prescribing-Information.pdf. Last revised 03/2020. Last accessed 06/17/2020.

Appendix H

30-Day Notice to Prior Authorize Koselugo™ (Selumetinib), Pemazyre™ (Pemigatinib), and Qinlock™ (Ripretinib)

Oklahoma Health Care Authority
July 2020

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

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 rather than inheriting it from a parent). 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. This can also transform into malignant peripheral nerve sheath tumors. Surgical resection can be performed; however, it can be challenging in certain areas of the body or not feasible. Selumetinib is the first U.S. Food and Drug Administration (FDA) approved medical management for this condition. In a Phase 2 study of selumetinib, the overall response rate was 66%, no patients had a complete response (disappearance of the target lesion), and 66% of patients had a partial response (decrease in target PN volume by ≥20% compared to baseline). In 82% of patients, there was a duration of response of ≥12 months.

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. FGFR mutations may be associated with a favorable prognosis. Pemigatinib was studied in a Phase 2 study in 146 previously treated patients with FGFR2

fusions or rearrangements, patients with other FGF/FGFR alterations, or in patients with no alterations. In 35% of patients with FGFR2 fusions or rearrangements, an objective response was achieved.

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 specific for these mutations have improved 2-year overall survival to approximately 80%.

Market News and Updates[6,7]

Anticipated Patent Expiration(s):

- Koselugo™ (selumetinib): December 2026
- Qinlock™ (ripretinib): June 2032
- Pemazyre™ (pemigatinib): January 2035

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

- **April 2020:** The FDA approved Koselugo™ (selumetinib) for the treatment of pediatric patients, 2 years of age and older, with NF1 who have symptomatic, inoperable PN.
- **April 2020:** The FDA approved Pemazyre™ (pemigatinib) for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement.
- **May 2020:** The FDA approved Qinlock™ (ripretinib) for the treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

Product Summaries[2,8,9]

Koselugo™ (Selumetinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Treatment of pediatric patients, 2 years of age and older, with NF1 who have symptomatic, inoperable PN
- **How Supplied:** 10mg and 25mg oral capsules
- **Dose:** 25mg/m^2 twice daily on an empty stomach; dose should be reduced to 20mg/m^2 twice daily for moderate hepatic impairment (Child-Pugh B)
- **Cost:** Wholesale Acquisition Cost (WAC) is $72.70 per 10mg capsule and $181.75 per 25mg capsule, resulting in a cost of $10,905 per 30 days for a patient requiring 25mg twice daily

Pemazyre™ (Pemigatinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement
- **How Supplied:** 4.5mg, 9mg, and 13.5mg oral tablets
- **Dose:** 13.5mg once daily for 14 consecutive days followed by 7 days off therapy in 21-day cycles; alternative strengths available for dose reductions/modifications if adverse reactions occur
- **Cost:** WAC of $1,214.29 per tablet for all available strengths (4.5mg, 9mg, and 13.5mg), resulting in a cost of $17,000.06 per 21-day cycle based on the recommended dose of 13.5mg once daily for 14 days

Qinlock™ (Ripretinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Treatment of adult patients with advanced GIST who have received prior treatment with 3 or more kinase inhibitors, including imatinib
- **How Supplied:** 50mg oral tablets
- **Dose:** 150mg once daily with or without food
- **Cost:** WAC of $355.56 per 50mg tablet, resulting in a cost of $32,000.40 per 30 days based on the recommended dose of 150mg once daily

Recommendations

- The prior authorization of Koselugo™ (selumetinib), Pemazyre™ (pemigatinib), and Qinlock™ (ripretinib) with the following criteria listed in red:

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

1. Member meets all of the following:
    a. Pediatric patients 2 years of age and older; and
    b. 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. Used as a single-agent.

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[9] Qinlock™ Prescribing Information. Deciphera Pharmaceuticals. Available online at: https://www.qinlockhcp.com/content/files/prescribing-information.pdf. Last revised 05/2020. Last accessed 06/12/2020.

Appendix I

Calendar Year 2019 Annual Review of Topical Corticosteroids

Oklahoma Health Care Authority
July 2020

Current Prior Authorization Criteria

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

Tier-2 Topical Corticosteroids 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 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.

Tier-3 Topical Corticosteroids 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 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 form of that medication in Tier-3 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

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 0.025% (**Impoyz®**)	**C**
clobetasol propionate 0.05% (**Temovate®**)	**C,L,O, So**	augmented betamethasone dipropionate 0.05% (**Diprolene®**)	**L,O**	clobetasol propionate 0.05% (**Clobex®**)	**Sh,Spr**
fluocinonide 0.05%	**C,O,So**	betamethasone dipropionate 0.05% (**Diprosone®**)	**C,O**	clobetasol propionate 0.05% (**Olux®, Olux-E®**)	**F**
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 emollient 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**		
		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**	betamethasone dipropionate 0.05% (**Sernivo®**)	**Spr**
betamethasone valerate 0.1% (**Beta-Val®**)	**C,O,L**	betamethasone valerate 0.12% (**Luxiq®**)	**F**	hydrocortisone valerate 0.2% (**Westcort®**)	**C,O**
fluticasone propionate 0.05% (**Cutivate®**)	**C,O**	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (**Enstilar® Foam**)	**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**	desonide 0.05% (**Verdeso®**)	**F**	desonide 0.05%	**L**
hydrocortisone acetate 1%	**C,O**	fluocinolone acetonide 0.01% (**Synalar®**)	**C,So**	desonide emollient 0.05%	**C,O**
hydrocortisone acetate 2.5%	**C,L,O**	hydrocortisone 2.5% (**Texacort®**)	**So**		
hydrocortisone/urea 1%/10% (**U-Cort®**)	**C**	hydrocortisone/pramoxine 1%/1% (**Pramosone®**)	**C,L**		
triamcinolone acetonide 0.025%	**C,L**				

C = Cream; O = Ointment; L = Lotion; G = Gel; Sh = Shampoo; So = Solution; Spr = Spray; Sus = Suspension; F = Foam
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Utilization of Topical Corticosteroids: Calendar Year 2019

Comparison of Calendar Years: Topical Corticosteroids

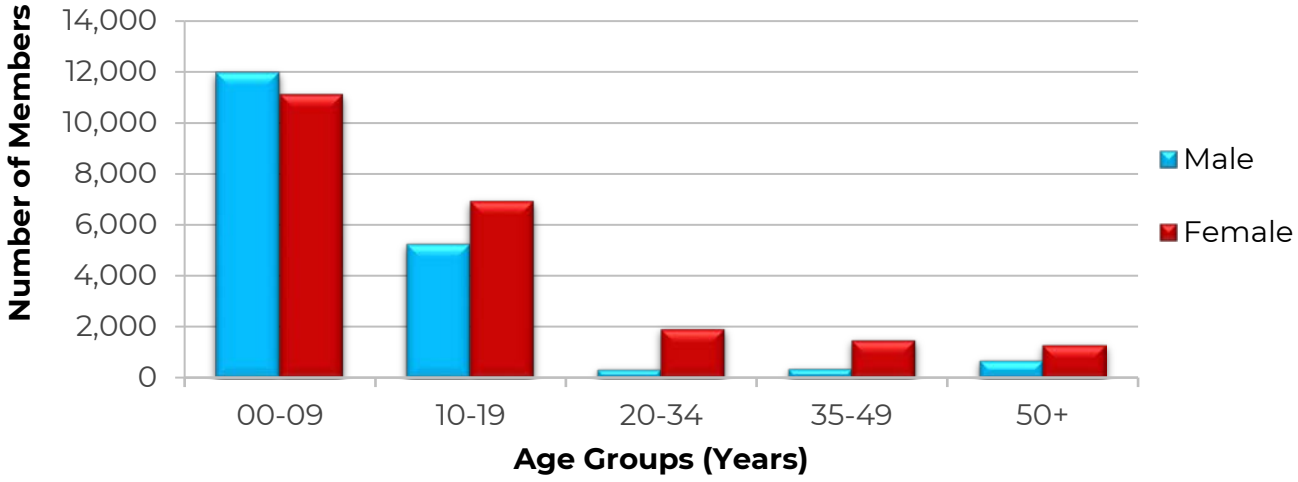
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	42,313	64,521	$1,340,151.31	$20.77	$1.29	4,125,925	1,040,816
2019	41,435	62,945	$1,335,355.36	$21.21	$1.27	4,102,834	1,051,041
% Change	**-2.10%**	**-2.40%**	**-0.40%**	**2.10%**	**-1.60%**	**-0.60%**	**1.00%**
Change	**-878**	**-1,576**	**-$4,795.95**	**$0.44**	**-$0.02**	**-23,091**	**10,225**

*Total number of unduplicated 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.
- The prior authorization criteria changes for the Topical Corticosteroids Product Based Prior Authorization (PBPA) Tier Chart voted on by the Drug Utilization Review (DUR) Board in July 2019 went into effect on November 12, 2019. Members who were using the products at the time the prior authorization went into effect were not “grandfathered”.
- Eucrisa® (crisaborole ointment) is a steroid-free, phosphodiesterase 4 inhibitor topical ointment indicated for the treatment of mild-to-

moderate atopic dermatitis in patients 2 years of age and older. Eucrisa® requires prior authorization but may pay 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. Utilization of Eucrisa® may account for decreased topical corticosteroid utilization.

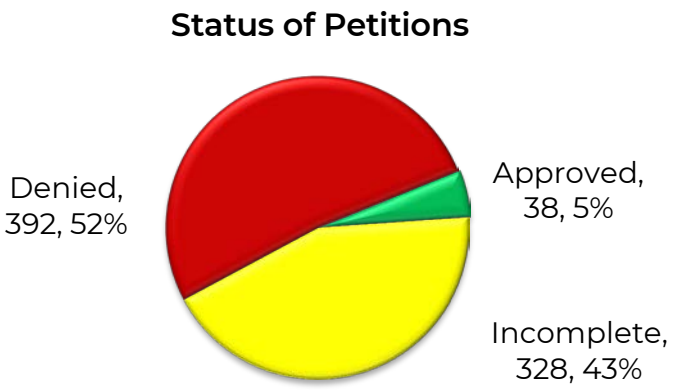
Demographics of Members Utilizing Topical Corticosteroids



Top Prescriber Specialties of Topical Corticosteroids by Number of Claims

Prior Authorization of Topical Corticosteroids

There were 758 prior authorization requests submitted for topical corticosteroids during calendar year 2019. The following chart shows the status of the submitted petitions for calendar year 2019.



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

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.
- Desonate® (desonide 0.05% gel): August 2020
- 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):

- **April 2019:** Tovet™ (clobetasol propionate 0.05% emulsion/foam), an AB-rated generic of Olux-E®, is now available. Clobetasol foam is indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 12 years of age and older. The recommended regimen is a thin layer applied to affected area(s) twice daily, morning and evening, for up to 2 consecutive weeks; therapy should be discontinued when control has been achieved. Clobetasol 0.05% emulsion/foam is available as the brand Olux-E®, branded-generic Tovet™, and generic clobetasol 0.05% emulsion/foam. Tovet™ has been added in red under clobetasol propionate 0.05% foam in the ultra-high to high potency Tier-3 section of the Topical Corticosteroids Tier chart to reflect this update.
- **July 2019:** The FDA expanded the approved indication for Enstilar® Foam (calcipotriene/betamethasone dipropionate 0.005%/0.064%) for

the topical treatment of plaque psoriasis to include patients 12 years of age and older. The FDA granted Enstilar® Foam pediatric exclusivity, extending the period of United States market exclusivity by an additional 6 months to December 10, 2031. This expanded indication is supported by the Enstilar® Pediatric Study in adolescents 12 to 17 years of age with psoriasis of the body and scalp, as well as data from adequate and well-controlled trials in adults. Additionally, the FDA expanded the approved indication for Taclonex® Topical Suspension (calcipotriene/betamethasone dipropionate 0.005%/0.064%) in the topical treatment of scalp and body plaque psoriasis to include patients 12 years of age and older. The safety and effectiveness of Enstilar® Foam and Taclonex® Topical Suspension in pediatric patients younger than 12 years of age have not been established.

- **March 2020:** Halog® (halcinonide 0.1% solution) was originally FDA approved in 1977. The solution formulation has been unavailable for many years with a listed obsolete date of May 2007. Sun Pharmaceutical Industries, Inc. has been authorized by the FDA to start marketing Halog® (halcinonide 0.1% solution) as of March 18, 2020, and the solution formulation is now available.

Recommendations

The College of Pharmacy recommends the placement of Halog® (halcinonide 0.1% solution) into Tier-2 of the medium-high to medium potency Topical Corticosteroid PBPA Tier chart based on net cost; current Tier-2 criteria will apply (changes shown in red):

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 0.025% (**Impoyz®**)	**C**
clobetasol propionate 0.05% (**Temovate®**)	**C,L,O, So**	augmented betamethasone dipropionate 0.05% (**Diprolene®**)	**L,O**	clobetasol propionate 0.05% (**Clobex®**)	**Sh,Spr**
fluocinonide 0.05%	**C,O,So**	betamethasone dipropionate 0.05% (**Diprosone®**)	**C,O**	clobetasol propionate 0.05% (**Olux®, Olux-E®, Tovet™**)	**F**

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
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**		
		halobetasol propionate/lactic acid 0.05%/10% (**Ultravate X®**)	**C**		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	**L**	betamethasone dipropionate/calcipotriene 0.064%/0.005% (**Taclonex®**)	**O,Spr Sus**	betamethasone dipropionate 0.05% (**Sernivo®**)	**Spr**
betamethasone valerate 0.1% (**Beta-Val®**)	**C,O,L**	betamethasone valerate 0.12% (**Luxiq®**)	**F**	hydrocortisone valerate 0.2% (**Westcort®**)	**C,O**

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluticasone propionate 0.05% (**Cutivate®**)	**C,O**	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (**Enstilar® Foam**)	**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**		
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**	desonide 0.05% (**Verdeso®**)	**F**	desonide 0.05%	**L**

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

C = Cream; O = Ointment; L = Lotion; G = Gel; Sh = Shampoo; So = Solution; Spr = Spray; Sus = Suspension; F = Foam

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Utilization Details of Topical Corticosteroids: Calendar Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 MEDICATIONS						
LOW POTENCY PRODUCTS						
HYDROCORTISONE CR 2.5%	4,590	3,691	$58,293.36	$0.90	$12.70	4.37%
TRIAMCINOLONE CR 0.025%	4,407	3,565	$57,916.72	$0.87	$13.14	4.34%
HYDROCORTISONE OINT 2.5%	2,802	1,920	$41,366.84	$1.16	$14.76	3.10%
TRIAMCINOLONE OINT 0.025%	2,468	1,994	$38,286.41	$0.96	$15.51	2.87%
HYDROCORTISONE CR 1%	1,896	1,581	$22,353.09	$1.13	$11.79	1.67%
HYDROCORTISONE OINT 1%	416	367	$5,341.78	$1.28	$12.84	0.40%
HYDROCORTISONE LOT 2.5%	394	331	$10,001.05	$1.42	$25.38	0.75%
DESONATE GEL 0.05%	303	194	$175,754.37	$22.55	$580.05	13.16%
CAPEX SHAMPOO 0.01%	159	85	$61,903.36	$17.13	$389.33	4.64%
TRIAMCINOLONE LOT 0.025%	135	124	$4,638.97	$1.88	$34.36	0.35%
HYDROCORTISONE CR 2.5%	4,590	3,691	$58,293.36	$0.90	$12.70	4.37%
SUBTOTAL	**17,570**	**13,852**	**$475,855.95**	**$1.89**	**$27.08**	**35.65%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE CR 0.1%	21,658	16,774	$294,596.12	$0.81	$13.60	22.06%
TRIAMCINOLONE OINT 0.1%	11,777	8,814	$183,052.54	$0.86	$15.54	13.71%
TRIAMCINOLONE CR 0.5%	2,277	1,720	$39,529.98	$1.25	$17.36	2.96%
MOMETASONE CR 0.1%	1,119	787	$27,480.03	$1.38	$24.56	2.06%
FLUTICASONE CR 0.05%	1,098	752	$25,861.32	$1.32	$23.55	1.94%
TRIAMCINOLONE OINT 0.5%	946	717	$18,702.84	$1.40	$19.77	1.40%
BETAMETHASONE VAL CR 0.1%	430	295	$15,756.51	$2.02	$36.64	1.18%
TRIAMCINOLONE LOT 0.1%	342	276	$10,788.49	$1.63	$31.55	0.81%
FLUTICASONE OINT 0.005%	263	162	$8,368.61	$1.54	$31.82	0.63%
MOMETASONE OINT 0.1%	245	157	$4,607.43	$1.03	$18.81	0.35%
BETAMETHASONE VAL OINT 0.1%	137	102	$4,950.86	$1.99	$36.14	0.37%
BETAMETH DIP LOT 0.05%	96	69	$3,940.02	$1.87	$41.04	0.30%
MOMETASONE SOL 0.1%	69	39	$1,637.64	$1.08	$23.73	0.12%
BETAMETHASONE VAL LOT 0.1%	38	30	$1,837.78	$2.66	$48.36	0.14%
TRIANEX OINT 0.05%	10	10	$451.40	$1.50	$45.14	0.03%
SUBTOTAL	**40,507**	**30,706**	**$641,589.86**	**$0.93**	**$15.84**	**48.06%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL CR 0.05%	945	620	$42,998.72	$2.43	$45.50	3.22%
CLOBETASOL SOL 0.05%	935	538	$36,634.68	$1.29	$39.18	2.74%
AUG BETAMETH CR 0.05%	831	549	$14,767.03	$0.88	$17.77	1.11%
FLUOCINONIDE SOL 0.05%	520	324	$23,054.19	$1.79	$44.33	1.73%
FLUOCINONIDE OINT 0.05%	277	162	$9,935.37	$1.60	$35.87	0.74%
FLUOCINONIDE CR 0.05%	221	144	$10,176.96	$2.37	$46.05	0.76%
CLOBETASOL OINT 0.05%	151	128	$4,496.97	$1.39	$29.78	0.34%
HALOBETASOL CR 0.05%	118	80	$6,112.13	$2.47	$51.80	0.46%
CLOBETASOL EMOL CR 0.05%	66	50	$3,576.67	$3.30	$54.19	0.27%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
AUG BETAMET GEL 0.05%	16	11	$1,451.11	$4.85	$90.69	0.11%
SUBTOTAL	**4,080**	**2,606**	**$153,203.83**	**$1.64**	**$37.55**	**11.48%**
TIER-1 TOTAL	**62,157**	**47,164**	**$1,270,649.64**	**$1.23**	**$20.44**	**95.19%**
TIER-2 MEDICATIONS						
LOW POTENCY PRODUCTS						
FLUOCINOLONE ACT CR 0.01%	4	4	$258.71	$4.98	$64.68	0.02%
SUBTOTAL	**4**	**4**	**$258.71**	**$4.98**	**$64.68**	**0.02%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TMC AER SPRAY 0.147MG/G	3	2	$493.92	$10.29	$164.64	0.04%
HC BUTYRATE OINT 0.1%	1	1	$58.62	$8.37	$58.62	0.00%
ALCLOMETASONE OINT 0.05%	1	1	$79.92	$2.66	$79.92	0.01%
SUBTOTAL	**5**	**4**	**$632.46**	**$7.44**	**$126.49**	**0.05%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
BETAMETH DIP OINT 0.05%	772	491	$63,089.86	$4.46	$81.72	4.72%
BETAMETH DIP CR 0.05%	1	1	$52.33	$1.74	$52.33	0.00%
CLOBETASOL GEL 0.05%	1	1	$109.38	$1.82	$109.38	0.01%
SUBTOTAL	**774**	**493**	**$63,251.57**	**$4.44**	**$81.72**	**4.73%**
TIER-2 TOTAL	**783**	**501**	**$64,142.74**	**$4.46**	**$81.92**	**4.80%**
TIER-3 MEDICATIONS						
LOW POTENCY PRODUCTS						
DESONIDE CR 0.05%	3	1	$247.87	$2.75	$82.62	0.02%
SUBTOTAL	**3**	**1**	**$247.87**	**$2.75**	**$82.62**	**0.02%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL AER 0.05%	1	1	$171.74	$5.72	$171.74	0.01%
CLOBETASOL PROP SHAM 0.05%	1	1	$143.37	$4.78	$143.37	0.01%
SUBTOTAL	**2**	**2**	**$315.11**	**$5.25**	**$157.56**	**0.02%**
TIER-3 TOTAL	**5**	**3**	**$562.98**	**$3.75**	**$112.60**	**0.04%**
TOTAL	**62,945**	**41,435***	**$1,335,355.36**	**$1.27**	**$21.21**	**100%**

*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.
CR = cream; OINT = ointment; LOT = lotion; SOL = solution; AER = aerosol; BETAMETH = betamethasone; DIP= dipropionate; VAL = valerate; EMOL = emollient; ACT = acetonide; AUG = augmented; PROP = propionate; HC = hydrocortisone; TMC = triamcinolone; SHAM = shampoo

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Appendix J

Calendar Year 2019 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Tramadol 100mg Tablet

Oklahoma Health Care Authority
July 2020

Current Prior Authorization Criteria

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®)◊	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	oxycodone/APAP ER tab (Xartemis® XR)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®)◊	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab (Opana® ER)◊
	morphine/ naltrexone ER cap (Embeda®)	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®)◊	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)	
		oxycodone/ naltrexone ER cap (Troxyca® ER)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
		tapentadol ER tab (Nucynta® ER)	

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
◊Brand name preferred.
PA = prior authorization; ER = extended-release; cap = capsule; tab = tablet; soln = solution; APAP = acetaminophen

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	oxymorphone IR tab (Opana®)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	tapentadol IR tab (Nucynta®)	dihydrocodeine/ APAP/caff cap (Trezix®)	
codeine tab		hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	
codeine/APAP (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	
dihydrocodone/ 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®)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
oxycodone IR cap (Oxy IR®)			**Oncology Only:**
oxycodone IR tab (Roxicodone®)			fentanyl SL spray (Subsys®)
tramadol/APAP tab (Ultracet®)			fentanyl SL tab (Abstral®)
tramadol tab (Ultram®)			fentanyl transmucosal lozenge (Actiq®)

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

- Tier-1 products are covered with no prior authorization necessary.
- Members with an oncology-related diagnosis are exempt from the prior authorization process and do not require pain contracts.
- 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. Members younger than 12 years of age require prior authorization approval for reimbursement of these products. Authorization 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; or
2. 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
3. A chronic pain diagnosis requiring time-released medication (for long-acting 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.

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 should 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. Members with a daily MME >90 MME per day will require a 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 include 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. Oncology, sickle cell disease, and hemophilia diagnoses are excluded from the MME limit.

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

1. Brand formulation Suboxone® SL films and generic buprenorphine/naloxone SL tablets are the preferred products. Authorization of Bunavail®, Zubsolv®, Cassipa®, and generic Suboxone® SL films requires a patient-specific, clinically significant reason why brand formulation Suboxone® SL films or generic buprenorphine/naloxone SL tablets are not appropriate; and
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 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) (Suboxone®) 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.

Medicaid Drug Rebate Program[1,2]

Medicaid coverage of a drug requires the manufacturer to have a federal rebate agreement with the Secretary of Health and Human Services (HHS). Participation in the federal drug rebate program requires Medicaid coverage with limited exceptions (e.g., cosmetic medications, fertility medications). Federal rebate amounts are based on the "best price" for each drug. Best price refers to the lowest price paid to a manufacturer for a drug by any commercial payer. Best prices are reported to the Centers for Medicare and Medicaid Services (CMS) by the manufacturer, but are not publicly available.

If a drug's price increases more quickly than inflation, an additional rebate penalty is included based on the change in price compared with the consumer price index (CPI). The CPI penalty of the federal rebate is designed to keep Medicaid net cost relatively flat despite increases in drug prices. As average wholesale price (AWP) increases, the rebated amount per unit (RAPU) increases as well, resulting in minimal effect on Medicaid net cost.

Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. In calendar year 2019, the Oklahoma Health Care Authority (OHCA) collected $4,104,732.47 in aggregate drug rebates for the Opioid Analgesics Product Based Prior Authorization (PBPA) category. 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.

Utilization of Opioid Analgesics and MAT Medications: Calendar Year 2019

Comparison of Calendar Years: Opioid Analgesics

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	88,222	301,129	$12,512,292.66	$41.55	$2.11	21,019,648	5,917,379
2019	73,865	236,581	$9,029,179.27	$38.17	$1.99	16,114,001	4,539,526
% Change	**-16.30%**	**-21.40%**	**-27.80%**	**-8.10%**	**-5.70%**	**-23.30%**	**-23.30%**
Change	**-14,357**	**-64,548**	**-$3,483,113.39**	**-$3.38**	**-$0.12**	**-4,905,647**	**-1,377,853**

*Total number of unduplicated 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.

- Aggregate drug rebates collected during calendar year 2019 for opioid analgesics: $4,104,732.47[Δ]

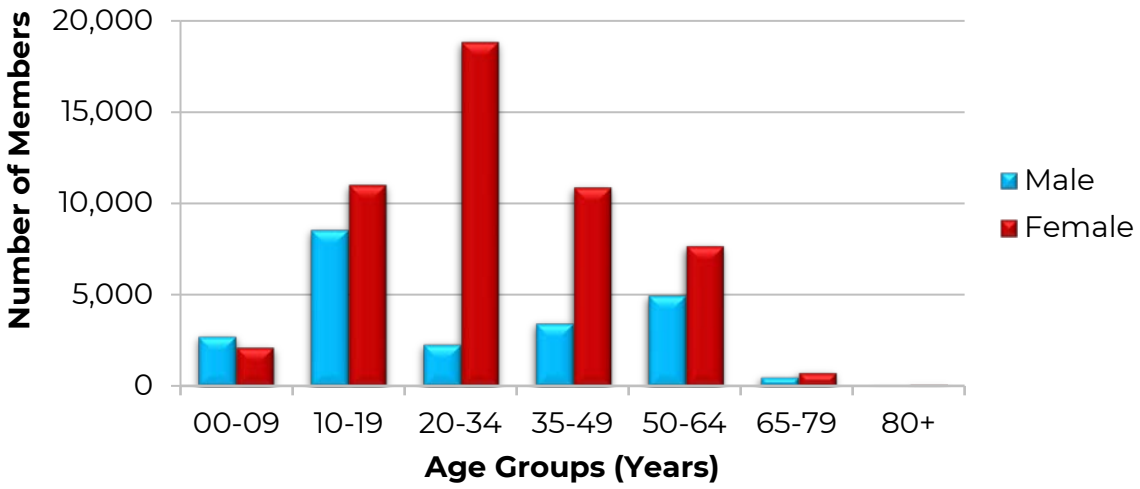
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Comparison of Calendar Years: MAT Medications

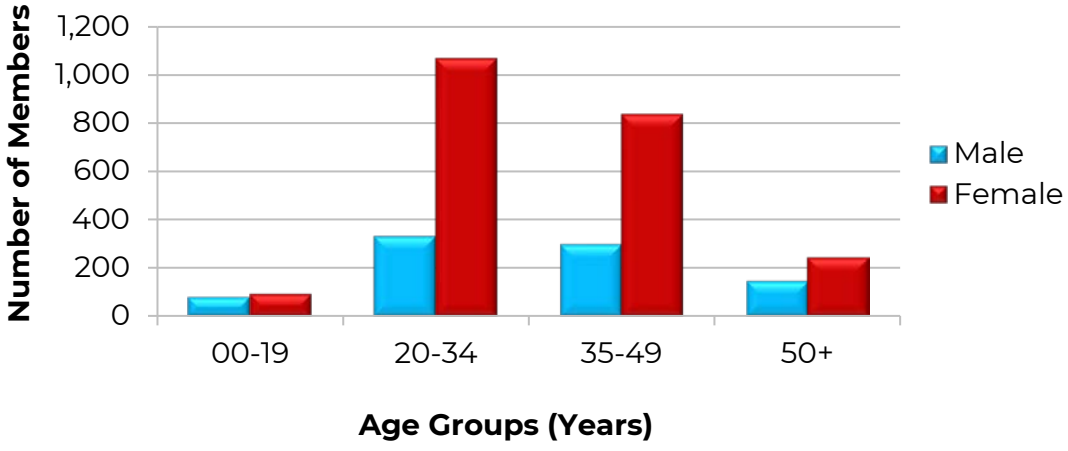
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2018	2,682	18,962	$5,512,404.65	$290.71	$11.05	1,039,588	498,734
2019	3,110	22,326	$6,197,497.38	$277.59	$10.56	1,215,739	586,818
% Change	**16.00%**	**17.70%**	**12.40%**	**-4.50%**	**-4.40%**	**16.90%**	**17.70%**
Change	**428**	**3,364**	**$685,092.73**	**-$13.12**	**-$0.49**	**176,151**	**88,084**

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

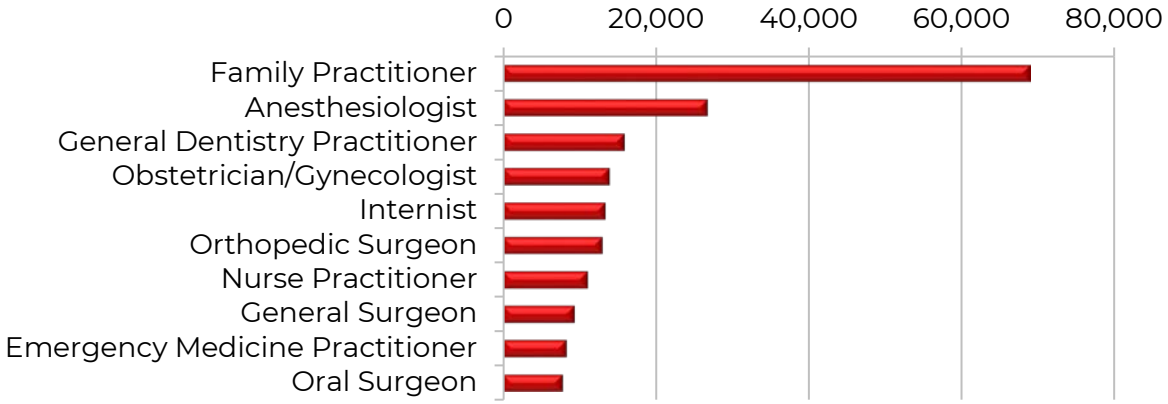
Demographics of Members Utilizing Opioid Analgesics



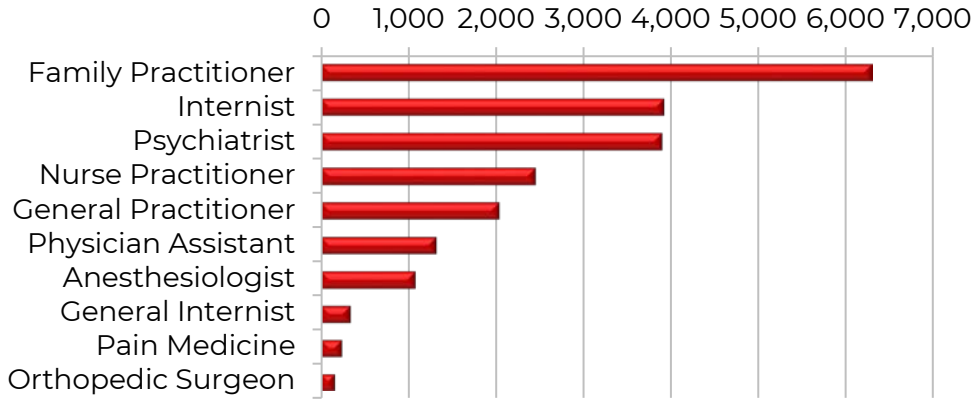
Demographics of Members Utilizing MAT Medications



Top Prescriber Specialties of Opioid Analgesics by Number of Claims



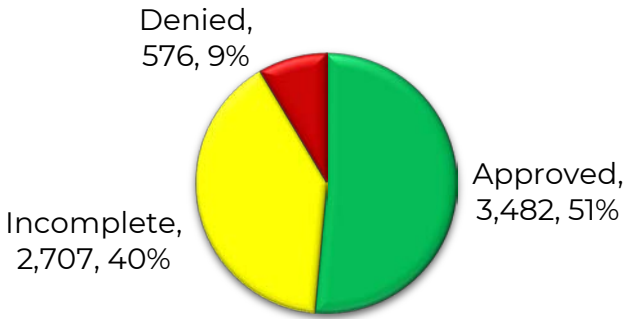
Top Prescriber Specialties of MAT Medications by Number of Claims



Prior Authorization of Opioid Analgesics and MAT Medications

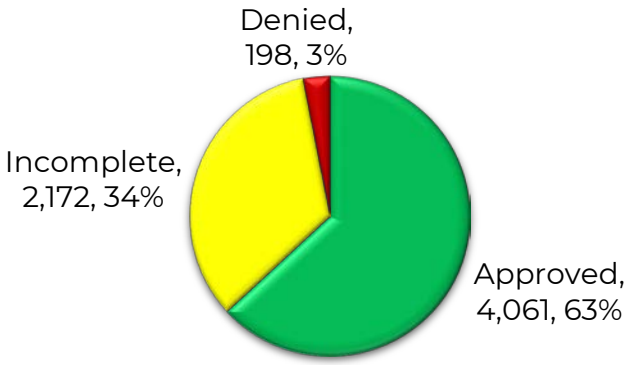
There were 6,765 prior authorization requests submitted for opioid analgesics during calendar year 2019. Computer edits are in place to detect diagnosis, quantity/day supply, and lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2019.

Status of Petitions: Opioid Analgesics



There were 6,431 prior authorizations submitted for MAT medications during calendar year 2019. 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 2019.

Status of Petitions: MAT Medications



Market News and Updates[3,4,5,6,7,8,9]

Anticipated Patent Expiration(s):

- Probuphine® (buprenorphine implant): April 2024
- 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
- Embeda® (morphine/naltrexone ER tablet): November 2029
- 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
- Sublocade® (buprenorphine ER injection): 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
- Xtampza® ER (oxycodone ER capsule): September 2036

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

- **June 2019:** The FDA approved an Abbreviated New Drug Application (ANDA) for tramadol 100mg IR tablets. The Wholesale Acquisition Cost (WAC) of tramadol 100mg is $1.44 per IR tablet. At a comparatively lower cost, the National Average Drug Acquisition Cost (NADAC) of

tramadol 50mg IR tablets (generic Ultram®) is $0.02 per IR tablet, or $0.04 per 100mg dose.

News:

- **May 2019:** As a result of Oklahoma Senate Bills 1446 and 848, effective May 21, 2019, the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) is requiring prescribers to indicate on the face of the prescription whether the opioid medication is for "acute pain" or "chronic pain". If the information is left off the prescription, the pharmacist may contact the prescriber for clarification and add the information to the back of the prescription.
- **September 2019:** The FDA Pediatric Advisory Committee (PAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee met to discuss the pediatric-focused safety review for OxyContin® and to discuss pediatric data considerations for opioid analgesics labeling. No new safety signals were identified for OxyContin® in the current pediatric safety review; therefore, the FDA recommended continuing ongoing, routine, post-market safety monitoring, along with completion of the post-marketing required studies and the committees agreed. To address the need for adequate pain management for pediatric patients that includes the use of opioids when appropriate, the committees discussed that product labeling should include appropriate pharmacokinetic, safety, and dosing information from clinical studies.
- **September 2019:** The U.S. Drug Enforcement Administration (DEA) proposed reducing the amount of 5 Schedule II opioid controlled substances that can be manufactured in the United States in 2020. The DEA proposed to reduce the amount of fentanyl produced by 31%, hydrocodone by 19%, hydromorphone by 25%, oxycodone by 9%, and oxymorphone by 55%, compared to amounts produced in 2019. Combined with morphine, the proposed quota would be a 53% decrease in the amount of allowable production of these opioids since 2016. The aggregate production quota set by the DEA each calendar year ensures that patients have the medications they need while also reducing excess production of controlled prescription drugs that can be diverted and misused.
- **October 2019:** The U.S. Department of HHS published a guide for appropriate tapering or discontinuation of long-term opioid use. The HHS guide provides advice to clinicians who are contemplating or initiating a change in opioid dosage and provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in risk for addiction. The HHS does not recommend opioids be tapered rapidly or discontinued suddenly

due to the significant risks of opioid withdrawal, unless there is a life-threatening situation confronting the individual patient.

Pipeline:

- **NKTR-181 (Oxycodegol):** In January 2020, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and DSaRM Advisory Committee did not recommend approval of the New Drug Application (NDA) for Nektar Therapeutics' NKTR-181 (oxycodegol), an experimental opioid analgesic. The committees cited concerns about the drug being misused or abused, the lack of data to determine the possible abuse when snorted or injected, and the potential for liver toxicity. According to Nektar, oxycodegol is the first full mu-opioid agonist molecule designed to provide potent pain relief but "without the high levels of euphoria that can lead to abuse and addiction with standard opioids." As a result of the committees' 27-0 vote against the approval of NKTR-181, Nektar decided to withdraw the NDA for oxycodegol and make no further investments into the program.

Recommendations

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

1. Placement of tramadol 100mg tablets into the Short-Acting Special PA category of the Opioid Analgesics Tier chart based on cost
   a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided
   b. An age restriction will apply for members younger than 12 years of age; authorization will require patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	oxymorphone IR tab (Opana®)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	tapentadol IR tab (Nucynta®)	dihydrocodeine/ APAP/caff cap (Trezix®)	**tramadol 100mg tab**

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Short-Acting			
codeine tab		hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	
codeine/APAP (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	
dihydrocodone/ 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®)			
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/APAP tab (Ultracet®)			fentanyl SL tab (Abstral®)
tramadol tab (Ultram®)			fentanyl transmucosal lozenge (Actiq®)

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

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.

Utilization Details of Opioid Analgesics: Calendar Year 2019

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	44,388	7,712	$787,400.30	$17.74	5.76
HYDROCOD/APAP TAB 7.5-325MG	33,275	16,162	$474,092.83	$14.25	2.06
HYDROCOD/APAP TAB 5-325MG	30,315	21,543	$365,030.39	$12.04	1.41
HYDROCOD/APAP SOL 7.5-325MG	5,915	5,494	$138,152.50	$23.36	1.08
HYDROCOD/IBU TAB 7.5-200MG	540	174	$13,345.26	$24.71	3.1
HYDROCOD/IBU TAB 10-200MG	79	15	$14,997.90	$189.85	5.27
HYDROCOD/IBU TAB 5-200MG	7	4	$1,434.24	$204.89	1.75
SUBTOTAL	**114,519**	**51,104**	**$1,794,453.42**	**$15.67**	**2.24**
IMMEDIATE-RELEASE OXYCODONE PRODUCTS					
OXYCOD/APAP TAB 10-325MG	16,915	3,355	$516,766.53	$30.55	5.04
OXYCOD/APAP TAB 5-325MG	13,194	10,322	$162,037.79	$12.28	1.28
OXYCOD/APAP TAB 7.5-325MG	7,861	3,300	$154,295.94	$19.63	2.38
OXYCODONE TAB 15MG	5,815	957	$128,923.70	$22.17	6.08
OXYCODONE TAB 10MG	4,951	1,100	$101,951.44	$20.59	4.5
OXYCODONE TAB 5MG	2,672	1,635	$33,983.26	$12.72	1.63
OXYCODONE TAB 20MG	2,150	412	$62,162.52	$28.91	5.22
OXYCODONE TAB 30MG	1,538	304	$53,076.66	$34.51	5.06
OXYCODONE SOL 5MG/5ML	1,184	1,090	$22,491.66	$19.00	1.09
OXYCODONE CAP 5MG	54	42	$1,682.48	$31.16	1.29
OXYCODONE CONC 100MG/5ML	13	7	$1,367.29	$105.18	1.86
OXYCOD/APAP TAB 2.5-325MG	12	7	$1,165.60	$97.13	1.71
OXYCOD/ASA TAB 4.8355-325 MG	7	7	$141.18	$20.17	1
SUBTOTAL	**56,366**	**22,538**	**$1,240,046.05**	**$22.00**	**2.5**
IMMEDIATE-RELEASE TRAMADOL PRODUCTS					
TRAMADOL TAB 50MG	25,967	9,772	$272,128.06	$10.48	2.66
TRAMADOL/APAP TAB 37.5-325MG	276	204	$4,081.72	$14.79	1.35
SUBTOTAL	**26,243**	**9,976**	**$276,209.78**	**$10.53**	**2.63**
CODEINE PRODUCTS					
APAP/CODEINE TAB 300-30MG	10,179	6,991	$124,500.34	$12.23	1.46
APAP/CODEINE TAB 300-60MG	5,212	1,561	$134,719.84	$25.85	3.34
BUT/APAP/CAF/COD 50/325/40/30MG	278	116	$14,834.37	$53.36	2.4
BUT/ASA/CAF/COD 50/325/40/30MG	182	64	$18,148.00	$99.71	2.84
APAP/CODEINE SOL 120-12MG/5ML	36	14	$744.30	$20.68	2.57
CODEINE SULF TAB 30MG	28	8	$1,337.51	$47.77	3.5
APAP/CODEINE TAB 300-15MG	16	14	$207.25	$12.95	1.14
CODEINE SULF TAB 60MG	10	2	$813.29	$81.33	5
CODEINE SULF TAB 15MG	1	1	$50.01	$50.01	1
SUBTOTAL	**15,942**	**8,771**	**$295,354.91**	**$18.53**	**1.82**
IMMEDIATE-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG	1,527	331	$53,415.41	$34.98	4.61

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
MORPHINE SULF TAB 30MG	407	91	$23,069.05	$56.68	4.47
MORPHINE SULF SOL 10MG/5ML	77	32	$1,453.07	$18.87	2.41
MORPHINE SULF SOL 100MG/5ML	72	48	$1,448.15	$20.11	1.5
MORPHINE SULF SOL 20MG/5ML	6	4	$200.12	$33.35	1.5
MORPHINE SULF INJ 4MG/ML	5	1	$446.11	$89.22	5
SUBTOTAL	**2,094**	**507**	**$80,031.91**	**$38.22**	**4.13**
IMMEDIATE-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHON TAB 4MG	722	172	$12,218.21	$16.92	4.2
HYDROMORPHON TAB 2MG	417	215	$5,557.13	$13.33	1.94
HYDROMORPHON TAB 8MG	190	51	$6,545.72	$34.45	3.73
HYDROMORPHON LIQ 1MG/ML	17	3	$9,353.21	$550.19	5.67
DILAUDID TAB 8MG	7	1	$3,991.18	$570.17	7
DILAUDID LIQ 1MG/ML	1	1	$460.39	$460.39	1
HYDROMORPHON INJ 500MG/50ML	1	1	$520.92	$520.92	1
SUBTOTAL	**1,355**	**444**	**$38,646.76**	**$28.52**	**3.05**
PENTAZOCINE PRODUCTS					
PENTAZ/NALOX TAB 50-0.5MG	401	110	$62,381.96	$155.57	3.65
SUBTOTAL	**401**	**110**	**$62,381.96**	**$155.57**	**3.65**
MEPERIDINE PRODUCTS					
MEPERIDINE SOL 50MG/5ML	262	209	$2,230.81	$8.51	1.25
MEPERIDINE TAB 50MG	114	102	$2,508.88	$22.01	1.12
MEPERIDINE TAB 100MG	14	6	$756.45	$54.03	2.33
MEPERIDINE INJ 100MG/ML	2	2	$15.50	$7.75	1
MEPERIDINE INJ 50MG/ML	1	1	$16.95	$16.95	1
SUBTOTAL	**393**	**320**	**$5,528.59**	**$14.07**	**1.23**
IMMEDIATE-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG	75	12	$7,674.66	$102.33	6.25
OXYMORPHONE TAB 5MG	37	8	$1,410.24	$38.11	4.63
SUBTOTAL	**112**	**20**	**$9,084.90**	**$81.12**	**5.6**
IMMEDIATE-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA TAB 50MG	72	13	$39,119.27	$543.32	5.54
NUCYNTA TAB 100MG	5	3	$3,150.52	$630.10	1.67
NUCYNTA TAB 75MG	1	1	$653.90	$653.90	1
SUBTOTAL	**78**	**17**	**$42,923.69**	**$550.30**	**4.59**
IMMEDIATE-RELEASE FENTANYL PRODUCTS					
FENTANYL LOZ 400MCG	2	1	$2,392.71	$1,196.36	2
SUBTOTAL	**2**	**1**	**$2,392.71**	**$1,196.36**	**2**
SHORT-ACTING SUBTOTAL	**217,505**	**93,808**	**$3,847,054.68**	**$17.69**	**2.32**
LONG-ACTING OPIOID ANALGESICS					
EXTENDED-RELEASE OXYCODONE PRODUCTS					
OXYCONTIN TAB 20MG ER	1,652	277	$656,319.37	$397.29	5.96
OXYCONTIN TAB 10MG ER	1,621	334	$336,008.87	$207.28	4.85
OXYCONTIN TAB 15MG ER	917	168	$295,811.10	$322.59	5.46

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OXYCONTIN TAB 30MG ER	604	117	$345,994.52	$572.84	5.16
OXYCONTIN TAB 40MG ER	375	77	$280,629.51	$748.35	4.87
OXYCONTIN TAB 60MG ER	265	48	$284,268.80	$1,072.71	5.52
OXYCONTIN TAB 80MG ER	215	34	$331,260.47	$1,540.75	6.32
XTAMPZA ER CAP 18MG	34	7	$16,509.63	$485.58	4.86
XTAMPZA ER CAP 13.5MG	28	6	$10,795.46	$385.55	4.67
XTAMPZA ER CAP 36MG	28	3	$26,619.43	$950.69	9.33
XTAMPZA ER CAP 9MG	27	4	$6,927.02	$256.56	6.75
XTAMPZA ER CAP 27MG	4	1	$2,711.86	$677.97	4
OXYCODONE TAB 10MG ER	3	1	$315.07	$105.02	3
OXYCODONE TAB 20MG ER	1	1	$49.04	$49.04	1
OXYCODONE TAB 40MG ER	1	1	$204.62	$204.62	1
SUBTOTAL	**5,775**	**1,079**	**$2,594,424.77**	**$449.25**	**5.35**
EXTENDED-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG ER	2,881	485	$55,522.13	$19.27	5.94
MORPHINE SULF TAB 30MG ER	2,034	338	$55,625.59	$27.35	6.02
MORPHINE SULF TAB 60MG ER	466	95	$22,129.24	$47.49	4.91
MORPHINE SULF TAB 100MG ER	83	21	$6,300.30	$75.91	3.95
EMBEDA CAP 20-0.8MG	83	22	$28,100.38	$338.56	3.77
EMBEDA CAP 30-1.2MG	43	11	$19,905.57	$462.92	3.91
MORPHINE SULF CAP 30MG ER	37	6	$5,505.06	$148.79	6.17
MORPHINE SULF CAP 10MG ER	32	5	$4,652.95	$145.40	6.4
MORPHINE SULF CAP 20MG ER	23	5	$4,570.11	$198.70	4.6
MORPHINE SULF CAP 60MG ER	19	3	$6,308.79	$332.04	6.33
MORPHINE SULF CAP 50MG ER	14	4	$4,099.50	$292.82	3.5
MORPHABOND TAB 15MG ER	9	2	$3,057.25	$339.69	4.5
MORPHINE SULF TAB 200MG ER	5	1	$750.62	$150.12	5
MORPHABOND TAB 30MG ER	4	2	$2,688.62	$672.16	2
MORPHINE SULF CAP 45MG ER	3	2	$836.17	$278.72	1.5
MORPHINE SULF CAP 40MG ER	3	1	$2,567.85	$855.95	3
MORPHABOND TAB 60MG ER	2	1	$2,171.02	$1,085.51	2
KADIAN CAP 40MG ER	1	1	$317.21	$317.21	1
MORPHINE SULF CAP 80MG ER	1	1	$596.39	$596.39	1
MORPHINE SULF CAP 100MG ER	1	1	$692.94	$692.94	1
SUBTOTAL	**5,744**	**1,007**	**$226,397.69**	**$39.41**	**5.7**
BUPRENORPHINE PAIN PRODUCTS					
BUPRENORPHINE DIS 20MCG/HR	676	154	$383,623.43	$567.49	4.39
BUPRENORPHINE DIS 10MCG/HR	675	308	$209,234.73	$309.98	2.19
BUPRENORPHINE DIS 15MCG/HR	521	180	$241,095.50	$462.76	2.89
BELBUCA MIS 300MCG	229	81	$113,737.26	$496.67	2.83
BUPRENORPHINE DIS 5MCG/HR	198	107	$40,880.65	$206.47	1.85
BELBUCA MIS 600MCG	174	45	$124,830.06	$717.41	3.87
BELBUCA MIS 450MCG	159	57	$107,154.77	$673.93	2.79

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BELBUCA MIS 150MCG	131	56	$42,129.24	$321.60	2.34
BUTRANS DIS 10MCG/HR	100	47	$43,004.32	$430.04	2.13
BUTRANS DIS 20MCG/HR	99	40	$74,175.47	$749.25	2.48
BELBUCA MIS 900MCG	96	16	$75,523.78	$786.71	6
BUTRANS DIS 15MCG/HR	75	29	$46,279.81	$617.06	2.59
BUPRENORPHINE DIS 7.5MCG/HR	71	29	$21,073.60	$296.81	2.45
BELBUCA MIS 750MCG	70	21	$53,225.61	$760.37	3.33
BUTRANS DIS 5MCG/HR	41	17	$11,752.99	$286.66	2.41
BELBUCA MIS 75MCG	33	21	$10,470.23	$317.28	1.57
BUTRANS DIS 7.5MCG/HR	21	14	$8,460.01	$402.86	1.5
SUBTOTAL	**3,369**	**1,222**	**$1,606,651.46**	**$476.89**	**2.76**
EXTENDED-RELEASE FENTANYL PRODUCTS					
FENTANYL DIS 25MCG/HR	715	170	$26,859.47	$37.57	4.21
FENTANYL DIS 50MCG/HR	459	122	$24,514.55	$53.41	3.76
FENTANYL DIS 12MCG/HR	401	86	$34,381.58	$85.74	4.66
FENTANYL DIS 75MCG/HR	295	68	$22,519.68	$76.34	4.34
FENTANYL DIS 100MCG/HR	191	47	$18,057.77	$94.54	4.06
FENTANYL DIS 37.5MCG/HR	81	14	$35,154.25	$434.00	5.79
FENTANYL DIS 62.5MCG/HR	6	3	$3,952.32	$658.72	2
DURAGESIC DIS 50MCG/HR	4	1	$3,194.79	$798.70	4
SUBTOTAL	**2,152**	**511**	**$168,634.41**	**$78.36**	**4.21**
EXTENDED-RELEASE HYDROCODONE PRODUCTS					
HYSINGLA ER TAB 40 MG	369	54	$196,925.01	$533.67	6.83
HYSINGLA ER TAB 20 MG	355	73	$94,626.40	$266.55	4.86
HYSINGLA ER TAB 30 MG	294	61	$114,238.54	$388.57	4.82
HYSINGLA ER TAB 60 MG	100	15	$73,822.82	$738.23	6.67
HYSINGLA ER TAB 80 MG	35	7	$34,744.87	$992.71	5
ZOHYDRO ER CAP 10MG	6	1	$3,253.80	$542.30	6
HYSINGLA ER TAB 100 MG	3	1	$4,003.56	$1,334.52	3
SUBTOTAL	**1,162**	**212**	**$521,615.00**	**$448.89**	**5.48**
METHADONE PRODUCTS					
METHADONE TAB 10MG	388	57	$7,058.38	$18.19	6.81
METHADONE TAB 5MG	93	15	$1,801.12	$19.37	6.2
METHADONE SOL 5MG/5ML	59	41	$831.84	$14.10	1.44
METHADONE SOL 10MG/5ML	1	1	$14.12	$14.12	1
SUBTOTAL	**541**	**114**	**$9,705.46**	**$17.94**	**4.75**
EXTENDED-RELEASE TRAMADOL PRODUCTS					
TRAMADOL TAB 100MG ER	112	45	$5,203.79	$46.46	2.49
TRAMADOL TAB 200MG ER	91	23	$6,781.99	$74.53	3.96
TRAMADOL TAB 300MG ER	48	15	$4,372.14	$91.09	3.2
SUBTOTAL	**251**	**83**	**$16,357.92**	**$65.17**	**3.02**
EXTENDED-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 8MG ER	19	4	$4,110.86	$216.36	4.75

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
HYDROMORPHONE TAB 32MG ER	11	1	$12,740.39	$1,158.22	11
HYDROMORPHONE TAB 12MG ER	9	1	$2,296.89	$255.21	9
SUBTOTAL	**39**	**6**	**$19,148.14**	**$490.98**	**6.5**
EXTENDED-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG ER	13	1	$2,671.79	$205.52	13
OXYMORPHONE TAB 20MG ER	12	1	$4,320.79	$360.07	12
OXYMORPHONE TAB 40MG ER	3	1	$1,896.07	$632.02	3
SUBTOTAL	**28**	**3**	**$8,888.65**	**$317.45**	**9.33**
EXTENDED-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA ER TAB 50MG	11	2	$4,431.49	$402.86	5.5
NUCYNTA ER TAB 250MG	4	1	$5,869.60	$1,467.40	4
SUBTOTAL	**15**	**3**	**$10,301.09**	**$686.74**	**5**
LONG-ACTING SUBTOTAL	**19,076**	**4,240**	**$5,182,124.59**	**$271.66**	**4.5**
OPIOID TOTAL	**236,581**	**73,865***	**$9,029,179.27**	**$38.17**	**3.2**

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

Utilization Details of MAT Medications: Calendar Year 2019

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUPRENORPHINE MAT PRODUCTS					
SUBOXONE MIS 8-2MG	9,098	1,367	$4,446,832.61	$488.77	6.66
BUPREN/NALOX SUB 8-2MG	5,006	814	$530,239.71	$105.92	6.15
BUPRENORPHINE SUB 8MG	2,510	435	$183,531.21	$73.12	5.77
BUPREN/NALOX MIS 8-2MG	979	529	$382,276.38	$390.48	1.85
BUPREN/NALOX SUB 2-0.5MG	218	62	$17,506.83	$80.31	3.52
SUBOXONE MIS 2-0.5MG	174	42	$37,264.80	$214.17	4.14
BUPRENORPHINE SUB 2MG	166	58	$7,239.04	$43.61	2.86
ZUBSOLV SUB 5.7-1.4MG	131	19	$71,757.20	$547.76	6.89
SUBOXONE MIS 4-1MG	124	44	$48,479.24	$390.96	2.82
SUBOXONE MIS 12-3MG	78	16	$63,928.05	$819.59	4.88
SUBLOCADE INJ 300MG/1.5ML	28	15	$44,509.48	$1,589.62	1.87
ZUBSOLV SUB 8.6-2.1MG	27	3	$24,333.30	$901.23	9
SUBLOCADE INJ 100MG/0.5ML	17	6	$27,040.00	$1,590.59	2.83
BUPREN/NALOX MIS 2-0.5MG	15	9	$2,747.05	$183.14	1.67
ZUBSOLV SUB 2.9-0.71MG	12	3	$5,843.18	$486.93	4
BUPREN/NALOX MIS 4-1MG	12	7	$3,451.83	$287.65	1.71
BUNAVAIL MIS 4.2-0.7MG	2	2	$1,169.25	$584.63	1
BUNAVAIL MIS 6.3-1MG	1	1	$900.86	$900.86	1
SUBTOTAL	**18,598**	**3,432**	**$5,899,050.02**	**$317.19**	**5.42**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
NALTREXONE PRODUCTS					
NALTREXONE TAB 50MG	3,603	757	$136,650.90	$37.93	4.76
VIVITROL INJ 380MG	125	41	$161,796.46	$1,294.37	3.05
SUBTOTAL	**3,728**	**798**	**$298,447.36**	**$80.06**	**4.67**
MAT TOTAL	**22,326**	**3,110***	**$6,197,497.38**	**$277.59**	**7.18**

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

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Appendix K

Calendar Year 2019 Annual Review of Amyloidosis Medications

Oklahoma Health Care Authority
July 2020

Current Prior Authorization Criteria

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; and
   b. Genetic confirmation of transthyretin (*TTR*) gene mutation (e.g., Val30Met); and
3. Onpattro® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or be an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
4. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
5. Prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H_1) antagonist, and IV histamine-2 (H_2) antagonist 60 minutes prior to Onpattro® administration to reduce the risk of infusion-related reaction(s); and
6. Onpattro® will not be approved for concomitant use with Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), or Vyndamax™ (tafamidis); and
7. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Onpattro® approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; and

   b. Genetic confirmation of transthyretin (*TTR*) gene mutation (e.g., Val30Met); and
3. Tegsedi® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or be an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
4. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
5. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
6. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
7. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
8. Tegsedi® will not be approved for concomitant use with Onpattro® (patisiran), Vyndaqel® (tafamidis meglumine), or Vyndamax™ (tafamidis); and
9. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Tegsedi® approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
11. A quantity limit of 4 syringes per 28 days will apply.

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

1. An FDA approved indication for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
   a. Genetic confirmation of transthyretin (*TTR*) mutation (e.g., Val122Ile) or wild-type amyloidosis; and
   b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
   a. Nuclear scintigraphy; or
   b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and

5. Vyndaqel® or Vyndamax™ must be prescribed by or in consultation with a cardiologist or geneticist (or be an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
6. Prescriber must verify Vyndaqel® or Vyndamax™ will not be used concomitantly with Onpattro® (patisiran) or Tegsedi® (inotersen); and
7. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 4 Vyndaqel® capsules or 1 Vyndamax™ capsule per day will apply.

Utilization of Amyloidosis Medications: Calendar Year 2019

There was no SoonerCare utilization of amyloidosis medications during calendar year 2019.

Prior Authorization of Amyloidosis Medications

There were no prior authorization requests submitted for amyloidosis medications during calendar year 2019.

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

Anticipated Patent Expiration(s):

- Vyndaqel® (tafamidis meglumine): April 2024
- Onpattro® (patisiran): November 2030
- Tegsedi® (inotersen): April 2031
- Vyndamax™ (tafamidis): August 2035

Pipeline:

- **AG10:** AG10 is an investigational, orally-administered small molecule designed to potently stabilize tetrameric transthyretin (TTR), stopping the molecular events that give rise to transthyretin amyloidosis (ATTR). In a Phase 2 clinical study in patients with symptomatic ATTR cardiomyopathy (ATTR-CM), AG10 was generally well tolerated, demonstrated >90% average TTR stabilization at day 28, and increased serum TTR concentrations in a dose-dependent manner, an indicator predicting survival in a retrospective study of ATTR-CM patients. AG10 is being studied in an open-label extension of a Phase 2 clinical study in patients with ATTR-CM. Additionally, a Phase 3 clinical study (ATTRibute-CM) in patients with ATTR-CM has been initiated.
- **CAEL-101:** CAEL-101 is a first-in-class monoclonal antibody (mAb) designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with amyloid light chain (AL) amyloidosis. AL amyloidosis is a rare systemic disorder

that causes misfolded immunoglobulin light chain protein to build up in and around tissues, resulting in progressive and widespread organ damage, most commonly to the heart and kidneys. In a Phase 1a/1b study, CAEL-101 demonstrated improved organ function, including cardiac and renal function, in 27 patients with relapsed and refractory AL amyloidosis who previously had no organ response to standard of care therapy (e.g., plasma cell directed chemotherapy, autologous stem cell transplant). Further, CAEL-101 showed a statistically significant improvement from baseline in global longitudinal strain, an endpoint that has been correlated with survival in patients with AL amyloidosis. CAEL-101 received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) as a therapy for patients with AL amyloidosis and as a radio-imaging agent in AL amyloidosis.

- **PRX004:** PRX004, a potential treatment for ATTR amyloidosis, is a mAb designed to deplete the pathogenic, non-native forms of the TTR protein. Prothena Corporation reported interim data from the first-in-human dosing in a Phase 1 clinical study of PRX004 in patients with hereditary ATTR (hATTR) amyloidosis. In the interim analysis, PRX004 was found to be generally safe and well tolerated and demonstrated pharmacokinetic profiles consistent with that of an immunoglobulin gamma 1 (IgG1) mAb. For the 3 patients in the 10mg/kg dose-level (the highest dose-level in the interim analysis), the maximum observed reductions in misTTR (the non-native forms of TTR) levels occurred within 24 hours of the first infusion and were reduced by 54%, 66%, and 76%. PRX004 did not appear to impact levels of normal tetrameric TTR.

Recommendations

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

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Appendix L

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 16, 2020

FDA Approves First Treatment for Adult Onset Still's Disease, a Severe and Rare Disease

The FDA has approved Ilaris (canakinumab) injection for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD). Ilaris was previously approved for Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years of age and older.

AOSD is a rare and serious autoinflammatory disease of unknown origin. Autoinflammatory diseases are caused by abnormalities of the immune system, which trigger an inflammatory response that can damage the body's own tissues. Characteristics of AOSD have considerable overlap with SJIA, which include fever, arthritis, rash, and elevated markers for inflammation. The overlapping features of AOSD and SJIA suggest this is a disease continuum rather than 2 separate diseases.

The role of interleukin-1 (IL-1), a type of cytokine important in regulating the body's immune system, is well-established in AOSD and SJIA. Ilaris works by blocking the effects of IL-1 and suppressing inflammation in patients with this autoinflammatory disorder. The safety and efficacy of Ilaris for the treatment of patients with AOSD was established using comparable pharmacokinetic exposure and extrapolation of established efficacy of canakinumab in patients with SJIA, as well as the safety of canakinumab in patients with AOSD and other diseases.

Common side effects reported by patients treated with Ilaris are infections (colds and upper respiratory tract infections), abdominal pain, and injection-site reactions. The prescribing information for Ilaris includes a warning for potential increased risk of serious infections due to IL-1 blockade. Macrophage activation syndrome (MAS) is a known, life-threatening disorder that may develop in patients with rheumatic conditions, in particular Still's disease, and should be aggressively treated. Treatment with immunosuppressants may increase the risk of malignancies. Patients are advised not to receive live vaccinations during treatment.

Ilaris was granted Priority Review designation, under which the FDA's goal is to take action on an application within 6 months where the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

FDA NEWS RELEASE

For Immediate Release: June 16, 2020

FDA Warns Four Manufacturers of Unapproved Injectable Drugs Labeled as Homeopathic

The FDA has issued warning letters to 4 companies for selling unapproved injectable drug products labeled as homeopathic that can pose serious risks to patient health and violate federal law, as part of the agency's efforts to protect Americans from potentially harmful products that are labeled as homeopathic.

The FDA is particularly concerned about unapproved injectable drug products labeled as homeopathic because they are injected directly into the body, often directly into the bloodstream and bypass some of the body's key natural defenses against toxins, toxic ingredients, and dangerous organisms that can cause serious and life-threatening

harm. Additionally, unapproved drugs that claim to cure, treat, or prevent serious conditions may cause consumers to delay or stop medical treatments that have been found safe and effective through the FDA review process. No currently marketed drug products labeled as homeopathic have been approved by the FDA for any use and the agency cannot assure these drugs meet modern standards for safety, effectiveness, and quality. Products labeled as homeopathic can be made from a wide range of substances, including ingredients derived from plants, healthy or diseased animal or human sources, minerals and chemicals, and they can include known poisons or toxins. These drugs are often marketed as natural, safe, and effective alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Additionally, the lack of premarket quality review is particularly concerning for injectable drugs, which generally pose a greater risk of harm to users because the route of administration for these products bypasses some of the body's natural defenses.

The FDA issued the warning letters to Hervert Pharmaceuticals, LLC; MediNatura, Inc.; 8046255 Canada, Inc., doing business as Viatrexx; and World Health Advanced Technologies, Ltd. The products included in the warning letters are new drugs because they are not generally recognized as safe and effective for their labeled uses, and the FDA has not approved these products. Some drugs, such as "Enercel," marketed by World Health Advanced Technologies, Ltd., are intended for serious diseases such as tuberculosis and hepatitis B and C.

Many of the drugs were labeled to contain potentially toxic ingredients such as nux vomica, belladonna (deadly nightshade), mercurius solubilis (mercury), and plumbum aceticum (lead). For example, nux vomica contains strychnine, which is a highly toxic, well-studied poison that is used to kill rodents. The agency is concerned that these potentially toxic ingredients present additional risks of serious harm when delivered directly into the body, including directly into the bloodstream.

Drugs labeled as homeopathic may also cause significant and even irreparable harm if they are poorly manufactured. Viatrexx was also cited for substandard manufacturing practices for sterile drugs. The foreign manufacturers of the injectable drugs sold by Hervert Pharmaceuticals, LLC; MediNatura New Mexico, Inc.; and Viatrexx were also placed on import alert 66-41 to stop these drugs from entering the United States.

The FDA has taken steps to clarify for both consumers and industry how the potential safety risks of these products are assessed. On Oct. 24, 2019, the FDA withdrew Compliance Policy Guide (CPG) 400.400 "Conditions Under Which Homeopathic Drugs May be Marketed," because it was inconsistent with the agency's risk-based approach to regulatory and enforcement actions. The FDA also issued a revision of its draft guidance, titled Drug Products Labeled as Homeopathic: Guidance for FDA Staff and Industry, for public comment. When finalized, this guidance will explain the categories of homeopathic drug products that the FDA intends to prioritize under our risk-based enforcement approach. In the interim, before the draft guidance is finalized, the FDA intends to apply its general approach to prioritizing risk-based regulatory and enforcement action.

The FDA encourages health care professionals and consumers to report adverse events or quality problems experienced with the use of any of these products to the FDA's MedWatch Adverse Event Reporting program. To report adverse drug events in animals, see How to Report Animal Drug Side Effects and Product Problems on the FDA website.

FDA NEWS RELEASE

For Immediate Release: June 15, 2020

Coronavirus (COVID-19) Update: FDA Warns of Newly Discovered Potential Drug Interaction That May Reduce Effectiveness of a COVID-19 Treatment Authorized for Emergency Use

The FDA is warning health care providers about a newly discovered potential drug interaction related to the investigational antiviral drug remdesivir, which has received emergency use authorization for the treatment of hospitalized COVID-19 patients with severe disease.

Based on a recently completed non-clinical laboratory study, the FDA is revising the fact sheet for health care providers that accompanies the drug to state that co-administration of remdesivir and chloroquine phosphate or hydroxychloroquine sulfate is not recommended as it may result in reduced antiviral activity of remdesivir. The agency is not aware of instances of this reduced activity occurring in the clinical setting but is continuing to evaluate all data related to remdesivir.

In addition, the FDA revised the fact sheet for health care providers to clarify dosing and administration recommendations and to provide additional safety data and supporting data from clinical trials conducted by both the National Institutes of Health (NIH) and the drug sponsor, Gilead Sciences Inc. The fact sheet for patients and caregivers was also updated to include additional information about possible allergic reactions and to alert patients to tell their health care providers if they are taking chloroquine phosphate or hydroxychloroquine sulfate.

Following an evaluation of the emergency use authorization criteria and the scientific evidence available, the FDA issued an emergency use authorization (EUA) in May 2020 allowing for remdesivir to be distributed in the United States for intravenous (IV) administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in adults and pediatric patients hospitalized with severe disease. The safety and efficacy of remdesivir for the treatment of COVID-19 continue to be evaluated, and preliminary clinical trial results have shown that on average, patients treated with remdesivir had more rapid time to recovery.

The EUA requires that fact sheets about using remdesivir in treating COVID-19 be made available to health care providers, patients, and caregivers. These fact sheets include information on possible side effects such as: increased levels of liver enzymes, which may be a sign of inflammation or damage to cells in the liver; and allergic reactions, which may include low blood pressure, high heart rate, low heart rate, shortness of breath, wheezing, angioedema, difficulty swallowing, rash, nausea, vomiting, sweating, shivering, and respiratory distress.

FDA NEWS RELEASE

For Immediate Release: June 15, 2020

Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine

The FDA revoked the EUA that allowed for chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was unavailable, or participation in a clinical trial was not feasible. The agency determined that the legal criteria for issuing an EUA are no longer met.

Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in

treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use. This is the statutory standard for issuance of an EUA.

The Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services originally requested the EUA covering chloroquine and hydroxychloroquine, and the FDA granted the EUA on March 28, 2020 based on the science and data available at the time. Today, in consultation with the FDA, BARDA sent a letter to the FDA requesting revocation of the EUA based on up-to-date science and data. The FDA has a responsibility to regularly review the appropriateness of an EUA, and as such, the agency will review emerging information associated with the emergency uses for the authorized products. Recent results from a large randomized clinical trial in hospitalized patients, a population similar to the population for which chloroquine and hydroxychloroquine were authorized for emergency use, demonstrated that hydroxychloroquine showed no benefit on mortality or in speeding recovery. This outcome was consistent with other new data, including data showing that the suggested dosing regimens for chloroquine and hydroxychloroquine are unlikely to kill or inhibit the virus that causes COVID-19. The totality of scientific evidence currently available indicate a lack of benefit.

Chloroquine and hydroxychloroquine are both FDA-approved to treat or prevent malaria. Hydroxychloroquine is also approved to treat autoimmune conditions such as chronic discoid lupus erythematosus, systemic lupus erythematosus, and rheumatoid arthritis. Both drugs have been prescribed for years to help patients with these debilitating, or even deadly, diseases, and the FDA has determined that these drugs are safe and effective when used for these diseases in accordance with their FDA-approved labeling. Of note, FDA approved products may be prescribed by physicians for off-label uses if they determine it is appropriate for treating their patients, including for COVID-19.

FDA NEWS RELEASE

For Immediate Release: June 12, 2020

FDA Approves Drug to Treat Infants and Children with HIV

The FDA approved Tivicay (dolutegravir) tablets and Tivicay PD (dolutegravir) tablets for suspension to treat human immunodeficiency virus 1 (HIV-1) infection in pediatric patients at least 4 weeks old and weighing at least 3kg (6.61 pounds) in combination with other antiretroviral treatments.

According to the U.S. Centers for Disease Control and Prevention (CDC), at the end of 2016, there were 2,238 children younger than 13 years old living with HIV in the United States and dependent areas, with 99 new HIV-1 infections diagnosed in this age group in 2017. Effective treatment is important in reducing the amount of virus in the blood. Tivicay and Tivicay PD are intended to treat pediatric patients at least 4 weeks old and 3kg who have never been treated for HIV or who have been treated, but not with an integrase strand transferase inhibitor (INSTI) class drug.

The safety and effectiveness of Tivicay and Tivicay PD were supported by a trial that included 75 HIV-1–infected infants, children, and adolescents 4 weeks to younger than 18 years old. The average age was 27 months old. This trial, where both the researchers and subjects knew which treatment was being administered, along with another trial, showed that the safety, effectiveness, and pharmacokinetics of Tivicay and Tivicay PD in pediatric patients was comparable to adults taking dolutegravir. At 24 weeks, 62% of

pediatric patients taking Tivicay or Tivicay PD had an undetectable viral load and at 48 weeks, 69% had an undetectable viral load. Also, on average, study subjects had higher levels of CD4 cells that help the body fight off infection.

The most common adverse reactions observed in adult patients treated with Tivicay are insomnia, fatigue, and headache. Patients with a hypersensitivity to dolutegravir should not take Tivicay or Tivicay PD. Tivicay and Tivicay PD should not be administered with dofetilide. Some patients reported hypersensitivity reactions such as rash and organ dysfunction. Patients should discontinue Tivicay or Tivicay PD if signs or symptoms of hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Patients taking dolutegravir regimens have reported liver toxicity. Patients with underlying hepatitis B or C may be at increased risk for worsening or elevated liver enzyme levels and should be monitored. Patients in the first trimester of pregnancy should consider an alternative treatment to dolutegravir due to the risk of neural tube defects and should be counseled about using effective contraception. Immune reconstitution inflammatory syndrome (IRIS), where the immune system begins to recover but then responds to a previously acquired infection with an inflammatory response that unexpectedly makes symptoms of the infection worse, has been reported in patients treated with combination antiretroviral therapy, including Tivicay and Tivicay PD. Tivicay tablets and Tivicay PD tablets for oral suspension are not substitutable on a milligram per milligram basis. This application received Priority Review designation from the FDA.

FDA NEWS RELEASE

For Immediate Release: June 11, 2020

FDA Approves New Therapy for Rare Disease Affecting Optic Nerve, Spinal Cord

The FDA approved Uplizna (inebilizumab-cdon) injection for IV use for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. NMOSD is a rare autoimmune disease of the central nervous system (CNS) that mainly affects the optic nerves and spinal cord. Uplizna is only the second approved treatment for the disorder.

In patients with NMOSD, the body's immune system mistakenly attacks healthy cells and proteins in the body, most often those in the optic nerves and spinal cord. Individuals with NMOSD typically have attacks of optic neuritis, which causes eye pain and vision loss. Individuals also can have attacks resulting in transverse myelitis, which often causes numbness, weakness, or paralysis of the arms and legs, along with loss of bladder and bowel control. Most attacks occur in clusters, days to months to years apart, followed by partial recovery during periods of remission. Approximately 50% of patients with NMOSD have permanent visual impairment and paralysis caused by NMOSD attacks. According to the NIH, women are more often affected by NMOSD than men and African Americans are at greater risk of the disease than are Caucasians. Estimates vary, but NMOSD is thought to impact approximately 4,000 to 8,000 patients in the United States.

NMOSD can be associated with antibodies that bind to a protein called AQP4. Binding of the anti-AQP4 antibody appears to activate other components of the immune system, causing inflammation and damage to the CNS.

The effectiveness of Uplizna for the treatment of NMOSD was demonstrated in a clinical trial of 230 adult patients that evaluated the efficacy and safety of IV Uplizna. In the trial, 213 of the 230 patients had antibodies against AQP4 (anti-AQP4 antibody positive). During the 197-day trial, the risk of an NMOSD relapse in the 161 anti-AQP4

antibody positive patients who were treated with Uplizna was reduced by 77% when compared to the placebo treatment group. There was no evidence of a benefit in patients who were anti-AQP4 antibody negative.

The prescribing information for Uplizna includes a warning for infusion reactions, potential depletion of certain proteins (hypogammaglobulinemia), potential increased risk of infection (including progressive multifocal leukoencephalopathy), and potential reactivation of hepatitis B and tuberculosis. The most common adverse reactions in the NMOSD clinical trial were urinary tract infection, headache, joint pain, nausea, and back pain. Women who are pregnant should not take Uplizna because it may cause harm to a developing fetus or newborn baby. The FDA advises health care professionals to inform females of reproductive age to use effective contraception during treatment with Uplizna and for 6 months after the last dose. Vaccination with live-attenuated or live vaccines is not recommended during treatment and should be administered at least 4 weeks prior to initiation of Uplizna.

FDA NEWS RELEASE

For Immediate Release: June 8, 2020

Federal Government Announces New Pilot Program to Help Stop Illegal Availability of Unapproved Opioids Online

The FDA and the National Telecommunications and Information Administration (NTIA) are launching a 120-day pilot to help reduce the availability of unapproved opioids illegally offered for sale online.

Under the pilot, the FDA will notify internet registries that are participating in the pilot (Neustar, Verisign, and Public Interest Registry) when the agency sends a warning letter to a website operator and the website operator does not respond adequately within the required timeframe. The internet registries will review the FDA's notifications and assess whether to take further voluntary action, including possible domain name suspensions or blocks. The NTIA, a branch of the U.S. Department of Commerce, responsible for telecommunications and information policy issues, will work with the internet registries involved in the pilot and partner with the FDA to assess its impact.

At the end of the pilot, the agencies will analyze its effectiveness as a potential solution to dealing with the illegal sale of unapproved opioids online.

The FDA remains committed to addressing the national opioid crisis on all fronts, with a continued focus on decreasing exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain treatment therapies; and taking action against those who contribute to the illegal sale and importation of unapproved opioids.

FDA NEWS RELEASE

For Immediate Release: June 4, 2020

FDA Approves Antibiotic to Treat Hospital-Acquired Bacterial Pneumonia and Ventilator Associated Bacterial Pneumonia

The FDA approved Recarbrio (imipenem/cilastatin/relebactam) to treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in patients 18 years of age and older. Recarbrio was previously FDA approved to treat patients with complicated urinary tract infections and complicated intra-abdominal infections who have limited or no alternative treatment options.

HABP/VABP occurs in hospitalized patients and can cause symptoms such as fever, chills, cough, chest pain, and increased oxygen requirements. Recarbrio is a combination

of imipenem/cilastatin/relebactam, and is administered via IV by a health care professional.

The safety and efficacy of Recarbrio for the treatment of HABP/VABP were evaluated in a randomized, controlled clinical trial of 535 hospitalized adults with HABP/VABP due to gram-negative bacteria in which 266 patients were treated with Recarbrio and 269 patients were treated with piperacillin/tazobactam, another antibacterial drug. Overall, 16% of patients who received Recarbrio and 21% of patients who received piperacillin/tazobactam died through day 28 of the study.

The most common adverse reactions observed in patients treated with Recarbrio for HABP/VABP included increased aspartate/alanine aminotransferases, anemia, diarrhea, hypokalemia, and hyponatremia. Before initiating therapy with Recarbrio, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta lactams and other allergens. Recarbrio should not be used in patients who are prone to seizures and other CNS disorders. *Clostridioides difficile*-associated diarrhea has been reported with use of nearly all antibacterial agents, including Recarbrio, and may range in severity from mild diarrhea to fatal colitis.

This application was granted a Qualified Infectious Disease Program (QIDP) designation. This designation is given to antibacterial and antifungal drug products intended to treat serious or life-threatening infections under the Generating Antibiotic Incentives Now (GAIN) title of the FDA Safety and Innovation Act. Additionally, as part of QIDP designation, the FDA granted this application Fast Track and Priority Review designations.

Current Drug Shortages Index (as of June 17, 2020):

The information provided in this section is provided voluntarily by manufacturers.

Alogliptin Tablets	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Aminophylline Injection, USP	***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***
Avycaz® (ceftazidime and avibactam) for Injection, 2 grams/0.5	***Currently in Shortage***
Azithromycin Tablets	***Currently in Shortage***
Belatacept (Nulojix®) Lyophilized Powder for Injection	***Currently in Shortage***
Bumetanide Injection, USP	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection, USP	***Currently in Shortage***
Bupivacaine Hydrochloride Injection, USP	***Currently in Shortage***
Calcitriol Injection USP 1MCG /ML	***Currently in Shortage***
Calcium Chloride Injection, USP	***Currently in Shortage***
Capreomycin Injection, USP	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***

Cefepime Injection	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cefoxitin for Injection, USP	***Currently in Shortage***
Cisatracurium Besylate Injection	***Currently in Shortage***
Continuous Renal Replacement Therapy (CRRT) Solutions	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Dicyclomine Oral Tablets/Capsules	***Currently in Shortage***
Diltiazem Hydrochloride	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection USP	***Currently in Shortage***
Diphenhydramine Injection	***Currently in Shortage***
Disulfiram Tablets	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dorzolamide Hydrochloride and Timolol Maleate (Cosopt®) Ophthalmic Solution	***Currently in Shortage***
Dorzolamide Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide®) Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection, USP	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Epinephrine Injection, Auto-Injector	***Currently in Shortage***
Erythromycin Lactobionate for Injection, USP	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Famotidine Injection	***Currently in Shortage***
Famotidine Tablets	***Currently in Shortage***
Fentanyl Citrate (Sublimaze®) Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Fluorescein Strips	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Furosemide Injection, USP	***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***
Hydrocortisone Tablets, USP	***Currently in Shortage***
Hydromorphone Hydrochloride Injection, USP	***Currently in Shortage***
Hydroxychloroquine Sulfate Tablets	***Currently in Shortage***
Hydroxypropyl (Lacrisert®) Cellulose Ophthalmic Insert	***Currently in Shortage***
Hydroxyzine Pamoate Oral Capsules	***Currently in Shortage***
Imipenem and Cilastatin for Injection, USP	***Currently in Shortage***

Ketamine Injection	***Currently in Shortage***
Ketoprofen Capsules	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Labetalol Hydrochloride Injection	***Currently in Shortage***
Letermovir (Prevymis™) Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Levetiracetam Extended-Release Oral Tablets, USP	***Currently in Shortage***
Levetiracetam Immediate-Release Oral Tablets, USP	***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, USP	***Currently in Shortage***
Loxapine Capsules	***Currently in Shortage***
Methadone Hydrochloride Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride (Quillivant XR®) for Extended-Release Oral Suspension	***Currently in Shortage***
Metoprolol Tartrate Injection, USP	***Currently in Shortage***
Metronidazole Injection, USP	***Currently in Shortage***
Midazolam Injection, USP	***Currently in Shortage***
Morphine Sulfate Injection, USP	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Nalbuphine Hydrochloride Injection	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Ondansetron Hydrochloride Injection	***Currently in Shortage***
Oxytocin Injection, USP Synthetic	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara®) Injection	***Currently in Shortage***
Physostigmine Salicylate Injection, USP	***Currently in Shortage***
Pindolol Tablets	***Currently in Shortage***
Potassium Acetate Injection, USP	***Currently in Shortage***
Procainamide Hydrochloride Injection, USP	***Currently in Shortage***
Promethazine (Phenergan®) Injection	***Currently in Shortage***
Propofol Injectable Emulsion	***Currently in Shortage***
Rabeprazole Sodium Delayed-Release Tablets	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sclerosol Intrapleural Aerosol	***Currently in Shortage***
Sertraline Hydrochloride Oral Solution, USP	***Currently in Shortage***
Sertraline Hydrochloride Tablets	***Currently in Shortage***
Sincalide (Kinevac®) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection, USP	***Currently in Shortage***

Sodium Bicarbonate Injection, USP	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection USP, 0.9% Vials and Syringes	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Tacrolimus Capsules	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Thiothixene Capsules	***Currently in Shortage***
Timolol Maleate Ophthalmic Gel Forming Solution	***Currently in Shortage***
Timolol Maleate Ophthalmic Solution	***Currently in Shortage***
Timolol Maleate Tablets	***Currently in Shortage***
Triamcinolone Acetonide (Triesence®) Injection, Suspension	***Currently in Shortage***
Trifluridine Ophthalmic Solution	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***