Oklahoma Health Care Authority

Drug Utilization Review Board

Wednesday,
June 12, 2019
4:00pm

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

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Melissa Abbott, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – June 12, 2019

DATE: June 5, 2019

Note: The DUR Board will meet at 4:00pm. The meeting will be held at 4345 N. Lincoln Blvd.

Enclosed are the following items related to the June 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/Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/ Angiotensin Receptor Blocker (ARB) Therapy in Patients with Diabetes and Hypertension (HTN) Mailing Update – Appendix B

Action Item – Vote to Prior Authorize Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase) – Appendix C

Action Item – Vote to Prior Authorize Plenvu® [Polyethylene Glycol (PEG)-3350/Sodium Ascorbate/Sodium Sulfate/Ascorbic Acid/Sodium Chloride/Potassium Chloride] – Appendix D

Action Item – Vote to Prior Authorize Consensi® (Amlodipine/Celecoxib) and Kapspargo™ Sprinkle [Metoprolol Succinate Extended-Release (ER)] – Appendix E

Action Item – Vote to Update the Prior Authorization Criteria For H.P. Acthar® Gel (Repository Corticotropin Injection) – Appendix F

Action Item – Vote to Prior Authorize Fulphila® (Pegfilgrastim-jmdb), Nivestym™ (Filgrastim-aafi), and Udenyca™ (Pegfilgrastim-cbqv) – Appendix G

Action Item – Vote to Prior Authorize Xyosted™ [Testosterone Enanthate Subcutaneous (Sub-Q) Auto-Injector] and Jatenzo® (Testosterone Undecanoate Oral Capsule) – Appendix H

Action Item – Vote to Prior Authorize Cablivi® (Caplacizumab-yhdp) – Appendix I

Action Item – Vote to Prior Authorize Dextenza® (Dexamethasone Ophthalmic Insert), Inveltys™ (Loteprednol Etabonate Suspension), Lotemax® SM (Loteprednol Etabonate Gel), and Oxervate™ (Cenegermin-bkbj) – Appendix J

Action Item – Vote to Prior Authorize Lorbrena® (Lorlatinib), Mvasi® (Bevacizumab-awwb), and Vizimpro® (Dacomitinib) – Appendix K

30-Day Notice to Prior Authorize Balversa™ (Erdafitinib) – Appendix L

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify MyCite® (Aripiprazole Tablets with Sensor), Aristada Initio® [Aripiprazole Lauroxil Extended-Release (ER) Injectable Suspension], and Perseris™ [Risperidone ER Subcutaneous (Sub-Q) Injectable Suspension] – Appendix M

Annual Review of ADHD and Narcolepsy Medications and 30-Day Notice to Prior Authorize Jornay PM™ [Methylphenidate Extended-Release (ER) Capsule], Evekeo ODT™ [Amphetamine Orally Disintegrating Tablet (ODT)], Adhansia XR™ (Methylphenidate ER Capsule), and Sunosi™ (Solriamfetol Tablet) – Appendix N

Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System), Bijuva™ (Estradiol/Progesterone Capsule), Cequa™ (Cyclosporine 0.09% Ophthalmic Solution), Corlanor® (Ivabradine Oral Solution), Crotan™ (Crotamiton 10% Lotion), Gloperba® (Colchicine Oral Solution), Glycate® (Glycopyrrolate Tablet), Khapzory™ (Levoleucovorin Injection), Qmiiz™ ODT [Meloxicam Orally Disintegrating Tablet (ODT)], Seconal Sodium™ (Secobarbital Sodium Capsule), TaperDex™ (Dexamethasone Tablet), Tiglutik™ (Riluzole Oral Suspension), TobraDex® ST (Tobramycin/Dexamethasone 0.3%/0.05% Ophthalmic Suspension), Tolsura™ (Itraconazole Capsule), and Yutiq™ (Fluocinolone Acetonide Intravitreal Implant) – Appendix O

Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Cassipa® (Buprenorphine/Naloxone) and Levorphanol – Appendix P

Industry News and Updates – Appendix Q

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 12, 2019 @ 4:00pm

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

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

1. Call to Order

A. Roll Call – Dr. Cothran

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. April 10, 2019 DUR Minutes – Vote
B. April 10, 2019 DUR Recommendations Memorandum
C. May 8, 2019 DUR Recommendations Memorandum

Items to be presented by Dr. Abbott, Dr. Connell, Dr. Muchmore, Chairman:

4. Update on Medication Coverage Authorization Unit/Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB) Therapy in Patients with Diabetes and Hypertension (HTN) Mailing Update – See Appendix B

A. Medication Coverage Activity for May 2019
B. Pharmacy Helpdesk Activity for May 2019
C. Use of ACEI/ARB Therapy in Patients with Diabetes and HTN Mailing Update

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

5. Action Item – Vote to Prior Authorize Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase) – See Appendix C

A. Introduction
B. College of Pharmacy Recommendations

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

6. Action Item – Vote to Prior Authorize Plenvu® [Polyethylene Glycol (PEG)-3350/Sodium Ascorbate/Sodium Sulfate/Ascorbic Acid/Sodium Chloride/Potassium Chloride] – See Appendix D

A. Introduction
B. College of Pharmacy Recommendations

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

7. Action Item – Vote to Prior Authorize Consensi® (Amlodipine/Celecoxib) and Kapspargo™ Sprinkle [Metoprolol Succinate Extended-Release (ER)] – See Appendix E

A. Introduction
B. College of Pharmacy Recommendations

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

8. Action Item – Vote to Update the Prior Authorization Criteria for H.P. Acthar® Gel (Repository Corticotropin Injection) – See Appendix F

A. College of Pharmacy Recommendations

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

9. Action Item – Vote to Prior Authorize Fulphila® (Pegfilgrastim-jmdb), Nivestym™ (Filgrastim-aafi), and Udenyca™ (Pegfilgrastim-cbqv) – See Appendix G

A. Introduction
B. College of Pharmacy Recommendations

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

10. Action Item – Vote to Prior Authorize Xyosted™ [Testosterone Enanthate Subcutaneous (Sub-Q) Auto-Injector] and Jatenzo® (Testosterone Undecanoate Oral Capsule) – See Appendix H

A. Introduction
B. College of Pharmacy Recommendations

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

11. Action Item – Vote to Prior Authorize Cablivi® (Caplacizumab-yhdp) – See Appendix I

A. Introduction
B. College of Pharmacy Recommendations

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

12. Action Item – Vote to Prior Authorize Dextenza® (Dexamethasone Ophthalmic Insert), Inveltys™ (Loteprednol Etabonate Suspension), Lotemax® SM (Loteprednol Etabonate Gel), and Oxervate™ (Cenegermin-bkbj) – See Appendix J

A. Introduction
B. College of Pharmacy Recommendations

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

13. Action Item – Vote to Prior Authorize Lorbrena® (Lorlatinib), Mvasi® (Bevacizumab-awwb), and Vizimpro® (Dacomitinib) – See Appendix K

A. Introduction
B. Market News and Updates
C. Recommendations

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

14. 30-Day Notice to Prior Authorize Balversa™ (Erdafitinib) – See Appendix L

A. Introduction
B. Market News and Updates
C. Balversa™ (Erdafitinib) Product Summary
D. Recommendations

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

15. Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify MyCite® (Aripiprazole Tablets with Sensor), Aristada Initio® [Aripiprazole Lauroxil Extended-Release (ER) Injectable Suspension], and Perseris™ [Risperidone ER Subcutaneous (Sub-Q) Injectable Suspension] – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of Atypical Antipsychotic Medications
C. Prior Authorization of Atypical Antipsychotic Medications
D. Medicaid Drug Rebate Program
E. Market News and Updates
F. Abilify MyCite® (Aripiprazole Tablets with Sensor) Product Summary
G. Aristada Initio® (Aripiprazole Lauroxil ER Injectable Suspension) Product Summary
H. Perseris™ (Risperidone ER Sub-Q Injectable Suspension) Product Summary
I. College of Pharmacy Recommendations
J. Utilization Details of Atypical Antipsychotic Medications

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

16. Annual Review of ADHD and Narcolepsy Medications and 30-Day Notice to Prior Authorize Jornay PM™ [Methylphenidate Extended-Release (ER) Capsule], Evekeo ODT™ [Amphetamine

Orally Disintegrating Tablet (ODT)], Adhansia XR™ (Methylphenidate ER Capsule), and Sunosi™ (Solriamfetol Tablet) – See Appendix N

A. Current Prior Authorization Criteria
B. Utilization of ADHD and Narcolepsy Medications
C. Prior Authorization of ADHD and Narcolepsy Medications
D. Medicaid Drug Rebate Program
E. Market News and Updates
F. Jornay PM™ (Methylphenidate Hydrochloride ER Capsule) Product Summary
G. Adhansia XR™ (Methylphenidate Hydrochloride ER Capsule) Product Summary
H. Sunosi™ (Solriamfetol Tablet) Product Summary
I. College of Pharmacy Recommendations
J. Utilization Details of ADHD and Narcolepsy Medications

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

17. Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System), Bijuva™ (Estradiol/Progesterone Capsule), Cequa™ (Cyclosporine 0.09% Ophthalmic Solution), Corlanor® (Ivabradine Oral Solution), Crotan™ (Crotamiton 10% Lotion), Gloperba® (Colchicine Oral Solution), Glycate® (Glycopyrrolate Tablet), Khapzory™ (Levoleucovorin Injection), Qmiiz™ ODT [Meloxicam Orally Disintegrating Tablet (ODT)], Seconal Sodium™ (Secobarbital Sodium Capsule), TaperDex™ (Dexamethasone Tablet), Tiglutik™ (Riluzole Oral Suspension), TobraDex® ST (Tobramycin/Dexamethasone 0.3%/0.05% Ophthalmic Suspension), Tolsura™ (Itraconazole Capsule), and Yutiq™ (Fluocinolone Acetonide Intravitreal Implant) – See Appendix O

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Special Formulations
D. Prior Authorization of Special Formulations
E. Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) Product Summary
F. Bijuva™ (Estradiol/Progesterone Capsule) Product Summary
G. Cequa™ (Cyclosporine 0.09% Ophthalmic Solution) Product Summary
H. Corlanor® (Ivabradine Oral Solution) Product Summary
I. Crotan™ (Crotamiton 10% Lotion) Product Summary
J. Gloperba® (Colchicine Oral Solution) Product Summary
K. Glycate® (Glycopyrrolate Tablet) Product Summary
L. Khapzory™ (Levoleucovorin Injection) Product Summary
M. Qmiiz™ ODT [Meloxicam Orally Disintegrating Tablet (ODT)] Product Summary
N. Seconal Sodium™ (Secobarbital Sodium Capsule) Product Summary
O. TaperDex™ (Dexamethasone Tablet) Product Summary
P. Tiglutik™ (Riluzole Oral Suspension) Product Summary
Q. TobraDex® ST (Tobramycin/Dexamethasone 0.3%/0.05% Ophthalmic Suspension) Product Summary
R. Tolsura™ (Itraconazole Capsule) Product Summary
S. Yutiq™ (Fluocinolone Acetonide Intravitreal Implant) Product Summary
T. College of Pharmacy Recommendations
U. Utilization Details of Special Formulations

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

18. Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Cassipa® (Buprenorphine/Naloxone) and Levorphanol – See Appendix P

A. Current Prior Authorization Criteria
B. Utilization of Opioid Analgesics and MAT Medications
C. Prior Authorization of Opioid Analgesics and MAT Medications
D. Market News and Updates
E. Cassipa® (Buprenorphine/Naloxone) Product Summary
F. Levorphanol Product Summary
G. College of Pharmacy Recommendations
H. Utilization Details of Opioid Analgesics

I. Utilization Details of MAT Medications

Non-Presentation; Questions Only:

19. Industry News and Updates – See Appendix Q

A. Introduction

B. News and Updates

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

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

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

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

A. Botulinum Toxins

B. Qbrexza™ (Glycopyrronium)

C. Spinal Muscular Atrophy Medications

D. Topical Corticosteroids

**Future business subject to change.*

22. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF APRIL 10, 2019

BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.	x	
Markita Broyles, D.Ph.; MBA	x	
Darlla D. Duniphin, MHS; PA-C	x	
Theresa Garton, M.D.	x	
Carla Hardzog-Britt, M.D.	x	
Ashley Huddleston, Pharm.D.; BCOP		x
John Muchmore, M.D.; Ph.D.; Chairman	x	
Lee Munoz, D.Ph.	x	
James Osborne, Pharm.D.	x	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Terry Cothran, D.Ph.; Pharmacy Director	x	
Melissa Abbott, Pharm.D.; Clinical Pharmacist	x	
Michyla Adams, Pharm.D.; Clinical Pharmacist	x	
Wendi Chandler, Pharm.D.; Clinical Pharmacist	x	
Sarai Connell, Pharm.D.; MBA; Resident	x	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Thomas Ha, Pharm.D.; Clinical Pharmacist		x
Bethany Holderread, Pharm.D.; Clinical Coordinator	x	
Shellie Keast, Ph.D.; Assistant Professor	x	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	x	
Regan Smith, Pharm.D.; Clinical Pharmacist		x
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist		x
Graduate Students: Michael Nguyen, Pharm.D.		x
Corby Thompson, Pharm.D.		x
Laura Tidmore, Pharm.D.		x
Reagan Williams, Pharm.D.		x
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony, Deputy State Medicaid Director		x
Marlene Asmussen, R.N.; Population Care Management Director		x
Burl Beasley, D.Ph.; M.P.H.; M.S. Pharm.; Sr. Director of Pharmacy	x	
Kelli Brodersen, Marketing Coordinator		x
Susan Eads, J.D.; Director of Litigation	x	
Robert Evans, M.D.; Sr. Medical Director		x
Michael Herndon, D.O.; Chief Medical Officer		x
Nancy Nesser, Pharm.D.; J.D.; Pharmacy Director		x
Thomas Nunn, D.O.; Medical Director	x	
Rebecca Pasternik-Ikard, J.D.; M.S.; R.N.; State Medicaid Director; CEO		x
Jill Ratterman, D.Ph.; Clinical Pharmacist	x	
Kerri Wade, Pharmacy Operations Manager	x	

OTHERS PRESENT:		
Bob Atkins, Biogen	Jason Russell, Genzyme	Mark Friederich, DZ
Edward Drea, Sanofi-Genzyme	Jomy Joseph, Sanofi-Genzyme	Ron Cain, Pfizer
Frances Bauman, Novo Nordisk	Jim Chapman, AbbVie	Brant Hildebrand, Gilead
Brian Maves, Pfizer	Jim Dunlap, PhRMA	

PRESENT FOR PUBLIC COMMENT:	
Jomy Joseph	Sanofi-Genzyme

AGENDA ITEM NO. 1: CALL TO ORDER

1A: ROLL CALL

Dr. Muchmore called the meeting to order. Roll call by Dr. Cothran established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: PUBLIC COMMENT FORUM

2A: AGENDA ITEM NO. 13 JOMY JOSEPH

ACTION: NONE REQUIRED

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

3A: MARCH 13, 2019 DUR MINUTES – VOTE

3B: MARCH 13, 2019 DUR RECOMMENDATIONS MEMORANDUM

Materials included in agenda packet; presented by Dr. Cothran

Dr. Munoz moved to approve; seconded by Dr. Anderson

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/LONG-ACTING BETA$_2$-AGONIST UTILIZATION: PEDIATRIC MEMBERS

4A: MEDICATION COVERAGE ACTIVITY FOR MARCH 2019

4B: PHARMACY HELPDESK ACTIVITY FOR MARCH 2019

4C: LONG-ACTING BETA$_2$-AGONIST UTILIZATION: PEDIATRIC MEMBERS

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE TAKHZYRO™ (LANADELUMAB-FLYO) AND TO UPDATE THE PRIOR AUTHORIZATION CRITERIA FOR CINRYZE® (C1 ESTERASE INHIBITOR), HAEGARDA® (C1 ESTERASE INHIBITOR), AND KALBITOR® (ECALLANTIDE)

5A: INTRODUCTION

5B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Chandler

Dr. Anderson moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE ADCETRIS® (BRENTUXIMAB VEDOTIN), BELEODAQ® (BELINOSTAT), CALQUENCE® (ACALABRUTINIB), FOLOTYN® (PRALATREXATE), ISTODAX® (ROMIDEPSIN), POTELIGEO® (MOGAMULIZUMAB-KPKC), TRUXIMA® (RITUXIMAB-ABBS), ZEVALIN® (IBRITUMOMAB TIUXETAN), AND ZOLINZA® (VORINOSTAT)

6A: INTRODUCTION

6B: MARKET NEWS AND UPDATES

6C: RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Schmidt

Dr. Hardzog-Britt moved to approve; seconded by Dr. Munoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE COPIKTRA™ (DUVELISIB)

7A: INTRODUCTION

7B: RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Schmidt
Dr. Anderson moved to approve; seconded by Dr. Broyles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE LUTATHERA® (LUTETIUM LU 177 DOTATATE) AND VITRAKVI® (LAROTRECTINIB)
8A: INTRODUCTION
8B: RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Schmidt
Dr. Munoz moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF LUNG CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LORBRENA® (LORLATINIB), MVASI® (BEVACIZUMAB-AWWB), AND VIZIMPRO® (DACOMITINIB)
9A: INTRODUCTION
9B: CURRENT PRIOR AUTHORIZATION CRITERIA
9C: UTILIZATION OF LUNG CANCER MEDICATIONS
9D: PRIOR AUTHORIZATION OF LUNG CANCER MEDICATIONS
9E: MARKET NEWS AND UPDATES
9F: PRODUCT SUMMARIES
9G: RECOMMENDATIONS
9H: UTILIZATION DETAILS OF LUNG CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Schmidt
ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT
10A: SUMMARY
10B: MEDICAID DRUG REBATE PROGRAM
10C: ALTERNATIVE PAYMENT MODELS
10D: DRUG APPROVAL TRENDS
10E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
10F: TOP 10 THERAPEUTIC CLASSES BY REIMBURSEMENT
10G: TOP 10 MEDICATIONS BY REIMBURSEMENT
10H: COST PER CLAIM
10I: CONCLUSION
10J: TOP 100 REIMBURSED DRUGS BY FISCAL YEAR
10K: TOP 50 MEDICATIONS BY TOTAL NUMBER OF CLAIMS
10L: TOP 10 TRADITIONAL AND SPECIALTY THERAPEUTIC CATEGORIES BY FISCAL YEAR
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND 30-DAY NOTICE TO PRIOR AUTHORIZE FULPHILA® (PEGFILGRASTIM-JMDB), NIVESTYM™ (FILGRASTIM-AAFI), AND UDENYCA™ (PEGFILGRASTIM-CBQV)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF G-CSFS
11C: PRIOR AUTHORIZATION OF G-CSFS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF G-CSFS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: **ANNUAL REVIEW OF ANTI-DIABETIC MEDICATIONS**

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ANTI-DIABETIC MEDICATIONS
12C: PRIOR AUTHORIZATION OF ANTI-DIABETIC MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF NON-INSULIN ANTI-DIABETIC MEDICATIONS
12G: UTILIZATION DETAILS OF INSULIN MEDICATIONS

Materials included in agenda packet; presented by Dr. Nawaz

ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: **30-DAY NOTICE TO PRIOR AUTHORIZE CABLIVI® (CAPLACIZUMAB-YHDP)**

13A: INTRODUCTION
13B: CABLIVI® (CAPLACIZUMAB-YHDP) PRODUCT SUMMARY
13C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Chandler

ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: **30-DAY NOTICE TO PRIOR AUTHORIZE ALDURAZYME® (LARONIDASE) AND NAGLAZYME® (GALSULFASE)**

14A: INTRODUCTION
14B: ALDURAZYME® (LARONIDASE) PRODUCT SUMMARY
14C: NAGLAZYME® (GALSULFASE) PRODUCT SUMMARY
14D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Connell

ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: **ANNUAL REVIEW OF ANTIHYPERTENSIVE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CONSENSI® (AMLODIPINE/CELECOXIB) AND KAPSPARGO™ SPRINKLE [METOPROLOL SUCCINATE EXTENDED-RELEASE (ER)]**

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTIHYPERTENSIVE MEDICATIONS
15C: PRIOR AUTHORIZATION OF ANTIHYPERTENSIVE MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: CONSENSI® (AMLODIPINE/CELECOXIB TABLETS) PRODUCT SUMMARY
15F: KAPSPARGO™ SPRINKLE (METOPROLOL SUCCINATE ER CAPSULES) PRODUCT SUMMARY
15G: COLLEGE OF PHARMACY RECOMMENDATIONS
15H: UTILIZATION DETAILS OF ANTIHYPERTENSIVE MEDICATIONS

Materials included in agenda packet; presented by Dr. Abbott

ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: **INDUSTRY NEWS AND UPDATES**

16A: INTRODUCTION
16B: NEWS AND UPDATES

Materials included in agenda packet; Non-presentation; Questions only

ACTION: NONE REQUIRED

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

Materials included in agenda packet; presented by Dr. Cothran

ACTION: NONE REQUIRED

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

No live meeting scheduled in May 2019. May 2019 will be a packet only meeting.

18A: BOWEL PREPARATION MEDICATIONS
18B: H.P. ACTHAR® GEL (REPOSITORY CORTICOTROPIN INJECTION)
18C: OPHTHALMIC ANTI-INFLAMMATORIES
18D: TESTOSTERONE PRODUCTS
**Future business subject to change.*
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: ADJOURNMENT
The meeting was adjourned at 4:56pm.

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

Memorandum

Date: April 11, 2019

To: Nancy Nesser, Pharm.D.; J.D.
Pharmacy Director
Oklahoma Health Care Authority (OHCA)

Burl Beasley, D.Ph.; M.P.H.; M.S. Pharm.
Pharmacy Director
OHCA

From: Bethany Holderread, Pharm.D.
Clinical Coordinator
Pharmacy Management Consultants

Subject: Drug Utilization Review (DUR) Board Recommendations from Meeting of April 10, 2019

Recommendation 1: Long-Acting Beta$_2$-Agonist Utilization: Pediatric Members

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Takhzyro™ (Lanadelumab-flyo) and to Update the Prior Authorization Criteria for Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), and Kalbitor® (Ecallantide)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Takhzyro™ (lanadelumab-flyo) with criteria similar to Cinryze® and Haegarda® (C1 esterase inhibitors) and to update the current Cinryze® and Haegarda® criteria to be consistent with current guideline recommendations (changes shown in red):

Cinryze® (C1 Esterase Inhibitor), ~~and~~ Haegarda® (C1 Esterase Inhibitor), and Takhzyro™ (Lanadelumab-flyo) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Must be used for *prophylaxis* of HAE; and
3. Not currently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. History of at least 1 or more abdominal or respiratory HAE attacks per month, or history of laryngeal attacks, or 3 or more emergency medical treatments per year; or
5. ~~Member meets the following:~~ Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
   a. ~~Documented intolerance, insufficient response, or contraindication to attenuated androgens (e.g., danazol, stanozolol, oxandrolone, methyltestosterone); and~~
   b. ~~Documented intolerance, insufficient response, or contraindication to antifibrinolytic agents (e.g., ε – aminocaproic acid, tranexamic acid); or~~
   c. ~~Recent hospitalization for severe episode of angioedema; and~~
6. Authorization of Takhzyro™ (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze® or Haegarda® (C1 esterase inhibitor); and
7. Cinryze® Dosing:
   a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
   b. Initial doses should be administered in an outpatient setting by a health care provider (members can be taught by their health care provider to self-administer Cinryze® IV); and
   c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); or
8. Haegarda® Dosing:
   a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
   b. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
   c. A quantity limit of 2 treatments per week or 8 treatments 28 days will apply; or
9. Takhzyro™ Dosing:
   a. The recommended dose of Takhzyro™ is 300mg sub-Q every 2 weeks (dosing every 4 weeks may be considered in some members); and
   b. Prescriber must verify member or caregiver has been trained by a health care provider on proper storage and sub-Q administration of Takhzyro™; and
   c. A quantity limit of (2) 300mg/2mL vials per 28 days will apply.

Additionally, the College of Pharmacy recommends updating the current Kalbitor® (ecallantide) criteria based on net cost (changes shown in red):

Ruconest® (C1 Esterase Inhibitor) and Kalbitor® (Ecallantide) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Ruconest® and Kalbitor® must be used for *treatment* of acute attacks of HAE; and

3. A patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) and Firazyr® (icatibant) must be provided.

Recommendation 3: Vote to Prior Authorize Adcetris® (Brentuximab Vedotin), Beleodaq® (Belinostat), Calquence® (Acalabrutinib), Folotyn® (Pralatrexate), Istodax® (Romidepsin), Poteligeo® (Mogamulizumab-kpkc), Truxima® (Rituximab-abbs), Zevalin® (Ibritumomab Tiuxetan), and Zolinza® (Vorinostat)

MOTION CARRIED by unanimous approval.

- Update the prior authorization criteria to reflect new U.S. Food and Drug Administration (FDA) approved indications and guideline recommendations; changes can be seen in the following criteria listed in red (only criteria with updates listed)
- The prior authorization of Adcetris® (brentuximab vedotin), Beleodaq® (belinostat), Calquence® (acalabrutinib), Folotyn® (pralatrexate), Istodax® (romidepsin), Poteligeo® (mogamulizumab-kpkc), Truxima® (rituximab-abbs), Zevalin® (ibritumomab tiuxetan), and Zolinza® (vorinostat) with the following criteria listed in red

Keytruda® (Pembrolizumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. A diagnosis of metastatic NSCLC; and
2. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for PD-L1 expression as follows:
    a. As a single-agent, first-line: ≥50%; or
    b. First-line in combination: no expression required; or
    c. As a single-agent, second-line: ≥1%; and
4. Member meets 1 of the following:
    a. Previously untreated, metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel; or
    b. Previously untreated, metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or
    c. New diagnosis as first-line therapy (member has not received chemotherapy to treat disease) if:
        i. Tumor does not express sensitizing Epidermal Growth Factor Receptor (EGFR) mutations or Anaplastic Lymphoma Kinase (ALK) translocations; or
    d. Single-agent for disease progression on or after platinum-containing chemotherapy (cisplatin or carboplatin):
        i. Members with EGFR-mutation-positive should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations*; and
            1. *Examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib*
        ii. Members with ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to

receiving pembrolizumab. *This does not apply if tumors do not have these mutations*; and

1. *Examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib.*

Keytruda® (Pembrolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Member meets 1 of the following:
   a. Adjuvant treatment of melanoma with involvement of lymph node(s) following complete resection; or
   b. A diagnosis of unresectable or metastatic melanoma; and
2. Pembrolizumab must be used as a single-agent; and
3. Member meets 1 of the following:
   a. Pembrolizumab is being used as first-line therapy; or
   b. Pembrolizumab is being used as second-line therapy or subsequent therapy for disease progression if not previously used; and
4. The member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)]; and
5. For adjuvant treatment of melanoma, dose as follows:
   a. 200mg every 3 weeks; and
   b. Maximum duration of 1 year.

Keytruda® (Pembrolizumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Relapsed or progressive disease; and
2. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Member must have been previously treated with sorafenib.

Keytruda® (Pembrolizumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. A diagnosis of recurrent, locally advanced or metastatic MCC; and
2. No history of prior systemic chemotherapy; and
3. Pembrolizumab must be used as a single-agent; and
4. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)].

Adcetris® (Brentuximab Vedotin) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. As a single-agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease; or
2. In combination with cyclophosphamide, doxorubicin, and prednisone (CHP) for primary treatment or in relapsed/refractory disease with regional nodes.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Systemic Diagnosis]:

1. In previously untreated disease in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); or
2. In members who have received ≥1 line of therapy as a single-agent.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Classical Hodgkin Lymphoma Diagnosis]:

1. In previously untreated Stage III or IV disease in combination with doxorubicin, vinblastine, and dacarbazine; or

2. In relapsed/refractory disease after failure of ≥2 multi-agent chemotherapy regimens in non-autologous stem cell transplant (SCT) candidates or after failure of autologous SCT as a single-agent; or
3. In relapsed/refractory disease if not previously used in combination with multi-agent chemotherapy; or
4. Consolidation following autologous SCT in members at high risk of relapse or progression.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High Grade Lymphoma Diagnosis]:

1. As a single-agent; and
2. CD30+ disease; and
3. For DLBCL relapsed/refractory disease in non-autologous stem cell transplant (SCT) candidates; or
4. For members who have transformed to DLBCL from follicular lymphoma or marginal zone lymphoma and received ≥2 lines of therapy for indolent or transformed disease.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single-agent as primary treatment or in relapsed/refractory disease.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. Treatment of previously untreated CD30+ disease in combination with cyclophosphamide, doxorubicin, and prednisone (CHP); or
2. In members who have received ≥1 line of therapy as a single-agent.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Adult T-Cell Leukemia/Lymphoma Diagnosis]:

1. CD30+ disease; and
2. Member meets 1 of the following:
    a. In combination with cyclophosphamide, doxorubicin, and prednisone (CHP) in nonresponders to first-line therapy for chronic/smoldering subtype; or
    b. In combination with CHP for first-line therapy for acute or lymphoma subtype; or
    c. In combination with CHP for continued treatment in responders to first-line therapy for acute or lymphoma subtype; or
    d. In members who have received ≥1 line of therapy as a single-agent.

Adcetris® (Brentuximab Vedotin) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. CD30+ disease; and
2. As a single-agent; and
3. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Beleodaq® (Belinostat) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. As a single-agent for primary treatment or relapsed refractory with multifocal lesions, or cutaneous ALCL with regional nodes.

Beleodaq® (Belinostat) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. Primary treatment in Stage IV non Sézary or visceral disease (solid organ) with or without radiation therapy for local control; or
2. Primary treatment for large cell transformation with generalized cutaneous or extracutaneous lesions with or without skin-directed therapy; or
3. As a single-agent (with or without skin-directed therapy) in relapsed/refractory disease.

Beleodaq® (Belinostat) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Beleodaq® (Belinostat) Approval Criteria [Adult T-Cell Leukemia/Lymphoma Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Beleodaq® (Belinostat) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. As a single-agent; and
2. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Calquence® (Acalabrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As a single-agent in members who have received ≥1 prior therapy.

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Adult T-Cell Leukemia/Lymphoma Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. As a single-agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Folotyn® (Pralatrexate) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. As a single-agent; and
2. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Folotyn® (Pralatrexate) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single-agent as primary treatment or in relapsed/refractory disease.

Istodax® (Romidepsin) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single-agent as primary treatment or in relapsed/refractory disease.

Istodax® (Romidepsin) Approval Criteria [Anaplastic Large Cell Lymphoma (ALCL), Primary Cutaneous Diagnosis]:

1. As a single-agent in members with multifocal lesions or regional nodes either as primary treatment or in relapsed/refractory disease.

Istodax® (Romidepsin) Approval Criteria [Peripheral T-Cell Lymphoma (PTCL) Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Istodax® (Romidepsin) Approval Criteria [T-Cell Lymphoma, Extranodal NK/T-Cell Lymphoma, Nasal Type Diagnosis]:

1. As a single-agent; and
2. Relapsed/refractory disease following additional therapy with an alternate combination chemotherapy regimen not previously used.

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single-agent as primary treatment or in relapsed/refractory disease.

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Adult T-Cell Leukemia/Lymphoma Diagnosis]:

1. As a single-agent in relapsed/refractory disease.

Truxima® (Rituximab-abbs) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Rituxan® (rituximab) must be provided.

Zevalin® (Ibritumomab Tiuxetan) Approval Criteria [Follicular Lymphoma (FL) (Grade 1-2) Diagnosis]:

1. As a single-agent in relapsed or refractory disease.

Zevalin® (Ibritumomab Tiuxetan) Approval Criteria [Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL) Transformed to Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. As a single-agent; and
2. Member meets 1 of the following:
    a. Minimal or no chemotherapy prior to histologic transformation to DLBCL (FISH for MYC and BCL2 and/or BCL6 must show no translocation) and have partial response, no response, or progressive disease after chemoimmunotherapy; or
    b. ≥2 prior therapies of chemoimmunotherapy for indolent or transformed disease.

Zolinza® (Vorinostat) Approval Criteria [Primary Cutaneous Lymphomas – Mycosis Fungoides (MF)/Sézary Syndrome (SS) Diagnosis]:

1. As a single-agent as primary treatment or in relapsed/refractory disease.

Recommendation 4: Vote to Prior Authorize Copiktra™ (Duvelisib)

MOTION CARRIED by unanimous approval.

- Update the prior authorization criteria to reflect new FDA approved indications and guideline recommendations; changes can be seen in the following criteria listed in red (only criteria with updates listed)
- The prior authorization of Copiktra™ (duvelisib) with the following criteria listed in red

Gazyva® (Obinutuzumab) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. In combination with chlorambucil, bendamustine, or ibrutinib for first-line therapy; or
2. As a single-agent for relapsed or refractory disease.

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. As first-line or subsequent therapy for CLL/SLL; and
2. As a single-agent or in combination with bendamustine, rituximab, or obinutuzumab.

Imbruvica® (Ibrutinib) Approval Criteria [Waldenström's Macroglobulinemia (WM)/ Lymphoplasmacytic Lymphoma Diagnosis]:

1. As first-line or subsequent therapy; and
2. As a single-agent or in combination with rituximab.

Venclexta® (Venetoclax) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Member meets 1 of the following:
   a. Member must be 75 years of age or older; or
   b. If the member is younger than 75 years of age, they must be unable to tolerate intensive induction chemotherapy; and
2. Must be used as first-line therapy; and
3. Must be used in combination with azacitidine, or decitabine, or low-dose cytarabine (LDAC).

Copiktra™ (Duvelisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. A diagnosis of relapsed or refractory FL; and
2. Progression of disease following 2 or more lines of systemic therapy; and
3. Must be used as a single-agent.

Copiktra™ (Duvelisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. A diagnosis of relapsed or refractory CLL or SLL; and
2. Progression of disease following 2 or more lines of systemic therapy; and
3. Must be used as a single-agent.

Recommendation 5: Vote to Prior Authorize Lutathera® (Lutetium Lu 177 Dotatate) and Vitrakvi® (Larotrectinib)

MOTION CARRIED by unanimous approval.

Lutathera® (Lutetium Lu 177 Dotatate) Approval Criteria [Gastroenteropancreatic Neuroendocrine Tumor (GEP-NET) Diagnosis]:

1. Diagnosis of progressive locoregional advanced disease or metastatic disease; and
2. Positive imaging of somatostatin receptor; and
3. Must be used as second-line or subsequent therapy following progression on octreotide or lanreotide; or
4. May be used first-line for treatment of pheochromocytoma/paraganglioma.

Vitrakvi® (Larotrectinib) Approval Criteria [Solid Tumors With Neurotrophic Receptor Tyrosine Kinase (*NTRK*) Gene Fusion Diagnosis]:

1. Diagnosis of a solid tumor with a *NTRK* gene fusion without a known acquired resistance mutation; and
2. Disease is metastatic or surgical resection (or radioactive iodine refractory if thyroid carcinoma) is contraindicated; and
3. Documentation of no satisfactory alternative treatments or progression following acceptable alternative treatments.

Recommendation 6: Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Lorbrena® (Lorlatinib), Mvasi® (Bevacizumab-awwb), and Vizimpro® (Dacomitinib)

NO ACTION REQUIRED.

Recommendation 7: Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Granulocyte Colony-Stimulating Factors (G-CSFs) and 30-Day Notice to Prior Authorize Fulphila® (Pegfilgrastim-jmdb), Nivestym™ (Filgrastim-aafi), and Udenyca™ (Pegfilgrastim-cbqv)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Anti-Diabetic Medications

NO ACTION REQUIRED.

Recommendation 10: 30-Day Notice to Prior Authorize Cablivi® (Caplacizumab-yhdp)

NO ACTION REQUIRED.

Recommendation 11: 30-Day Notice to Prior Authorize Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Antihypertensive Medications and 30-Day Notice to Prior Authorize Consensi® (Amlodipine/Celecoxib) and Kapspargo™ Sprinkle [Metoprolol Succinate Extended-Release (ER)]

NO ACTION REQUIRED.

Recommendation 13: Industry News and Updates

NO ACTION REQUIRED.

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

NO ACTION REQUIRED.

Recommendation 15: Future Business

NO ACTION REQUIRED.

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

Memorandum

Date: May 9, 2019

To: Nancy Nesser, Pharm.D.; J.D.
Pharmacy Director
Oklahoma Health Care Authority (OHCA)

Burl Beasley, D.Ph.; M.P.H.; M.S. Pharm.
Pharmacy Director
OHCA

From: Melissa Abbott, Pharm.D.
Clinical Pharmacist
Pharmacy Management Consultants

Subject: Drug Utilization Review (DUR) Board Recommendations from Packet of May 8, 2019

Recommendation 1: 2019 Spring Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Annual Review of Bowel Preparation Medications and 30-Day Notice to Prior Authorize Plenvu® [Polyethylene Glycol (PEG)-3350/Sodium Ascorbate/Sodium Sulfate/Ascorbic Acid/Sodium Chloride/Potassium Chloride]

NO ACTION REQUIRED.

Recommendation 3: Annual Review of Ophthalmic Anti-Inflammatories and 30-Day Notice to Prior Authorize Dextenza® (Dexamethasone Ophthalmic Insert), Inveltys™ (Loteprednol Etabonate Suspension), Lotemax® SM (Loteprednol Etabonate Gel), and Oxervate™ (Cenegermin-bkbj)

NO ACTION REQUIRED.

Recommendation 4: Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Xyosted™ [Testosterone Enanthate Subcutaneous (Sub-Q) Auto-Injector] and Jatenzo® (Testosterone Undecanoate Oral Capsule)

NO ACTION REQUIRED.

Recommendation 5: Annual Review of H.P. Acthar® Gel (Repository Corticotropin Injection)

NO ACTION REQUIRED.

Recommendation 6: Annual Review of Jynarque® (Tolvaptan)

NO ACTION REQUIRED.

Recommendation 7: Industry News and Updates

NO ACTION REQUIRED.

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

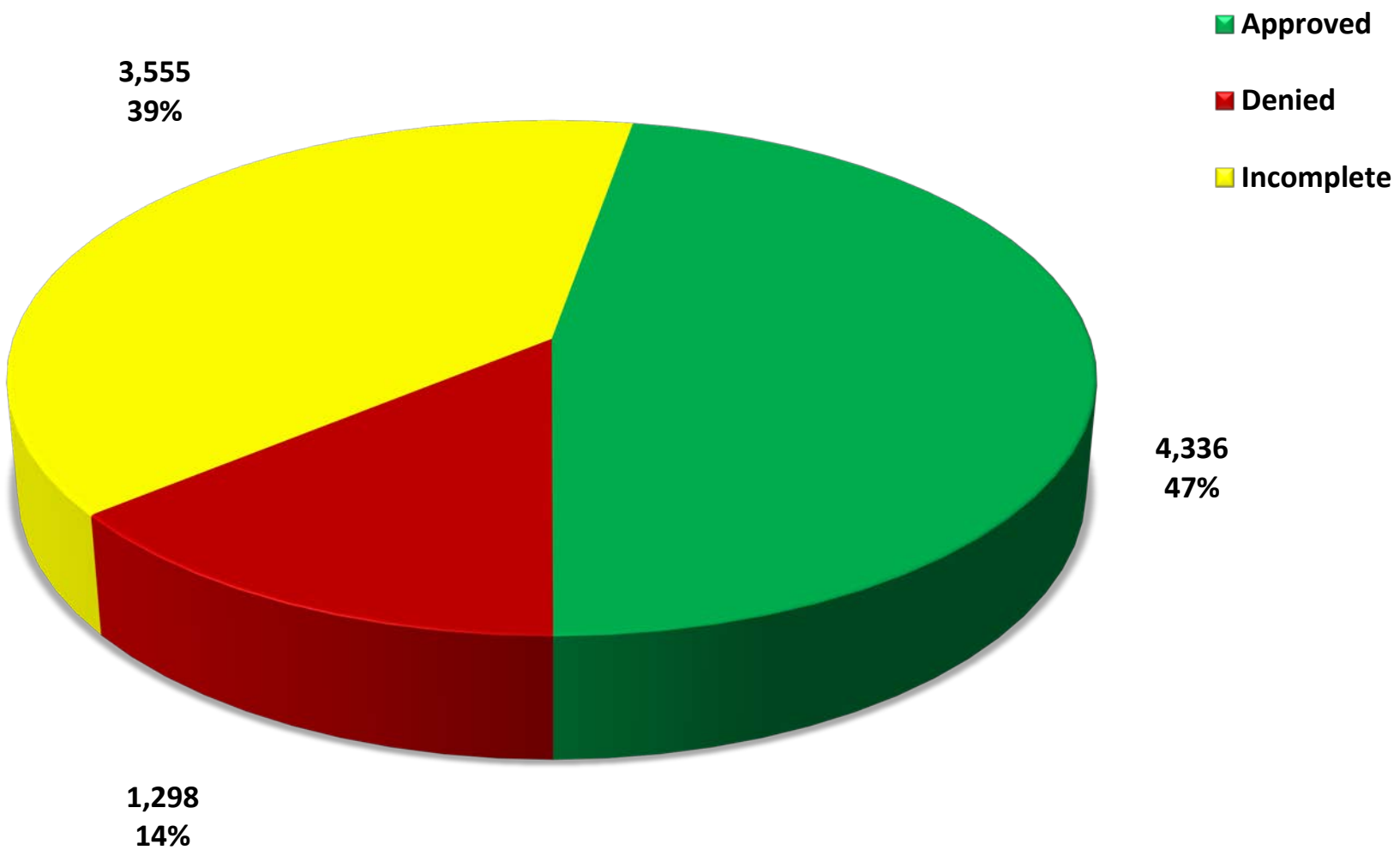
NO ACTION REQUIRED.

Recommendation 9: Future Business

NO ACTION REQUIRED.

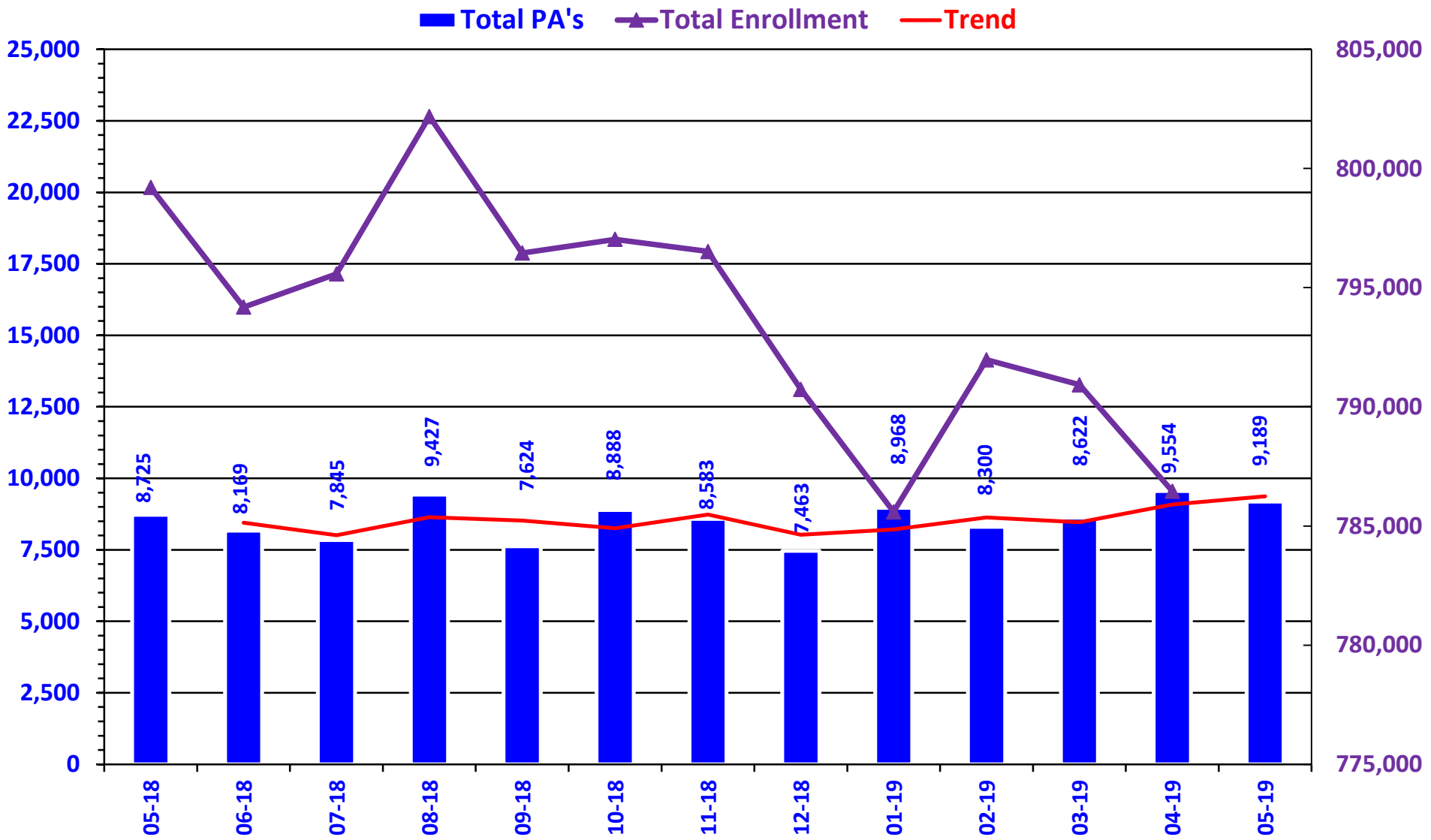
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: MAY 2019



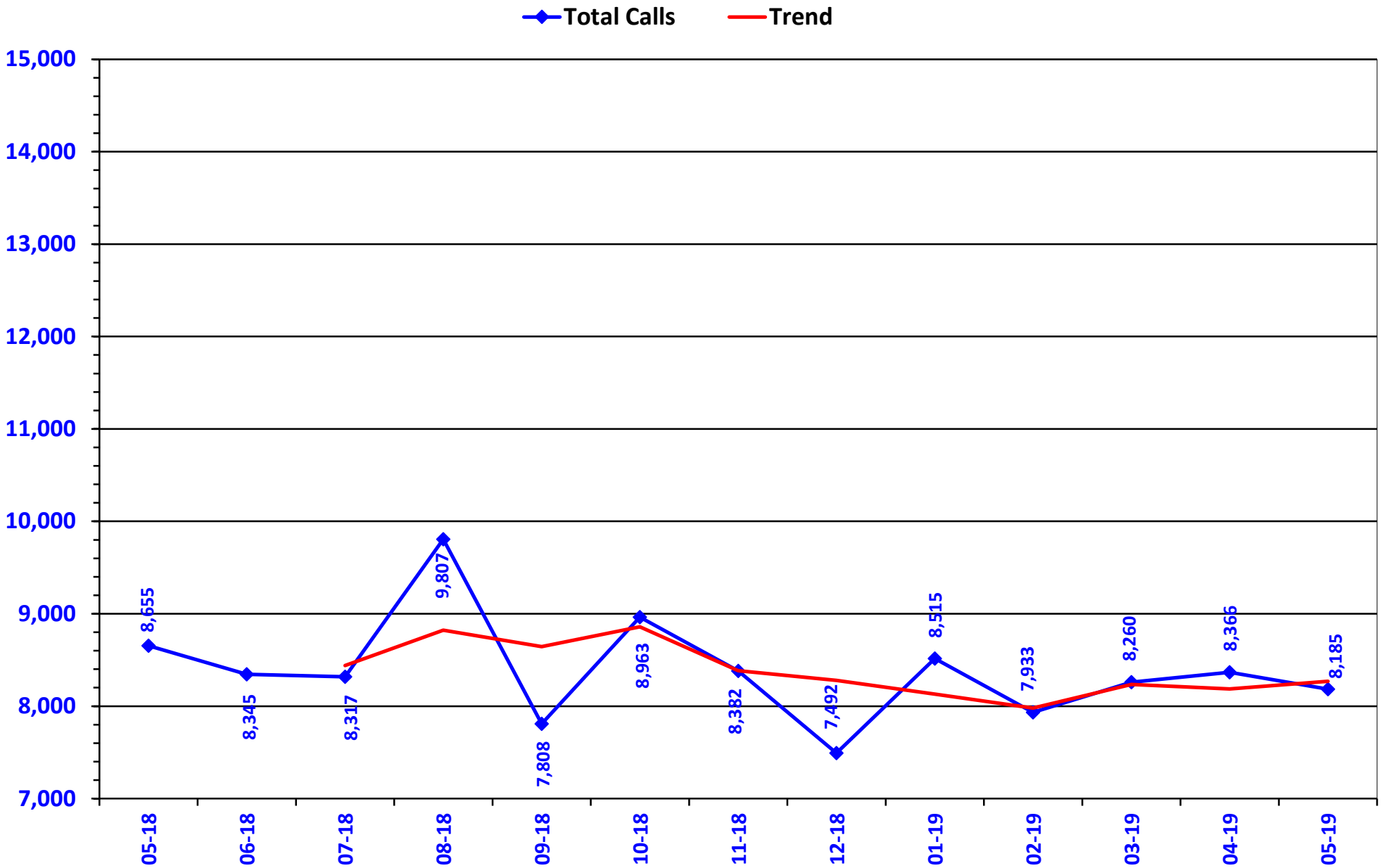
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: MAY 2018 – MAY 2019



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
MAY 2018 – MAY 2019



Prior Authorization Activity

5/1/2019 Through 5/31/2019

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	97	10	32	55	359
Analgesic - NonNarcotic	18	0	5	13	0
Analgesic, Narcotic	449	199	57	193	153
Angiotensin Receptor Antagonist	12	4	3	5	359
Antiasthma	91	26	23	42	297
Antibiotic	24	16	0	8	308
Anticonvulsant	185	74	15	96	285
Antidepressant	190	56	24	110	320
Antidiabetic	287	92	58	137	350
Antihistamine	36	8	9	19	359
Antimigraine	179	27	49	103	122
Antineoplastic	111	60	12	39	171
Antiparasitic	10	3	0	7	7
Antiulcers	151	46	57	48	113
Anxiolytic	22	4	3	15	203
Atypical Antipsychotics	272	123	32	117	345
Biologics	205	99	24	82	285
Bladder Control	60	12	20	28	359
Blood Thinners	324	176	32	116	331
Botox	29	24	2	3	344
Buprenorphine Medications	704	360	29	315	79
Calcium Channel Blockers	10	4	1	5	142
Cardiovascular	74	38	11	25	327
Chronic Obstructive Pulmonary Disease	171	34	48	89	286
Constipation/Diarrhea Medications	173	34	65	74	236
Contraceptive	14	7	4	3	306
Dermatological	350	102	99	149	109
Diabetic Supplies	444	270	12	162	205
Endocrine & Metabolic Drugs	151	83	10	58	131
Erythropoietin Stimulating Agents	23	9	5	9	95
Gastrointestinal Agents	102	29	27	46	219
Growth Hormones	93	71	8	14	158
Hematopoietic Agents	13	3	2	8	278
Hepatitis C	142	90	17	35	9
HFA Rescue Inhalers	60	1	3	56	22
Insomnia	20	5	6	9	249
Insulin	144	43	25	76	327
Miscellaneous Antibiotics	26	5	6	15	9
Multiple Sclerosis	50	26	9	15	227
Muscle Relaxant	48	3	13	32	24
Nasal Allergy	76	13	29	34	122
Neurological Agents	100	34	22	44	213
NSAIDs	22	1	3	18	13
Ocular Allergy	42	4	17	21	69
Ophthalmic Anti-infectives	12	4	1	7	20
Osteoporosis	20	10	2	8	307
Other*	369	75	79	215	260
Otic Antibiotic	23	1	5	17	9
Respiratory Agents	24	14	0	10	257
Statins	27	6	13	8	281

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Stimulant	651	337	73	241	351
Testosterone	67	13	27	27	337
Topical Antifungal	24	2	5	17	181
Topical Corticosteroids	67	1	39	27	57
Vitamin	93	23	42	28	202
Pharmacotherapy	121	106	1	14	262
Emergency PAs	0	0	0	0	
Total	**7,302**	**2,920**	**1,215**	**3,167**	
Overrides					
Brand	46	26	3	17	244
Compound	16	11	0	5	42
Cumulative Early Refill	1	0	0	1	0
Diabetic Supplies	16	13	1	2	121
Dosage Change	400	370	3	27	13
High Dose	6	5	0	1	276
Ingredient Duplication	12	9	0	3	28
Lost/Broken Rx	104	92	4	8	12
NDC vs Age	277	175	27	75	263
Nursing Home Issue	66	63	0	3	12
Opioid MME Limit	90	49	7	34	75
Opioid Quantity	38	30	1	7	158
Other*	101	80	5	16	9
Prescriber Temp Unlock	1	1	0	0	358
Quantity vs. Days Supply	644	444	29	171	245
STBS/STBSM	23	15	0	8	72
Stolen	6	3	1	2	9
Third Brand Request	40	30	2	8	11
Overrides Total	**1,887**	**1,416**	**83**	**388**	
Total Regular PAs + Overrides	**9,189**	**4,336**	**1,298**	**3,555**	

Denial Reasons	
Unable to verify required trials.	2,923
Does not meet established criteria.	1,311
Lack required information to process request.	608

Other PA Activity	
Duplicate Requests	671
Letters	12,856
No Process	14
Changes to Existing PAs	683
Helpdesk Initiated Prior Authorizations	650
PAs Missing Information	37

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

Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/ Angiotensin Receptor Blocker (ARB) Therapy in Patients with Diabetes and Hypertension (HTN) Mailing Update

Oklahoma Health Care Authority
June 2019

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

Many patients with type 2 diabetes mellitus (T2DM) also have comorbid hypertension (HTN), with rates between 20-60% depending on other risk factors. T2DM alone increases the risk of atherosclerotic cardiovascular disease (ASCVD), heart failure, and microvascular complications, but the risk is greatly increased when a patient has comorbid HTN. ASCVD complications are the leading cause of both morbidity and mortality in patients with T2DM and largely contribute to the health care costs of T2DM. The treatment of HTN in patients with T2DM has been shown to decrease ASCVD mortality. Current guidelines recommend therapy with a renin angiotensin system (RAS) antagonist [e.g., angiotensin converting enzyme inhibitor (ACEI), angiotensin receptor blocker (ARB), direct renin inhibitor (DRI)] in T2DM patients with HTN as first-line based on additional risk factors.

The American College of Cardiology (ACC) guideline recommends:

- Any first-line classes of antihypertensive agents [i.e., ACEI, ARB, calcium channel blocker (CCB), diuretic] in patients with T2DM and HTN
- ACEI or ARB therapy may be considered in the presence of albuminuria in adult patients with T2DM and HTN

The American Diabetes Association (ADA) guideline recommends:

- ACEI or ARB therapy in patients with T2DM and HTN with albuminuria to reduce the risk of progressive kidney disease

The American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE) guideline recommends:

- ACEI or ARB therapy in patients with T2DM and HTN to slow the progression of nephropathy and retinopathy

All of the guidelines recommend:

- Antihypertensive therapy based on the presence of comorbidities and patient demographics
- Not using an ACEI, ARB, or DRI in combination with each other

ACEI/ARB Therapy Mailing Summary

In February 2019, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) sent an educational letter to 108 providers of 288 unique members who had concurrent diagnoses of T2DM and HTN and who had not received treatment with an ACEI, ARB, or DRI based on their SoonerCare pharmacy claims history. The purpose of the educational mailing was to encourage providers to evaluate evidence-based prescribing practices for SoonerCare

members with comorbid T2DM and HTN and determine if they may benefit from therapy with an ACEI or ARB. Members who had pharmacy claims for Entresto® (sacubitril/valsartan) were not included in the claims review. The educational letter was sent to the last prescriber in SoonerCare pharmacy claims of the member's anti-diabetic medication. Providers were selected for this mailing if they were the last provider to prescribe the member's anti-diabetic medication, had ≥2 members that were identified in the claims analysis, and were not designated as a specialist provider (e.g., endocrinology, cardiology, emergency medicine). The letter included information on the current guidelines and a list of the provider's members identified in the claims analysis for them to evaluate if the members met clinical guidelines for treatment with an ACEI or ARB.

ACEI/ARB Therapy Mailing Results

Three months after the letters were sent out, a second claims analysis was performed. The claims analysis found that 22 members (7.6%) included in the mailing had paid claims for an ACEI or ARB after the letter was sent. There were 21 different prescribers who received letters regarding the 22 members recently started on an ACEI or ARB. The 21 prescribers' letters included a total of 60 unique SoonerCare members combined (20.8%), resulting in those members having been potentially evaluated to determine appropriate therapy. Many of the ACEIs and ARBs are relatively inexpensive; therefore, some members may be paying cash for these medications due to their monthly prescription limit. Pharmacy claims not billed to SoonerCare (e.g., cash claims, private insurance) are not included in the claims analyses.

Conclusions

Although only a moderate increase was observed in the second claims analysis, there was a trend showing that the identified members were potentially being evaluated for appropriate therapy. The purpose of this mailing was not to see all of the members started on ACEI or ARB therapy, but rather to ensure the providers were reviewing these members for appropriate therapy. The COP will continue to work with the OHCA to improve educational mailings with the goal of improving the quality of care for SoonerCare members with comorbid T2DM and HTN. New interventions will be implemented where appropriate, and results will be reported to the Drug Utilization Review (DUR) Board when available.

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[1] de Boer I, Bangalore S, Benetos A, et al. Diabetes and Hypertension: A Position Statement by the American Diabetes Association. *Diabetes Care* 2017; 40(9):S1273-S1284.

[2] American Diabetes Association. Treatment of Hypertension in Adults with Diabetes. *Diabetes Care* 2003; 26(1):S80-S82.

[3] Whelton P, Carey R, Aronow W, et al. 2017 High Blood Pressure Clinical Practice Guideline: Executive Summary. *Hypertension* 2017; 71:1269-1324.

[4] American Diabetes Association. Cardiovascular disease and risk management: Standards of Medical Care in Diabetes - 2018. *Diabetes Care* 2018; 41(1):S86-S104.

[5] Garber A, Abrahamson M, Barzilay J, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2018 Executive Summary. *Endocr Pract* 2018; 24(1).

Appendix C

Vote to Prior Authorize Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

Oklahoma Health Care Authority
June 2019

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

Aldurazyme® (laronidase) was approved by the U.S. Food and Drug Administration (FDA) in April 2003 as an enzyme replacement therapy (ERT) for patients with Hurler, Hurler-Scheie, and moderate-to-severe Scheie syndrome, also known as mucopolysaccharidosis I or MPS I. MPS I is a rare disorder caused by mutation(s) in the *IDUA* gene. The mutation(s) leads to a deficiency of the lysosomal hydrolase, alpha-L-iduronidase (IDUA), which is required for the degradation of heparan sulfate and dermatan. The syndrome that results from the mutation(s) depends on the combination of mutations on both alleles and on the presence of polymorphisms within the gene. The prevalence of MPS I is estimated to be 1 in 100,000, with Hurler syndrome accounting for 57% of cases, Hurler-Scheie syndrome accounting for 23% of cases, and Scheie syndrome accounting for 20% of cases. Hurler syndrome is the most severe form of MPS I, and is characterized by a broad spectrum of clinical symptoms including skeletal abnormalities, hepatosplenomegaly, and severe intellectual disability. Patients with Hurler syndrome typically die before the age of 10 years. Hurler-Scheie syndrome is intermediate in severity. The most common presenting complaint of Hurler-Scheie syndrome is joint pain, and patients typically live into their twenties. Scheie syndrome is the least severe form of MPS I with the most common presenting features being joint stiffness and corneal clouding. In general, average lifespan is the longest with Scheie syndrome, compared to the other subtypes, with most living until middle age. Laronidase is a recombinant form of human IDUA intended to provide exogenous enzyme for uptake into lysosomes and increase the catabolism of glycosaminoglycans (GAGs). Laronidase has a *Boxed Warning* for the risk of anaphylaxis. The recommended dosage of laronidase is 0.58mg/kg administered once weekly as an intravenous (IV) infusion. The Wholesale Acquisition Cost (WAC) for 1 single-use 2.9mg/5mL vial of Aldurazyme® is $880. The cost for a 15kg patient would be $10,560 per 28 days, with a yearly cost of $137,280. Dosing is weight-based; therefore, pricing will vary.

Naglazyme® (galsulfase) was approved by the FDA in May 2005 as an ERT indicated for patients with Maroteaux-Lamy syndrome, also known as MPS VI. Maroteaux-Lamy syndrome is caused by mutations in the gene encoding arylsulfatase B. The exact incidence of Maroteaux-Lamy syndrome is not known, but the birth prevalence is estimated to be 1 to 9 per 1,000,000 live births. Maroteaux-Lamy syndrome primarily affects the skeleton and soft tissues. Severely affected children present between 1 to 6 years of age, but disease progression can be slower in attenuated forms of the disease. Death typically occurs in the second or third decade of life. Galsulfase is a hydrolytic lysosomal GAG-specific enzyme produced by recombinant DNA technology to increase the catabolism of GAGs. The recommended dosage of galsulfase is 1mg/kg administered once weekly as an IV infusion. The WAC for 1 single-use 5mg/5mL vial of

Naglazyme® is $1,915. The cost for a 15kg patient would be $22,980 per 28 days, with a yearly cost of $298,740. Dosing is weight-based; therefore, pricing will vary.

Recommendations

The College of Pharmacy recommends the prior authorization of Aldurazyme® (laronidase) and Naglazyme® (galsulfase) with the following criteria:

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS I) confirmed by:
    a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity; or
    b. Molecular genetic testing to confirm pathogenic mutations in the *IDUA* gene; and
2. For Scheie syndrome, the provider must document that the member has moderate-to-severe symptoms; and
3. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. 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
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
    a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity; or
    b. Genetic testing to confirm diagnosis of MPS VI; and
2. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
3. 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
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

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[2] Jones S, Wynn R. Mucopolysaccharidoses: Treatment. *UpToDate*. Available online at: https://www.uptodate.com/contents/mucopolysaccharidoses-treatment?sectionName=HEMATOPOIETIC%20CELL%20TRANSPLANTATION&search=mucopolysaccharidosis&topicRef=2931&anchor=H1119956597&source=see_link#H1119956597. Last revised 02/01/2019. Last accessed 05/02/2019.

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[4] Naglazyme® Prescribing Information. Biomarin Pharmaceuticals, Inc. Available online at: https://www.naglazyme.com/. Last revised 03/2013. Last accessed 05/02/2019.
[5] Orphanet: Mucopolysaccharidosis type 1. Available online at: https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Lng=GB&Expert=579. Last revised 10/2011. Last accessed 05/02/2019.
[6] Valayannopoulos V, Nicely H, Harmatz P, Turbeville S. Mucopolysaccharidosis VI. *Orphanet Journal of Rare Disease* 2010; 5:5. https://doi.org/10.1186/1750-1172-5-5

Appendix D

Vote to Prior Authorize Plenvu® [Polyethylene Glycol (PEG)-3350/Sodium Ascorbate/Sodium Sulfate/Ascorbic Acid/ Sodium Chloride/Potassium Chloride]

Oklahoma Health Care Authority
June 2019

Introduction[1,2]

Plenvu® (PEG-3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/ potassium chloride) was approved by the U.S. Food and Drug Administration (FDA) in May 2018 and is indicated for cleansing of the colon in preparation for colonoscopy in adults. Plenvu® is available as a single-use carton that includes a disposable mixing container with lid, patient information, and 3 pouches labeled Dose 1, Dose 2 Pouch A, and Dose 2 Pouch B. Dose 1 contains 100g of PEG-3350, 9g of sodium sulfate, 2g of sodium chloride, and 1g of potassium chloride. Dose 2 Pouch A contains 40g of PEG-3350, 3.2g of sodium chloride, and 1.2g of potassium chloride. Dose 2 Pouch B contains 48.11g of sodium ascorbate and 7.54g of ascorbic acid. Two doses of Plenvu® are required for a complete preparation for colonoscopy, using a "2-Day" or "1-Day" dosing regimen. Plenvu® is the only FDA-approved bowel cleanser with same-day morning-of-colonoscopy dosing.

Cost Comparison:

Medication	Cost Per Treatment
Plenvu® (PEG-3350/sodium ascorbate/sodium sulfate/ascorbic acid/ sodium chloride/potassium chloride)	**$105.51**
Clenpiq™ (sodium picosulfate/magnesium oxide/anhydrous citric acid)	$131.08
Moviprep® (PEG-3350/sodium sulfate/sodium chloride/potassium chloride/ sodium ascorbate/ascorbic acid)	$101.24
PEG-3350/sodium sulfate/sodium bicarbonate/sodium chloride/potassium chloride (generic Gavilyte®-G)	$11.32

PEG-3350 = polyethylene glycol-3350
Costs do not reflect rebated prices or net costs. Costs are based on National Average Drug Acquisition Cost (NADAC), Wholesale Acquisition Cost (WAC), or State Maximum Allowable Cost (SMAC) if NADAC unavailable.

Recommendations

The College of Pharmacy recommends the prior authorization of Plenvu® (PEG-3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/potassium chloride) with criteria similar to the other prior authorized bowel preparation medications:

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

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and

2. A patient-specific, clinically significant reason other than convenience why the member cannot use other bowel preparation medications available without prior authorization must be provided.
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, Moviprep® is available without prior authorization. Other medications currently available without a prior authorization include: Colyte®, Gavilyte®, Golytely®, and Trilyte®.

[1] Plenvu® Prescribing Information. Salix Pharmaceuticals, Ltd. Available online at: https://shared.salix.com/shared/pi/plenvu-pi.pdf. Last revised 05/2018. Last accessed 05/03/2019.
[2] Salix Pharmaceuticals, Ltd. Salix Announces U.S. Launch of PLENVU®, the First and Only 1-Liter PEG Bowel Cleansing Preparation for Colonoscopies. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/salix-announces-us-launch-of-plenvu-the-first-and-only-1-liter-peg-bowel-cleansing-preparation-for-colonoscopies-300709082.html. Issued 09/11/2018. Last accessed 05/03/2019.

Appendix E

Vote to Prior Authorize Consensi® (Amlodipine/Celecoxib) and Kapspargo™ Sprinkle [Metoprolol Succinate Extended-Release (ER)]

Oklahoma Health Care Authority
June 2019

Introduction[1,2,3,4]

Consensi® (amlodipine/celecoxib) was approved by the U.S. Food and Drug Administration (FDA) in June 2018 for patients with osteoarthritis pain and hypertension (HTN). Consensi® is only available in a celecoxib strength of 200mg and is only to be taken once daily. Consensi® is supplied as amlodipine/celecoxib 2.5mg/200mg, 5mg/200mg, and 10mg/200mg tablets. It is recommended to use the lowest effective dosage of celecoxib for the shortest duration consistent with treatment goals. If analgesic therapy is no longer indicated, it is recommended to discontinue Consensi® and initiate the patient on alternative antihypertensive therapy. Cost information for Consensi® is not yet available.

Kapspargo™ Sprinkle (metoprolol succinate ER) was FDA approved in August 2018 for the treatment of HTN, angina pectoris, and heart failure. Kapspargo™ Sprinkle is supplied as 25mg, 50mg, 100mg, and 200mg ER capsules. The recommended dosage is based on indication (*refer to Kapspargo™ Sprinkle Prescribing Information for detailed dosing information*). For patients with swallowing difficulties, Kapspargo™ Sprinkle capsules can be opened and the contents can be sprinkled over soft food (such as applesauce, yogurt, or pudding) or administered via a nasogastric tube. The Wholesale Acquisition Cost (WAC) of Kapspargo™ Sprinkle is $1.92 per 100mg capsule, which results in a monthly cost of $57.60.

Recommendations

The College of Pharmacy recommends the prior authorization of Consensi® (amlodipine/ celecoxib) and Kapspargo™ Sprinkle (metoprolol succinate ER) with the following criteria:

Consensi® (Amlodipine/Celecoxib Tablets) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the individual components separately, which are available without prior authorization, must be provided; and
2. A quantity limit of 30 tablets per 30 days will apply.

Kapspargo™ Sprinkle [Metoprolol Succinate Extended-Release (ER) Capsules] Approval Criteria:

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

Additionally, the College of Pharmacy recommends the following changes to the Antihypertensive Medications Product Based Prior Authorization (PBPA) category based on net cost:

1. Moving Benicar® (olmesartan), Benicar HCT® (olmesartan/hydrochlorothiazide), and Azor® (amlodipine/olmesartan) from Tier-2 to Tier-1.
2. Moving Atacand® (candesartan) and Micardis® HCT (telmisartan/hydrochlorothiazide) from Tier-3 to Tier-2.

The recommended changes are shown in red in the following tier charts:

Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	**amlodipine/celecoxib (Consensi™)**
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	diltiazem CD 360mg (Cardizem® CD)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene® SR)	
diltiazem XR (Dilacor® XR)	nisoldipine (Sular®)	
felodipine (Plendil®)	verapamil (Covera-HS®)	
nicardipine (Cardene®)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine (Adalat®, Procardia®)		
nifedipine ER (Adalat® CC)		
nifedipine ER		
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		

XR, XL, ER = extended-release; SR = sustained-release; LA = long-acting; CD = controlled-delivery; PA = prior authorization
*All strengths other than 360mg.

Angiotensin Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**Tier-3**
irbesartan (Avapro®)	amlodipine/valsartan/HCTZ (Exforge® HCT)	azilsartan (Edarbi®)
irbesartan/HCTZ (Avalide®)	**candesartan (Atacand®)**	azilsartan/chlorthalidone (Edarbyclor®)
losartan (Cozaar®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	candesartan/HCTZ (Atacand® HCT)
losartan/HCTZ (Hyzaar®)	**telmisartan/HCTZ (Micardis® HCT)**	eprosartan (Teveten®)
olmesartan (Benicar®)		eprosartan/HCTZ (Teveten® HCT)
olmesartan/amlodipine (Azor®)		telmisartan/amlodipine (Twynsta®)
olmesartan/HCTZ (Benicar HCT®)		

Angiotensin Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**Tier-3**
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
valsartan/HCTZ (Diovan HCT®)		

HCTZ = hydrochlorothiazide

[1] Han DH. Consensi Approved to Treat Hypertension and Osteoarthritis Pain. *MPR*. Available online at: https://www.empr.com/home/news/consensi-approved-to-treat-hypertension-and-osteoarthritis-pain/. Issued 06/01/2018. Last accessed 05/07/2019.

[2] Consensi® Prescribing Information. Kitov Pharma. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210045s000lbl.pdf. Last revised 06/2018. Last accessed 05/07/2019.

[3] Sun Pharma. Sun Pharma Launches Novel Drug Kapspargo Sprinkle™ in USA. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20180806005199/en/Sun-Pharma-Launches-Drug-Kapspargo-Sprinkle%E2%84%A2-USA. Issued 08/06/2018. Last accessed 05/07/2019.

[4] Kapspargo™ Sprinkle Prescribing Information. Sun Pharmaceutical Industries, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210428s001lbl.pdf. Last revised 05/2018. Last accessed 05/07/2019.

Appendix F

Vote to Update the Prior Authorization Criteria for H.P. Acthar® Gel (Repository Corticotropin Injection)

Oklahoma Health Care Authority
June 2019

Recommendations

The College of Pharmacy recommends updating the H.P. Acthar® Gel (repository corticotropin injection) prior authorization criteria with the following changes noted in red:

H.P. Acthar® Gel (Repository Corticotropin Injection) Approval Criteria:

1. An FDA approved diagnosis of infantile spasms; and
    a. Member must be 2 years of age or younger; and
    b. Must be prescribed by, or in consultation with, a neurologist or an advanced care practitioner with a supervising prescriber that is a neurologist; or
2. An FDA approved diagnosis of multiple sclerosis (MS); and
    a. Member is experiencing an acute exacerbation; and
    b. Must be prescribed by, or in consultation with, a neurologist or an advanced care practitioner with a supervising prescriber that is a neurologist or a prescriber that specializes in MS; and
    c. Prescriber must rule out pseudo-exacerbation from precipitating factors (e.g., pain, stress, infection, premenstrual syndrome); and
    d. Symptoms of acute exacerbation last at least 24 hours; and
    e. Member must be currently stable within the last 30 days on an immunomodulator agent, unless contraindicated; and
    f. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy [e.g., intravenous (IV) methylprednisolone, IV dexamethasone, oral prednisone] must be provided; and
    g. A quantity limit of daily doses of up to 120 units for up to 3 weeks for acute exacerbation will apply ~~Therapy will be limited to 5 weeks per approval (3 weeks of treatment, followed by taper). Additional approval, beyond the initial 5 weeks, will require prescriber documentation of response to initial treatment and need for continued treatment~~; or
3. An FDA approved diagnosis of nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus to induce a diuresis or a remission of proteinuria; and
    a. Must be prescribed by, or in consultation with, a nephrologist or an advanced care practitioner with a supervising prescriber that is a nephrologist; and
    b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy (e.g., prednisone) must be provided; or
4. An FDA approved diagnosis of the following disorders or diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; or edematous states; and

a. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy must be provided.

Appendix G

Vote to Prior Authorize Fulphila® (Pegfilgrastim-jmdb), Nivestym™ (Filgrastim-aafi), and Udenyca™ (Pegfilgrastim-cbqv)

Oklahoma Health Care Authority
June 2019

Introduction[1,2,3]

- **Fulphila® (pegfilgrastim-jmdb)** was approved by the U.S. Food and Drug Administration (FDA) in June 2018 as the first biosimilar to Neulasta® (pegfilgrastim). Fulphila® is indicated for prophylaxis of febrile neutropenia in patients with non-myeloid malignancies who receive myelosuppressive chemotherapy. Neulasta® was first FDA approved in 2002 and is also indicated for hematopoietic subsyndrome of acute radiation syndrome (H-ARS), in addition to the above listed indication for prophylaxis of febrile neutropenia. Pegfilgrastim is a pegylated derivative of filgrastim and has a longer elimination half-life compared to filgrastim.
- **Nivestym™ (filgrastim-aafi)** was FDA approved in July 2018 as a biosimilar to Neupogen® (filgrastim). Nivestym™ is indicated for prophylaxis of febrile neutropenia in patients with acute myeloid leukemia receiving induction or consolidation chemotherapy and in patients with non-myeloid malignancies who receive myeloablative chemotherapy followed by bone marrow transplantation or who receive myelosuppressive chemotherapy, for harvesting of peripheral blood stem cells, and for symptomatic chronic (severe) neutropenic disorder. Neupogen® was first FDA approved in 1991 and has all of the above listed indications, as well as an additional indication for H-ARS.
- **Udenyca™ (pegfilgrastim-cbqv)** was FDA approved in November 2018 as a biosimilar to Neulasta® (pegfilgrastim). Udenyca™ is the first pegfilgrastim biosimilar approved by both the FDA and the European Commission. Udenyca™ is indicated for prophylaxis of febrile neutropenia in patients with non-myeloid malignancies who receive myelosuppressive chemotherapy.

Recommendations

The College of Pharmacy recommends the prior authorization of Fulphila® (pegfilgrastim-jmdb), Nivestym™ (filgrastim-aafi), and Udenyca™ (pegfilgrastim-cbqv) with the following criteria (changes shown in red):

Fulphila® (Pegfilgrastim-jmdb) and Udenyca™ (Pegfilgrastim-cbqv) 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.

Granix® (Tbo-filgrastim), Nivestym™ (Filgrastim-aafi), and Zarxio® (Filgrastim-sndz) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Neupogen® (filgrastim) must be provided.

[1] U.S. Food and Drug Administration (FDA). FDA News Release. FDA Approves First Biosimilar to Neulasta® to Help Reduce the Risk of Infection During Cancer Treatment. Available online at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm609805.htm. Issued 06/04/2018. Last accessed 05/02/2019.

[2] Pfizer News Release. U.S. FDA Approves Pfizer's Biosimilar Nivestym® (Filgrastim-aafi). Available online at: https://www.pfizer.com/news/press-release/press-release-detail/u_s_fda_approves_pfizer_s_biosimilar_nivestym_filgrastim_aafi-0. Issued 07/20/2018. Last accessed 05/02/2019.

[3] Coherus News Release. U.S. FDA Approves Udenyca™ (Pegfilgrastim-cbqv). *Globe Newswire*. Available online at: https://investors.coherus.com/news-releases/news-release-details/us-fda-approves-udenycatm-pegfilgrastim-cbqv. Issued 11/02/2018. Last accessed 05/02/2019.

Appendix H

Vote to Prior Authorize Xyosted™ [Testosterone Enanthate Subcutaneous (Sub-Q) Auto-Injector] and Jatenzo® (Testosterone Undecanoate Oral Capsule)

Oklahoma Health Care Authority
June 2019

Introduction[1,2,3,4]

Xyosted™ (testosterone enanthate sub-Q auto-injector) was approved by the U.S. Food and Drug Administration (FDA) in September 2018 as the first FDA-approved sub-Q auto-injector product for testosterone replacement therapy and is intended for once weekly, at-home, self-administration using a single-dose, disposable QuickShot® auto-injector. Xyosted™ is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). The safety and efficacy of Xyosted™ in adult males with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") and in males younger than 18 years of age have not been established. Xyosted™ has a *Boxed Warning* for blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction (MI), non-fatal stroke, and cardiovascular (CV) death, with greater risk for MACE in patients with CV risk factors or established CV disease. Due to this risk, Xyosted™ should only be used for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies. Xyosted™ is contraindicated in men with hypogonadal conditions, such as "age-related hypogonadism", that are not associated with structural or genetic etiologies. Xyosted™ is supplied as 0.5mL of sterile solution in a single-dose auto-injector for sub-Q administration in 3 strengths: 50mg/0.5mL, 75mg/0.5mL, and 100mg/0.5mL. The recommended starting dose of Xyosted™ is 75mg administered sub-Q in the abdominal region once weekly. The dose should be individualized based on the patient's serum testosterone concentration response to the drug (*refer to Xyosted™ prescribing information for dose adjustment recommendations*). The Wholesale Acquisition Cost (WAC) of Xyosted™ is $118.75 per single-dose auto-injector, regardless of strength, which results in a monthly cost of $475.00, based on once weekly dosing.

Jatenzo® (testosterone undecanoate oral capsule) was approved by the FDA in March 2019 and is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). The safety and efficacy of Jatenzo® in males younger than 18 years of age have not been established. Jatenzo® has a *Boxed Warning* for BP increases that can increase the risk of MACE, including non-fatal MI, non-fatal stroke, and CV death, with greater risk for MACE in patients with CV risk factors or established CV disease. Due to this risk, Jatenzo® should only be used for the treatment of men with hypogonadal conditions associated with structural or genetic

etiologies. Jatenzo® is contraindicated in men with hypogonadal conditions, such as "age-related hypogonadism", that are not associated with structural or genetic etiologies. Jatenzo® is supplied as gelatin capsules for oral use in 3 strengths: 158mg, 198mg, and 237mg. The recommended starting dose of Jatenzo® is 237mg taken orally twice daily with food. The same dose should be administered in the morning and evening. The minimum recommended dose of Jatenzo® is 158mg twice daily; the maximum recommended dose is 396mg [administered as (2) 198mg capsules] twice daily. The dose should be individualized based on the patient's serum testosterone concentration response to the drug (*refer to Jatenzo® prescribing information for dose adjustment recommendations*). Cost information for Jatenzo® is not yet available.

Recommendations

The College of Pharmacy recommends the following changes to the Testosterone Products Product Based Prior Authorization (PBPA) category:

1. The placement of Xyosted™ (testosterone enanthate sub-Q auto-injector) into Tier-2. Current Tier-2 criteria will apply. Additionally, the member must be trained by a health care professional on sub-Q administration and storage of Xyosted™ sub-Q auto-injector.
2. The placement of Jatenzo® (testosterone undecanoate oral capsule) into the Special Prior Authorization (PA) Tier. Current Special PA criteria will apply.

The proposed changes are shown in red in the following Testosterone Products Tier Chart and Approval Criteria:

Testosterone Products		
Tier-1*	**Tier-2**	**Special PA**
methyltestosterone powder	**testosterone enanthate sub-Q auto-injector (Xyosted™)**	fluoxymesterone oral tab (Androxy®)
testosterone cypionate IM inj (Depo-Testosterone®)	testosterone nasal gel (Natesto®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone patch (Androderm®)	testosterone buccal tab (Striant®)
testosterone topical gel (Androgel®)+	testosterone topical gel (Fortesta®, Testim®, Vogelxo®)	testosterone pellets (Testopel®)
	testosterone topical solution (Axiron®)	**testosterone undecanoate oral cap (Jatenzo®)**
	testosterone undecanoate IM inj (Aveed®)	

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

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis:
    a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchiectomy; or
    b. Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or

c. Delayed puberty; or
d. Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal females with breast cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and

2. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
3. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
4. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

Testosterone Products Tier-2 Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A trial of at least 2 Tier-1 products (must include at least 1 injectable and 1 topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 products must be provided; or
4. Prior stabilization on a Tier-2 product (within the past 180 days); and
5. Approvals will be for the duration of 1 year; and
6. For Xyosted™ [testosterone enanthate subcutaneous (sub-Q) auto-injector]:
   a. Member must be trained by a health care professional on sub-Q administration and storage of Xyosted™ sub-Q auto-injector.

Testosterone Products Special Prior Authorization (PA) Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone must be provided; and
3. Approvals will be for the duration of 1 year.

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[1] Antares Pharma News Release. Antares Receives FDA Approval of Xyosted™ (Testosterone Enanthate) Injection for Testosterone Replacement Therapy in Adult Males. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2018/10/01/1587623/0/en/Antares-Receives-FDA-Approval-of-Xyosted-Testosterone-Enanthate-Injection-for-Testosterone-Replacement-Therapy-in-Adult-Males.html. Issued 10/01/2018. Last accessed 05/02/2019.

[2] FDA News Release. FDA Approves New Oral Testosterone Capsule for Treatment of Men with Certain Forms of Hypogonadism. Available online at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm634585.htm. Issued 03/27/2019. Last accessed 05/02/2019.

[3] Xyosted™ (Testosterone Enanthate) Prescribing Information. Antares Pharma, Inc. Available online at: https://www.xyosted.com/PI.pdf. Last revised 09/2018. Last accessed 05/02/2019.

[4] Jatenzo® (Testosterone Undecanoate) Prescribing Information. Clarus Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/206089s000lbl.pdf. Last revised 03/2019. Last accessed 05/02/2019.

Appendix I

Vote to Prior Authorize Cablivi® (Caplacizumab-yhdp)

Oklahoma Health Care Authority
June 2019

Introduction[1,2]

Cablivi® (caplacizumab-yhdp) is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), to be used in combination with plasma exchange and immunosuppressive therapy. It is supplied as a sterile, preservative-free, lyophilized powder in a single-dose vial (SDV). It is available in a carton containing (1) 11mg Cablivi® SDV, (1) 1mL sterile water for injection prefilled glass syringe (diluent for Cablivi®), 1 sterile vial adapter, 1 sterile hypodermic needle (30 gauge), and 2 individually packaged alcohol swabs. Caplacizumab should be administered upon the initiation of plasma exchange therapy. The recommended dosing of caplacizumab for the first day of treatment is an 11mg intravenous (IV) bolus injection given at least 15 minutes prior to plasma exchange followed by an 11mg subcutaneous (sub-Q) injection after completion of plasma exchange. On subsequent days of treatment when daily plasma exchange is ongoing, the dosing is 11mg sub-Q once daily following plasma exchange. For treatment after the plasma exchange period, the dosing is 11mg sub-Q once daily continuing for 30 days following the last daily plasma exchange. If after the initial treatment course, sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days.

Cost: The Wholesale Acquisition Cost (WAC) of Cablivi® (caplacizumab) is $7,300 per vial. This results in an approximate cost per treatment of $299,300. This cost is based on a 10-day duration of plasma exchange followed by 30 days of caplacizumab treatment. Disease course may vary, making plasma exchange duration patient-specific; therefore, cost may vary per treatment. It is estimated that, on average, 7 to 10 days of plasma exchange may be required to achieve a response (indicated by normalization of the platelet count). Additionally, the cost provided does not include continued treatment beyond 30 days post-plasma exchange. In clinical trials, continued treatment for up to 28 days following the 30 days after plasma exchange was required for some patients who continued to have signs of persistent disease.

Recommendations

The College of Pharmacy recommends the prior authorization of Cablivi® (caplacizumab-yhdp) with the following criteria:

Cablivi® (Caplacizumab-yhdp) Approval Criteria:

1. An FDA approved diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP); and
2. Member must be undergoing plasma exchange therapy; and

   a. Dates of initiation of plasma exchange therapy must be listed on the prior authorization request; and
   b. Authorizations will be for the duration of plasma exchange and for 30 days after discontinuation of plasma exchange; and
3. Member must be utilizing immunosuppressant therapy; and
4. Cablivi® must be prescribed by, or in consultation with, a hematologist; and
5. A quantity limit of 11mg per day will apply. Initial approvals will be for the duration of plasma exchange plus 30 days. Reauthorization, after completing 30 days post-plasma exchange, may be considered if the prescriber documents sign(s) of persistent underlying disease remain. Reauthorization will be for a maximum of 28 days.

[1] Cablivi® Prescribing Information. Ablynx N.V. Available online at: http://products.sanofi.us/cablivi/cablivi.pdf. Last revised 02/2019. Last accessed 05/14/2019.
[2] George JN, Cuker A. Acquired TTP: Initial treatment. *UpToDate*. Available online at: https://www.uptodate.com/contents/acquired-ttp-initial-treatment#H407079. Last revised 03/29/2019. Last accessed 05/14/2019.

Appendix J

Vote to Prior Authorize Dextenza® (Dexamethasone Ophthalmic Insert), Inveltys™ (Loteprednol Etabonate Suspension), Lotemax® SM (Loteprednol Etabonate Gel), and Oxervate™ (Cenegermin-bkbj)

Oklahoma Health Care Authority
June 2019

Introduction[1,2,3,4]

Dextenza® (dexamethasone ophthalmic insert) is a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery. Dextenza® is a single-use, sterile, ophthalmic insert that releases a 0.4mg dose of dexamethasone for up to 30 days following insertion. Dextenza® is inserted in the lower lacrimal punctum and into the canaliculus by a physician. It is resorbable and does not require removal.

Cost Comparison:

Medication	Cost Per Unit[+]	Cost Per Treatment, 1 Eye[Δ]	Cost Per Treatment, Both Eyes[Δ]
Dextenza® (dexamethasone 0.4mg ophthalmic insert)	**$538.83**	**$538.83**	**$1,077.66**
dexamethasone sodium phosphate 0.1% solution	$9.16	$137.40	$274.80
prednisolone acetate 1% suspension	$6.27*	$94.05	$188.10

[+]Unit = single Dextenza® insert or milliliter (mL)
*Cost per mL for prednisolone acetate 1% suspension based on average cost per mL of the 3 different available volumes.
[Δ]Cost per treatment based on FDA recommended dosing for disorders of the eye and 1 Dextenza® insert or a 30 day-supply of dexamethasone sodium phosphate 0.1% solution or prednisolone acetate 1% suspension.
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.

Inveltys™ (loteprednol etabonate suspension) is a corticosteroid indicated for the treatment of postoperative inflammation and pain following ocular surgery. Inveltys™ is a 1% (10mg/mL loteprednol etabonate) sterile, ophthalmic suspension supplied in a 5mL plastic dropper bottle containing 2.8mL of suspension. After shaking the bottle for 1 to 2 seconds, the recommended dosing is 1 to 2 drops into the affected eye(s) twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the postoperative period.

Cost Comparison:

Medication	Cost Per mL	Cost Per Treatment, 1 Eye[Δ]	Cost Per Treatment, Both Eyes[Δ]
Inveltys™ (loteprednol etabonate 1% suspension)	**$80.36**	**$401.80**	**$803.60**
Lotemax® (loteprednol etabonate 0.5% suspension)	$45.55	$455.50	$911.00
prednisolone acetate 1% suspension	$6.27*	$62.70	$125.40

*Cost per mL for prednisolone acetate 1% suspension based on average cost per mL of the 3 different available volumes.
[Δ]Cost per treatment based on FDA recommended dosing for postoperative inflammatory disorder of the eye for 2 weeks following the procedure.
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.

Lotemax® SM (loteprednol etabonate gel) is a corticosteroid indicated for the treatment of postoperative inflammation and pain following ocular surgery. Lotemax® SM is a 0.38% (3.8mg/mL loteprednol etabonate) sterile, ophthalmic submicron gel supplied in a 10mL plastic bottle with a controlled-drop tip containing 5 grams of gel. After inverting the closed bottle and shaking once to fill the dropper tip, the recommended dosing is 1 drop into the affected eye(s) 3 times daily beginning the day after surgery and continuing throughout the first 2 weeks of the postoperative period.

Cost Comparison:

Medication	Cost Per Unit[+]	Cost Per Treatment, 1 Eye[Δ]	Cost Per Treatment, Both Eyes[Δ]
Lotemax® SM (loteprednol etabonate 0.38% gel)	**$38.15**	**$190.75**	**$381.50**
Lotemax® (loteprednol etabonate 0.5% gel)	$36.63	$183.15	$366.30
prednisolone acetate 1% suspension	$6.27*	$62.70	$125.40

[+]Unit = gram or mL

*Cost per mL for prednisolone acetate 1% suspension based on average cost per mL of the 3 different available volumes.

[Δ]Cost per treatment based on FDA recommended dosing for postoperative inflammatory disorder of the eye for 2 weeks following the procedure.

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.

Oxervate™ (cenegermin-bkbj) is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (NK). Oxervate™ is a 0.002% (20mcg/mL cenegermin-bkbj) sterile, ophthalmic solution in a multiple-dose vial. It is supplied in a weekly, insulated carton containing 7 multiple-dose vials and a delivery system kit. The delivery system kit contains 8 vial adapters, 45 pipettes, 45 sterile disinfectant wipes, and a dose card. Within 5 hours of leaving the pharmacy, the weekly carton should be refrigerated between 36 to 46°F (2 to 8°C) for up to 14 days. Opened vials may be refrigerated in the original weekly carton between 36 to 46°F (2 to 8°C) or stored at room temperature up to 77°F (25°C), for up to 12 hours (any unused portion should be discarded after 12 hours). The recommended dosing is 1 drop into the affected eye(s), 6 times per day at 2-hour intervals, for 8 weeks.

Cost: The Wholesale Acquisition Cost (WAC) of Oxervate™ is $1,685.71 per 1mL vial. This results in a cost per 8-week treatment of $94,399.76 for 1 eye. If both eyes are treated simultaneously, the cost per 8-week treatment is $188,799.52.

Recommendations

The College of Pharmacy recommends the prior authorization of Dextenza® (dexamethasone ophthalmic insert) with the following criteria:

Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria:

1. An FDA approved indication of the treatment of ocular 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 2 inserts per 30 days will apply.

Additionally, the College of Pharmacy recommends the placement of Inveltys™ (loteprednol etabonate 1% suspension) and Lotemax® SM (loteprednol etabonate 0.38% gel) into Tier-2 of the Ophthalmic Corticosteroids Product Based Prior Authorization (PBPA) category. Current Tier-2 criteria will apply. Recommended changes are shown in red in the following tier chart.

Ophthalmic Corticosteroids	
Tier-1	**Tier-2**
dexamethasone (Maxidex®) 0.1% susp	fluorometholone (FML Forte®) 0.25% susp
dexamethasone sodium phosphate 0.1% soln	fluorometholone (FML S.O.P®) 0.1% oint
difluprednate (Durezol®) 0.05% emul	**loteprednol (Inveltys™) 1% susp**
fluorometholone (Flarex®) 0.1% susp	loteprednol (Lotemax®) 0.5% gel
fluorometholone (FML Liquifilm®) 0.1% susp	loteprednol (Lotemax®) 0.5% oint
loteprednol (Lotemax®) 0.5% susp	**loteprednol (Lotemax® SM) 0.38% gel**
prednisolone acetate (Omnipred®) 1% susp	prednisolone acetate (Pred Forte®) 1% susp
prednisolone acetate (Pred Mild®) 0.12% susp	
prednisolone sodium phosphate 1% soln	

soln = solution; susp = suspension; emul = emulsion; oint = ointment
Tier structure based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Ophthalmic Corticosteroids Tier-2 Approval Criteria:

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

Finally, the College of Pharmacy recommends the prior authorization of Oxervate™ (cenegermin-bkbj) with the following criteria:

Oxervate™ (Cenegermin-bkbj) Approval Criteria:

1. An FDA approved diagnosis of neurotrophic keratitis; and
2. Oxervate™ must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has persistent epithelial defect (PED) (stage 2 disease) or corneal ulceration (stage 3 disease) of at least 2 weeks duration that is refractory to 1 or more conventional non-surgical treatments for neurotrophic keratitis; and

    a. Specific non-surgical treatments and dates of trials must be listed on the prior authorization request; and
4. Prescriber must verify that the member has evidence of decreased corneal sensitivity within the area of the PED or corneal ulcer and outside of the area of the defect in at least 1 corneal quadrant; and
5. Prescriber must verify the member has been counseled on the proper administration and storage of Oxervate™; and
6. Approvals will be for a maximum duration of 8 weeks of total therapy per eye; and
7. A quantity limit of 2 weekly kits per 14 days will apply. A quantity limit override will be approved for 4 weekly kits per 14 days with prescriber documentation of treatment in both eyes.

[1] Dextenza® Prescribing Information. Ocular Therapeutix. Available online at: http://www.dextenza.com/wp-content/uploads/2018/12/Content-of-Labeling-Clean-19Nov2018-NMO.pdf. Last revised 11/2018. Last accessed 05/14/2019.
[2] Inveltys™ Prescribing Information. Kala Pharmaceuticals, Inc. Available online at: https://www.inveltys.com/pdf/INVELTYS_Package_Insert_Aug_2018.pdf. Last revised 08/2018. Last accessed 05/14/2019.
[3] Lotemax® SM Prescribing Information. Bausch + Lomb, Inc. Available online at: http://www.bausch.com/Portals/69/-/m/BL/United%20States/USFiles/Package%20Inserts/Pharma/lotemax-sm-package-insert.pdf?ver=2019-02-23-195833-923. Last revised 02/2019. Last accessed 05/14/2019.
[4] Oxervate™ Prescribing Information. Dompé. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761094s000lbl.pdf. Last revised 08/2018. Last accessed 05/14/2019.

Appendix K

Vote to Prior Authorize Lorbrena® (Lorlatinib), Mvasi® (Bevacizumab-awwb), and Vizimpro® (Dacomitinib)

Oklahoma Health Care Authority
June 2019

Introduction[1,2,3]

Lorbrena® (Lorlatinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):**
  - Patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on:
    - Crizotinib and at least 1 other ALK inhibitor for metastatic disease; or
    - Alectinib as the first ALK inhibitor therapy for metastatic disease; or
    - Ceritinib as the first ALK inhibitor therapy for metastatic disease
  - This indication was approved under accelerated approval based on tumor response rate and duration of response; continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial
- **How Supplied:** 25mg and 100mg oral tablets
- **Dose:** 100mg by mouth once daily
- **Cost:** Wholesale Acquisition Cost (WAC) of $535.19 per 100mg tablet, resulting in a monthly cost of $16,055.70

Mvasi® (Bevacizumab-awwb):

- **Therapeutic Class:** Vascular endothelial growth factor (VEGF)-specific angiogenesis inhibitor
- **Indication(s):**
  - Metastatic colorectal cancer, with intravenous (IV) 5-fluorouracil (5-FU)-based chemotherapy for first- or second-line treatment
  - Metastatic colorectal cancer, with fluoropyrimidine/irinotecan- or fluoropyrimidine/oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab-containing regimen
  - Non-squamous (NSq) NSCLC, with carboplatin and paclitaxel for first-line treatment of unresectable, locally advanced, recurrent or metastatic disease
  - Glioblastoma, as a single-agent for adult patients with progressive disease following prior therapy
  - Metastatic renal cell carcinoma (mRCC) with interferon alfa
  - Cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan in persistent, recurrent, or metastatic disease
- **How Supplied:** 100mg/4mL and 400mg/16mL single-dose vials

- **Dose:**
  - Metastatic Colorectal Cancer:
    - 5mg/kg IV every 2 weeks with bolus-IFL (irinotecan/leucovorin/5-FU); or
    - 10 mg/kg IV every 2 weeks with FOLFOX4 (leucovorin/5-FU/oxaliplatin); or
    - 5mg/kg IV every 2 weeks or 7.5mg/kg IV every 3 weeks with fluoropyrimidine/irinotecan- or fluoropyrimidine/oxaliplatin-based chemotherapy after progression on a first-line bevacizumab-containing regimen
  - NSq NSCLC: 15mg/kg IV every 3 weeks with carboplatin/paclitaxel
  - Glioblastoma: 10mg/kg IV every 2 weeks
  - mRCC: 10mg/kg IV every 2 weeks with interferon alfa
  - Persistent, Recurrent, and Metastatic Cervical Cancer: 15mg/kg IV every 3 weeks with paclitaxel/cisplatin or paclitaxel/topotecan
- **Cost:** Not yet available

Vizimpro® (Dacomitinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** First-line treatment of patients with metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations
- **How Supplied:** 15mg, 30mg, and 45mg oral tablets
- **Dose:** 45mg by mouth once daily
- **Cost:** WAC of $413.33 per 45mg oral tablet, resulting in a monthly cost of $12,399.90

Market News and Updates[4]

New Indication(s) and Label Update(s):

- **August 2018:** The U.S. Food and Drug Administration (FDA) updated the prescribing information for Keytruda® (pembrolizumab) and Tecentriq® (atezolizumab) to require the use of an FDA-approved companion diagnostic test to determine programmed death-ligand 1 (PD-L1) levels in tumor tissue from patients with locally advanced or metastatic urothelial cancer who are cisplatin-ineligible.
- **December 2018:** The FDA approved Tecentriq® (atezolizumab) in combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic NSq NSCLC with no EGFR or ALK genomic tumor aberrations.
- **March 2019:** The FDA approved Tecentriq® (atezolizumab) for PD-L1 positive, unresectable, locally advanced or metastatic triple-negative breast cancer.
- **March 2019:** The FDA approved Tecentriq® (atezolizumab) in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (SCLC).
- **April 2019:** The FDA approved Keytruda® (pembrolizumab) for the first-line treatment of patients with stage 3 NSCLC who are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC. Patients' tumors must have no EGFR or ALK

genomic aberrations and must express PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-approved test.

- **April 2019:** The FDA approved Keytruda® (pembrolizumab) to be used in combination wtih Inlyta® (axitinib) for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
- **May 2019:** The FDA approved Cyramza® (ramucirumab) as a single-agent for hepatocellular carcinoma (HCC) in patients who have an alpha fetoprotein (AFP) ≥400ng/mL and have previously been treated with sorafenib.

Recommendations

- The prior authorization of Lorbrena® (lorlatinib), Mvasi® (bevacizumab-awwb), and Vizimpro® (dacomitinib) with the following criteria listed in red
- Updating the prior authorization criteria for Cyramza® (ramucirumab), Keytruda® (pembrolizumab), and Tecentriq® (atezolizumab) to reflect new FDA approved indications; changes and new criteria noted in red

Lorbrena® (Lorlatinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. A diagnosis of metastatic NSCLC; and
2. Tumor expresses anaplastic lymphoma kinase (ALK) translocation; and
3. Used as a single-agent as second-line therapy following disease progression on either alectinib or ceritinib; or
4. Used as a single-agent as third-line or greater therapy following disease progression on crizotinib and 1 other ALK inhibitor (i.e., ceritinib, alectinib).

Mvasi® (Bevacizumab-awwb) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab), which is available without prior authorization, must be provided.

Vizimpro® (Dacomitinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. A diagnosis of metastatic NSCLC; and
2. Member has not received prior epidermal growth factor receptor (EGFR) therapy for metastatic disease; and
3. Member must meet 1 of the following:
    a. EGFR exon 19 deletion; or
    b. Exon 21 L858R substitution mutation.

Cyramza® (Ramucirumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. A diagnosis of HCC; and
2. Used as second-line or greater therapy; and
3. Previously failed sorafenib; and
4. Has an alpha-fetoprotein concentration ≥400ng/mL; and
5. Used as a single-agent.

Keytruda® (Pembrolizumab) Approval Criteria [Metastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. A diagnosis of metastatic NSCLC; and
2. The member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for PD-L1 expression as follows:
    a. Single-agent, first-line: ~~≥50%~~ 1%; or
    b. First-line in combination: no expression required; or
    c. Single-agent, second-line: ≥1%; and
4. Member meets 1 of the following:
    a. Previously untreated metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel; or
    b. Previously untreated metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or
    c. New diagnosis as first-line therapy (member has not received chemotherapy to treat disease) if:
        i. Tumor does not express sensitizing Epidermal Growth Factor Receptor (EGFR) mutations or Anaplastic Lymphoma Kinase (ALK) translocations; or
    d. Single-agent for disease progression on or after platinum-containing chemotherapy (cisplatin or carboplatin):
        i. Patients with EGFR-mutation-positive disease should have disease progression on an FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations*; and
            - *Examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib*
        ii. Patients with ALK genomic tumor aberrations should have disease progression on an FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations*; and
            - *Examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib.*

Keytruda® (Pembrolizumab) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. A diagnosis of stage 3 NSCLC; and
2. Ineligible for surgery or definitive chemoradiation; and
3. Tumor proportion scores for PD-L1 expression ≥1%; and
4. The member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member must have newly diagnosed or recurrent stage 4 clear-cell RCC; and
2. Have received no previous systemic therapy for advanced disease; and
3. Must be used in combination with Inlyta® (axitinib); and

4. The member has not previously failed other PD-1 inhibitors [e.g., Opdivo® (nivolumab)].

Tecentriq® (Atezolizumab) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. A diagnosis of non-squamous NSCLC; and
    a. First-line therapy; and
    b. The member does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations; and
    c. Atezolizumab must be used in combination with bevacizumab, paclitaxel, and carboplatin (maximum of 6 cycles); and
    d. Atezolizumab and bevacizumab may be continued after the above combination in members without disease progression; or
2. A diagnosis of NSCLC; and
    a. Subsequent therapy for metastatic disease; and
    b. Atezolizumab must be used as a single-agent only.

Tecentriq® (Atezolizumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. A diagnosis of SCLC; and
2. First-line therapy; and
3. Extensive-stage disease; and
4. Atezolizumab must be used in combination with carboplatin and etoposide.

Tecentriq® (Atezolizumab) Approval Criteria [Breast Cancer Diagnosis]:

1. Unresectable locally advanced or metastatic triple-negative breast cancer; and
2. In combination with nab-paclitaxel (Abraxane®); and
3. Member must have positive expression of programmed death ligand-1 (PD-L1); and
4. Member has not failed other immunotherapy(ies).

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[1] Lorbrena® Prescribing Information. Pfizer, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210868s000lbl.pdf. Last revised 11/2018. Last accessed 04/19/2019.

[2] Mvasi® Prescribing Information. Amgen, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761028s000lbl.pdf. Last revised 09/2017. Last accessed 04/19/2019.

[3] Vizimpro® Prescribing Information. Pfizer, Inc. Available online at: http://labeling.pfizer.com/ShowLabeling.aspx?id=11019. Last revised 09/2018. Last accessed 04/19/2019.

[4] FDA. Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/informationondrugs/approveddrugs/ucm279174.htm. Last revised 05/16/2019. Last accessed 05/17/2019.

Appendix L

30-Day Notice to Prior Authorize Balversa™ (Erdafitinib)

Oklahoma Health Care Authority
June 2019

Introduction[1]

The ability to target cancer treatment to a patient's specific genetic mutation or biomarker is becoming the standard, with advances being made in new disease types. Bladder cancer is the sixth most common cancer in the United States. Fibroblast growth factor receptor (FGFR) alterations are present in approximately 1 in 5 patients with recurrent and refractory bladder cancer. FGFRs regulate important biological processes including cell growth and division during development and tissue repair. In April 2019, the U.S. Food and Drug Administration (FDA) approved Balversa™ (erdafitinib) for the treatment of adult patients with locally advanced or metastatic bladder cancer that has a type of susceptible genetic alteration known as *FGFR3* or *FGFR2* and that has progressed during or following prior platinum-containing chemotherapy. Patients should be selected for therapy with erdafitinib using an FDA-approved companion diagnostic device. Erdafitinib is the first personalized treatment targeting susceptible FGFR genetic alterations for patients with metastatic bladder cancer.

Market News and Updates[2,3]

Pipeline:

- **Pemigatinib:** In October 2018, Incyte Corporation announced updated data from its ongoing Phase 2 trial evaluating pemigatinib, its selective FGFR inhibitor, in patients with advanced or surgically unresectable cholangiocarcinoma (bile duct cancer) who failed at least 1 previous treatment. In patients with *FGFR2* translocations who were followed for at least 8 months, interim study results demonstrated an overall response rate (ORR) of 40%, the primary endpoint, and a median progression free survival (PFS) of 9.2 months, a key secondary endpoint.
- **Derazantinib:** In January 2019, Basilea Pharmaceutica launched a collaboration with Roche to evaluate derazantinib, an oral FGFR kinase family inhibitor, to be used in combination with Roche's program death-ligand 1 (PD-L1) checkpoint inhibitor, Tecentriq® (atezolizumab), in patients with confirmed FGFR genomic alterations. Previously in early January 2019, Basilea unveiled interim data from a registration trial of derazantinib, posting an objective response rate of 21% in 29 patients with intrahepatic cholangiocarcinoma.

Balversa™ (Erdafitinib) Product Summary[4]

Balversa™ (Erdafitinib):

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** The treatment of adult patients with locally advanced or metastatic urothelial carcinoma meeting the following:

- Susceptible *FGFR3* or *FGFR2* genetic alterations; and
- Progressed during or following at least 1 line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy

- **How Supplied:** 3mg, 4mg, and 5mg oral tablets
- **Dose:** 8mg [(2) 4mg tablets] by mouth once daily with a dose increase to 9mg [(3) 3mg tablets] by mouth once daily based on serum phosphate (PO_4) levels and tolerability at 14 to 21 days
- **Cost:** Wholesale Acquisition Cost (WAC) of $360.00 per 4mg tablet and $270.00 per 3mg tablet; resulting in a monthly cost of $21,600.00 for the 8mg/day dose and $24,300.00 for the 9mg/day dose

Recommendations

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

1. A diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Tumor positive for *FGFR2* or *FGFR3* genetic mutation; and
3. Use in second-line or greater treatments including:
   a. Following at least 1 line of platinum-containing chemotherapy; and
   b. Within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

[1] U.S. Food and Drug Administration (FDA). FDA approves first targeted therapy for metastatic bladder cancer. Available online at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635906.htm. Issued 04/12/2019. Last accessed 04/25/2019.
[2] Incyte Corporation. Incyte Announces Positive Interim Data from Phase 2 Trial of Pemigatinib, Its Selective FGFR Inhibitor, in Patients with Cholangiocarcinoma. *Business Wire*. Available online at: https://investor.incyte.com/news-releases/news-release-details/incyte-announces-positive-interim-data-phase-2-trial-pemigatinib. Issued 10/21/2018. Last accessed 04/25/2019.
[3] Hale C. Basilea teams up with Roche to test bladder cancer combination. *Fierce Biotech*. Available online at: https://www.fiercebiotech.com/biotech/basilea-teams-up-roche-to-test-bladder-cancer-combination. Issued 01/24/2019. Last accessed 04/25/2019.
[4] Balversa™ Prescribing Information. Janssen Pharmaceutical Companies. Available online at: hhttp://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/BALVERSA-pi.pdf. Last revised 04/2019. Last accessed 04/25/2019.

Appendix M

Calendar Year 2018 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify MyCite® (Aripiprazole Tablets with Sensor), Aristada Initio® [Aripiprazole Lauroxil Extended-Release (ER) Injectable Suspension], and Perseris™ [Risperidone ER Subcutaneous (Sub-Q) Injectable Suspension]

Oklahoma Health Care Authority
June 2019

Current Prior Authorization Criteria

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	brexpiprazole (Rexulti®)
aripiprazole IM (Abilify Maintena®)	lurasidone (Latuda®)	cariprazine (Vraylar®)
aripiprazole lauroxil IM (Aristada®)		clozapine (Fazaclo®)
clozapine (Clozaril®)◊		clozapine oral susp (Versacloz®)
olanzapine (Zyprexa®)		iloperidone (Fanapt®)
paliperidone IM (Invega Sustenna®)		olanzapine/fluoxetine (Symbyax®)^
paliperidone IM (Invega Trinza®)**		paliperidone (Invega®)
quetiapine (Seroquel®)		
quetiapine ER (Seroquel XR®)		
risperidone (Risperdal®)		
risperidone IM (Risperdal Consta®)		
ziprasidone (Geodon®)		

ER = extended-release; IM = intramuscular; susp = suspension
*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.
◊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.
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and will require a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
^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.

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

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

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

a. Clozapine does not count towards a Tier-1 trial.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

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

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment for Major Depressive Disorder:

1. Authorization of Symbyax® (olanzapine/fluoxetine) or Rexulti® (brexpiprazole) for a diagnosis of major depressive disorder requires current use of an antidepressant, previous trials with at least 2 other antidepressants from both categories [a selective serotonin reuptake inhibitor (SSRI) and duloxetine], and a trial of aripiprazole tablets that did not yield adequate response. Tier structure applies.

Utilization of Atypical Antipsychotic Medications: Calendar Year 2018

Comparison of Calendar Years

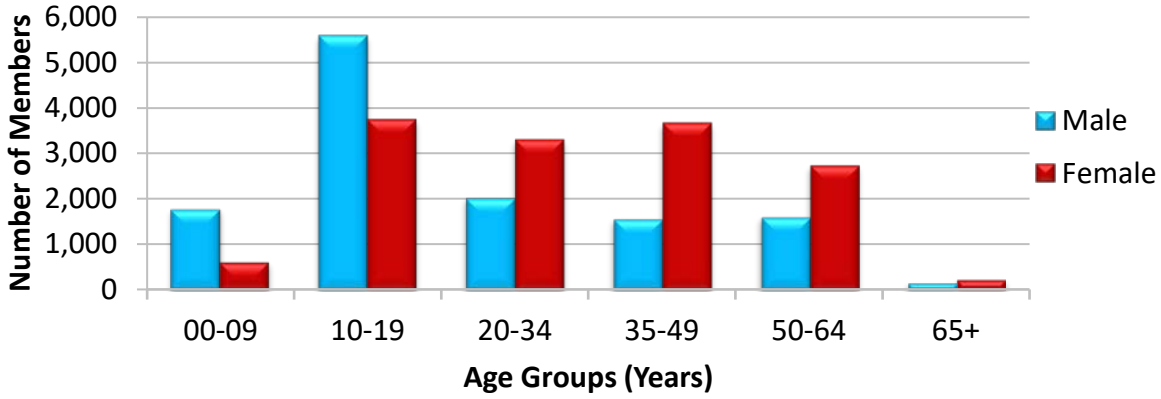
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	26,594	187,765	$37,749,432.99	$201.05	$6.50	7,604,775	5,810,115
2018	27,070	191,600	$44,747,492.98	$233.55	$7.47	7,626,594	5,987,351
% Change	**1.80%**	**2.00%**	**18.50%**	**16.20%**	**14.90%**	**0.30%**	**3.10%**
Change	**476**	**3,835**	**$6,998,059.99**	**$32.50**	**$0.97**	**21,819**	**177,236**

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

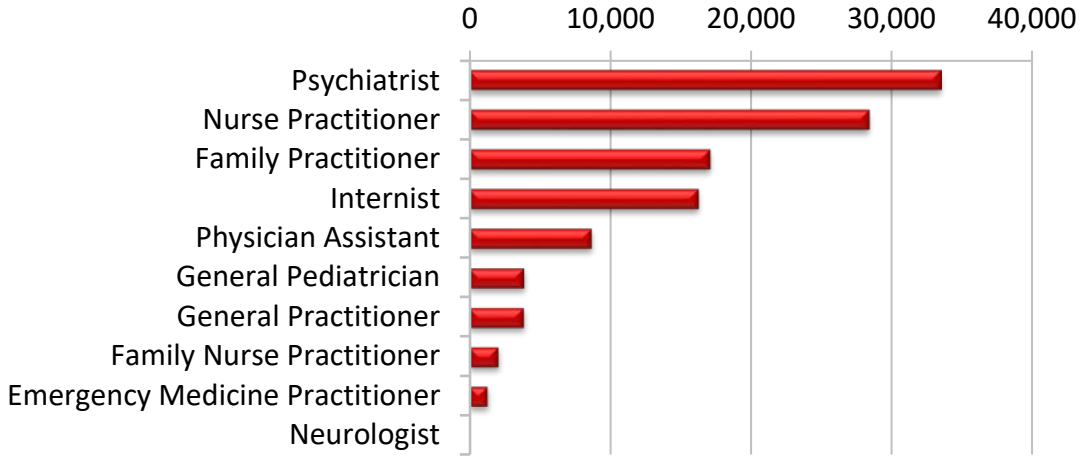
- Aggregate drug rebates collected during calendar year 2018 for atypical antipsychotic medications: $24,004,983.67[Δ]

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

Demographics of Members Utilizing Atypical Antipsychotic Medications



Top Prescriber Specialties of Atypical Antipsychotic Medications by Number of Claims



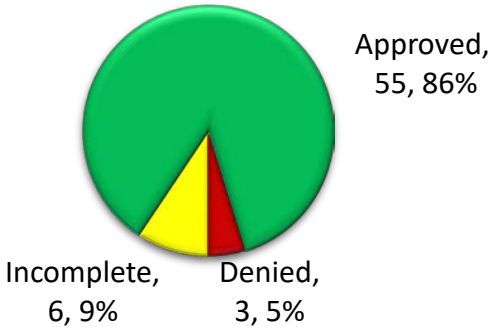
Prior Authorization of Atypical Antipsychotic Medications

There were 3,731 prior authorization requests submitted for atypical antipsychotic medications during calendar year 2018. Computer edits are in place to detect 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 2018.

Status of Petitions

There were 64 prior authorization requests submitted for a total of 52 unique members for atypical antipsychotic medications during calendar year 2018 that were referred for a psychiatric consultation. Most requests were for children 3 and 4 years of age. The following chart shows the status of the submitted petitions that were referred for a psychiatric consultation for calendar year 2018.

Status of Psychiatric Consultations



Medicaid Drug Rebate Program[1,2,3]

Medicaid coverage of a drug requires the manufacturer to have a federal rebate agreement with the Secretary of Health and Human Services (HHS). 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 payer. Best prices are reported to the Centers for Medicare & 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. Until the first quarter of 2017, the CPI penalty only applied to brand medications; however, following a senate vote in October 2015, the Medicaid CPI penalty was extended to generic drugs with an effective date of January 1, 2017. 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. The Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. In calendar year 2018, the Oklahoma Health Care Authority (OHCA) collected $24,004,983.67 in aggregate drug rebates for atypical antipsychotic medications. 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.

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

Patent Expiration(s):

- Risperdal Consta® [risperidone intramuscular (IM) injection]: June 2019

- Abilify Maintena® (aripiprazole IM injection): June 2025
- Saphris® (asenapine sublingual tablet): October 2026
- Rexulti® (brexpiprazole tablet): February 2027
- Perseris™ [risperidone extended-release (ER) subcutaneous (sub-Q) injection]: February 2028
- Vraylar® (cariprazine capsule): December 2028
- Invega Sustenna® (paliperidone IM injection): January 2031
- Fanapt® (iloperidone tablet): December 2031
- Abilify MyCite® (aripiprazole tablet with sensor): September 2034
- Aristada® (aripiprazole lauroxil IM injection): March 2035
- Invega Trinza® (paliperidone IM injection): April 2036

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

- **November 2017:** The FDA approved the first digital medicine system, Abilify MyCite® (aripiprazole tablet with sensor), a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor. The Abilify MyCite® System includes: Abilify MyCite®; the MyCite® Patch (a wearable sensor, developed by Proteus); the MyCite® APP, a smartphone application (app), used with a compatible smartphone to display information for the patient; and web-based portals for health care providers and caregivers that display a summary of aripiprazole ingestion over time. Abilify MyCite® is intended to track drug ingestion. Only functions of the app related to tracking drug ingestion have been approved by the FDA. The ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established. The use of Abilify MyCite® to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur. Aripiprazole is also currently available as an oral tablet (generic available) and IM injection.
- **July 2018:** The FDA approved Aristada Initio® (aripiprazole lauroxil) for the initiation of Aristada® (aripiprazole lauroxil), a long-acting injectable atypical antipsychotic for the treatment of schizophrenia in adults. Aristada Initio®, in combination with a single 30mg dose of oral aripiprazole, provides an alternative regimen to initiate patients onto any dose of Aristada® on day 1. Aristada® and Aristada Initio® both contain aripiprazole lauroxil; however, the 2 medications are not interchangeable because of differing pharmacokinetic profiles. Aristada Initio® utilizes proprietary NanoCrystal® technology and is designed to provide an ER formulation using a smaller particle size of aripiprazole lauroxil compared to Aristada®, thereby enabling faster dissolution and leading to more rapid achievement of relevant levels of aripiprazole. Aristada Initio® can be used for initiation onto any dose of Aristada® (441mg, 662mg, or 882mg monthly; 882mg once every 6 weeks; 1,064mg once every 2 months), offering a wide range of flexible dosing options for patients and health care providers. The first Aristada® dose may be administered on the same day as Aristada Initio® or up to 10 days thereafter.
- **July 2018:** The FDA approved Perseris™ (risperidone ER injectable suspension), the first once-monthly sub-Q risperidone long-acting injectable for the treatment of schizophrenia in adults. Perseris™ studies showed clinically relevant levels of risperidone

were reached after the first injection of Perseris™ without use of a loading dose or any supplemental oral risperidone. Perseris™ uses an ER delivery system to form a sub-Q depot that provides sustained levels of risperidone over 1 month. Initial peak risperidone plasma levels occur within 4 to 6 hours of dosing and are due to an initial release of drug during the depot formation process. Risperidone is also currently available as an oral tablet, orally disintegrating tablet, and oral solution, all of which are available in generic formulations. Risperidone is also available as an IM injection (Risperdal Consta®).

- **May 2019:** The FDA approved a supplemental New Drug Application (sNDA) for Vraylar® (cariprazine capsules) for expanded use to treat depressive episodes associated with bipolar I disorder (bipolar depression) in adults. Vraylar® is also FDA-approved to treat manic or mixed episodes associated with bipolar I disorder in adults and for the treatment of schizophrenia in adults. The FDA approval for the expanded indication of Vraylar® is based on 3 trials, RGH-MD-53, RGH-MD-54, and RGH-MD-56, in which cariprazine demonstrated greater improvement than placebo for the change from baseline to week 6 on the Montgomery Asberg Depression Rating scale (MADRS) total score. In all 3 studies, the Vraylar® 1.5mg dose demonstrated statistical significance over placebo. In the RGH-MD-54 trial, the Vraylar® 3mg dose demonstrated statistical significance over placebo. Common adverse events reported in the pivotal trials were nausea, akathisia, restlessness, and extrapyramidal symptoms.

Generic [Abbreviated New Drug Application (ANDA)] Approval(s):

- **January 2019:** The FDA approved the first generic version of Latuda® (lurasidone) 20mg, 40mg, 60mg, 80mg, and 120mg oral tablets by Lupin Pharmaceuticals for the treatment of adults with schizophrenia, for monotherapy treatment of adult patients with bipolar depression, and for adjunctive treatment with lithium or valproate in adults with bipolar depression. The market launch date and price of the generic formulation is currently unavailable.

Pipeline:

- **HP-3070:** A New Drug Application (NDA) was submitted to the FDA in December 2018 seeking approval of HP-3070 (asenapine transdermal system) for the treatment of schizophrenia. A Phase 3 clinical trial to evaluate the efficacy and safety of HP-3070 in patients diagnosed with schizophrenia was announced in January 2018. The primary endpoint of the study was change from baseline of the Positive and Negative Syndrome Scale (PANSS) total score. Efficacy and safety were assessed during the 6-week application period. The study results showed that when compared to placebo, the investigational product achieved statistically significant improvement from baseline in the change of the total PANSS score at 6 weeks. The systemic safety profile for the investigational product is consistent with that known for asenapine. The most common treatment-emergent adverse events observed in the clinical trial were application site reaction, headache, and extrapyramidal disorder.
- **NRX-100/NRX-101:** NRX-101 is a proprietary, oral fixed-dose combination of 2 FDA-approved drugs: D-cycloserine, an N-methyl-D-aspartate (NMDA) receptor modulator,

and lurasidone (Latuda®), a 5-HT_{2a} receptor antagonist. NRX-100 is ketamine, an anesthetic FDA approved for surgical procedures, but not approved for any psychiatric indications. NeuroRx's investigational treatment approach begins with a single intravenous (IV) infusion of NRX-100 (ketamine), followed by approximately 6 weeks of daily oral NRX-101. In November 2018, the FDA granted Breakthrough Therapy designation for the development of NRX-101 for treatment of severe bipolar depression with acute suicidal ideation and behavior (ASIB) after initial stabilization with ketamine or other effective therapy. The company recently reported results from its Phase 2 STABIL-B study of NRX-101 versus lurasidone in patients with severe bipolar depression and ASIB at the American Congress of Neuropsychopharmacology (ACNP). In this double-blind study, patients with severe bipolar depression and ASIB received either NRX-101 or lurasidone after stabilization with a single IV infusion of NRX-100 (ketamine). The study was not powered for efficacy; however, results of this 6-week Phase 2 study showed a statistically significant 11 point difference on the MADRS between NRX-101 and lurasidone groups at day 14 (P=0.03). Patients also maintained separation between groups over the 6-week duration of the trial, with a lower depression score in the NRX-101 group at a trend level of significance (P=0.059). None of the 10 NRX-101 patients met the trial's definition for relapse, while 2 of the 5 lurasidone patients relapsed. Relapse was defined as a ≥50% increase in MADRS depression scores versus baseline, suicidality levels requiring hospitalization [Columbia Suicide Severity Rating Scale (CSSRS) ≥4], or the need for a new treatment plan. The FDA previously issued a Special Protocol Agreement (SPA) for the design of the upcoming pivotal Phase 2b/3 clinical trial. NeuroRx is in the process of initiating its pivotal Phase 2b/3 study of NRX-101 under the SPA.

- **SEP-363856:** SEP-363856 is a novel agent being investigated for the treatment of patients with schizophrenia. The Phase 3 program for SEP-363856 is expected to be initiated between April 2019 and March 2020. SEP-363856 offers a novel mechanism of action that has the potential to be the first agent for the treatment of schizophrenia that is not a dopamine 2 (D_2) receptor antagonist. The Efficacy and Safety of SEP-363856 in the Treatment of Schizophrenia: A Four-Week, Randomized, Placebo-Controlled Trial of a Novel Compound with a Non-D_2 Mechanism of Action poster presentation was presented at the 2019 American Psychiatric Association Annual Meeting.

News:

- **December 2018:** A cohort study published in *The Journal of the American Medical Association (JAMA) of Psychiatry* found that antipsychotic treatment may be associated with increased mortality among children and youths and appears to underscore recommendations for careful medication use and monitoring in this population. Investigators found the risk of death associated with off-label antipsychotic use at doses higher than 50mg of chlorpromazine (or chlorpromazine equivalent) in patients 5 to 24 years of age was 3.5-fold greater than their counterparts not receiving antipsychotics. Using data from Tennessee Medicaid files, researchers retrospectively analyzed a large cohort of relatively healthy children and youth aged 5 to 24 years who began off-label use of oral antipsychotic therapy and compared them with children who received a

control medication (psychostimulants, antidepressants, or mood stabilizers) for the same indication. Researchers excluded patients with life-threatening somatic illnesses and those who were in the hospital when the medication was started. Patients with schizophrenia, other psychoses, and Tourette syndrome were excluded from the study because there are no alternatives to antipsychotics for these conditions. The analysis included 189,361 patients taking a control medication, 28,377 patients on a lower-dose antipsychotic (50mg or less of chlorpromazine or its equivalent), and 30,120 patients taking a higher-dose antipsychotic (greater than 50mg of chlorpromazine equivalent). The cutoff of 50mg chlorpromazine was the median dose. The most commonly prescribed medication among the lower-dose antipsychotic group was risperidone (66.0%). The most commonly prescribed antipsychotics in the higher-dose group were quetiapine (34.3%), aripiprazole (23.4%), and olanzapine (16.6%). Researchers determined causes of all deaths from death certificate data and excluded deaths due to unintentional injury. After adjustment for covariates, the risk of death in the higher-dose group was 80% greater than that in the control group [hazard ratio (HR), 1.80; 95% confidence interval (CI), 1.06-3.07]. In the higher-dose group, the adjusted risk of unexpected death was significantly increased (HR, 3.51; 95% CI, 1.54-7.96). In contrast, the risk of death from injury or suicide was not increased (HR, 1.03; 95% CI, 0.53-2.01). The HR was 4.29 (95% CI, 1.33-13.89) for cardiovascular (CV) deaths in the higher-dose antipsychotic group compared with the non-antipsychotic group. This finding is consistent with known antipsychotic adverse effects in children and youth. The study concludes the results appear to reinforce recommendations for careful prescribing and monitoring of antipsychotic regimens for children and youths and the need for larger antipsychotic safety studies in this population.

Abilify MyCite® (Aripiprazole Tablets with Sensor) Product Summary[16]

Indication(s): Abilify MyCite® (aripiprazole tablets with sensor) is a drug-device combination product indicated for the treatment of adults with schizophrenia, acute treatment of bipolar I disorder in adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate, maintenance treatment of bipolar I disorder in adults as monotherapy and as adjunct to lithium or valproate, and adjunctive treatment of adults with major depressive disorder (MDD).

Limitations of use:

- The ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established.
- The use of Abilify MyCite® to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur.

Dosing:

- The Abilify MyCite® System includes aripiprazole tablets embedded with an IEM sensor (Abilify MyCite®), a wearable sensor (MyCite® patch) that detects the signal from the IEM sensor after ingestion and transmits data via Bluetooth to a smartphone, a smartphone app (MyCite® APP) to display information to the patient, and a web-based

portal for health care providers and caregivers. Aripiprazole tablet with sensor is available in 6 strengths: 2mg, 5mg, 10mg, 15mg, 20mg, and 30mg. Each strength is dispensed as a 30-day kit containing 30 aripiprazole tablets embedded with an IEM sensor co-packaged with 7 MyCite® Patches.

- The recommended starting dose of Abilify MyCite® ranges from 2mg per day to 30mg per day depending on the diagnosis; Abilify MyCite® should be administered once daily without regard to meals.
- Abilify MyCite® should be swallowed whole and should not be divided, crushed, or chewed.
- Prior to the initial patient use of Abilify MyCite® System, it is recommended to facilitate use of the combination product and its components (patch, smartphone app, web portal) and ensure the patient is capable and willing to use smartphones and apps.
- Patients should be instructed to download the MyCite® App, follow the *Instructions for Use*, and ensure the MyCite® App is compatible with their specific smartphone. The MyCite® App allows the patient to review their objective medication ingestion data as well as activity level and self-reported mood and quality of rest. Only functions of the MyCite® App related to tracking drug ingestion have been approved by the FDA.
- It can take up to 2 hours for the MyCite® App and web portal to detect the ingestion of Abilify MyCite®. In some cases, the ingestion of the tablet may not be detected. If the tablet is not detected after ingestion, do not repeat the dose.
- The status of the MyCite® Patch is indicated by a status icon in the MyCite® App to inform the user that the patch is properly adhered and fully functioning. Patients should ensure that the MyCite® App is paired with the patch prior to use. The MyCite® Patch should be applied only when instructed by the MyCite® App on the left side of the body just above the lower edge of the rib cage. The MyCite® Patch should not be placed in areas where the skin is scraped, cracked, inflamed, or irritated, or in a location that overlaps the area of the most recently removed patch. Patients should keep the MyCite® Patch on when showering, swimming, or exercising. The MyCite® Patch should be changed weekly or sooner as needed. The MyCite® App will prompt the patient to change the patch and will direct the patient to apply and remove the patch correctly. Patients undergoing a magnetic resonance imaging (MRI) scan should remove their patch and replace it with a new one as soon as possible. If there is skin irritation, patients should be instructed to remove the patch.

Boxed Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis and Suicidal Thoughts and Behaviors

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Abilify MyCite® is not approved for the treatment of patients with dementia-related psychosis.
- There is an increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. The safety and effectiveness of Abilify MyCite® have not been established in pediatric patients.

Contraindication(s): Known hypersensitivity to aripiprazole tablets

Efficacy: The approval of Abilify MyCite® was in part based on the clinical trial data and experience of oral aripiprazole (Abilify®). The ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Month	Cost Per Year
Abilify MyCite® (aripiprazole tablets with sensor)	**$55.00**	**$1,650.00**	**$19,800.00**
aripiprazole oral tablets	$0.25-$0.47	$7.50-$14.10	$90.00-$169.20

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.

Aristada Initio® (Aripiprazole Lauroxil ER Injectable Suspension) Product Summary[17,18]

Indication(s): Aristada Initio® (aripiprazole lauroxil ER injectable suspension) in combination with oral aripiprazole tablet, is indicated for the initiation of Aristada® (aripiprazole lauroxil ER injectable suspension) when used for the treatment of schizophrenia in adults.

Dosing:

- Aristada Initio® is available as a 675mg ER single-dose pre-filled syringe.
- Aristada Initio® should be administered as (1) 675mg injection with (1) 30mg dose of oral aripiprazole tablet in conjunction with the first Aristada® injection.
- Aristada Initio® is only to be used as a single dose and is not for repeated dosing.
- Aristada Initio® should be administered by IM injection in either the deltoid or gluteal muscle by a health care professional.
- For patients who are naïve to aripiprazole, tolerability should be established with oral aripiprazole prior to initiating treatment with Aristada Initio®.
- Use of Aristada Initio® should be avoided in known CYP2D6 poor metabolizers.
- Use of Aristada Initio® should be avoided with strong CYP2D6 or CYP3A4 inhibitors and strong CYP3A4 inducers.
- Aristada Initio® is not interchangeable with Aristada®.

Boxed Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- Aristada Initio® is not approved for the treatment of patients with dementia-related psychosis.

Contraindication(s): Known hypersensitivity to aripiprazole

Efficacy: The effectiveness of Aristada Initio®, in combination with oral aripiprazole, for initiation of Aristada® when used for the treatment of schizophrenia in adults was established

by adequate and well-controlled studies of oral aripiprazole and Aristada® in adult patients with schizophrenia. Aristada Initio® is also supported by a single pharmacokinetic bridging study.

Cost Comparison: There are 2 options for initiating treatment with Aristada®:

- **Option #1:** Administer 21 consecutive days of oral aripiprazole tablets in conjunction with the first Aristada® injection.
- **Option #2:** Administer 1 injection of Aristada Initio® 675mg and (1) 30 mg dose of oral aripiprazole tablet in conjunction with the first Aristada® injection.

Option #1		
Medication	**Cost Per Unit**	**Cost Per Initiation (21-Day Supply)**
aripiprazole oral tablets	$0.25-$0.47	$5.25-$9.87

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.

Option #2		
Medication	**Cost Per Unit**	**Cost Per Initiation (1-Day Supply)**
Aristada Initio® (aripiprazole lauroxil ER injectable suspension)	**$1,981.73**	**$1,981.73**
aripiprazole 30mg oral tablet	$0.47	$0.47

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.

Perseris™ (Risperidone ER Sub-Q Injectable Suspension) Product Summary[19]

Indication(s): Perseris™ (risperidone ER sub-Q injectable suspension) is an atypical antipsychotic indicated for the treatment of schizophrenia in adults.

Dosing:

- Perseris™ is available as 90mg and 120mg ER injectable suspensions.
- For patients who have never taken risperidone, it is recommended to establish tolerability with oral risperidone before initiating Perseris™.
- Perseris™ may be initiated at a dose of 90mg or 120mg.
- Supplementation with oral risperidone is not recommended with Perseris™.
- Prior to use with Perseris™, the product should be constituted by coupling the liquid and powder syringes and passing the contents back and forth between the syringes. Failure to fully mix Perseris™ could result in incorrect dosage.
- Perseris™ should be administered monthly by sub-Q injection in the abdomen by a health care professional. Perseris™ should not be administered by any other route.
- More than 1 dose (90mg or 120mg) of Perseris™ should not be administered per month.

Boxed Warning: Increased Mortality in Elderly Patients with Dementia-Related Psychosis

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Perseris™ is not approved for the treatment of patients with dementia-related psychosis.

Contraindication(s): Known hypersensitivity to risperidone, paliperidone, or other components of Perseris™

Efficacy: The efficacy of Perseris™ was demonstrated in an 8-week, randomized, double-blind, placebo-controlled study that evaluated the efficacy, safety, and tolerability of Perseris™ (90mg and 120mg sub-Q every 4 weeks) compared with placebo in 354 adults (age 18 to 55 years) experiencing acute exacerbations of schizophrenia.

- Patients were required to have a PANSS total score of 80 to 120 (moderate to severely ill) at the screening visit, occurring 3 to 8 days before the start of double-blind treatment, without an improvement in the PANSS total score of ≥20% between screening and the first dosing day. At the screening visit, all patients received 2 doses of 0.25mg oral risperidone 24 hours apart to establish tolerability. Patients were then placed in an inpatient setting, if not already hospitalized, and tapered off their current oral antipsychotic medication (if they were taking one) over a period of 3 to 8 days. Patients were randomized to receive 2 doses of sub-Q Perseris™ (90mg or 120mg) or placebo 28 days apart (on day 1 and day 29). No supplemental oral risperidone was permitted during the study.
- The primary endpoint was the change in PANSS total score from baseline to end of study (day 57). Both Perseris™ 90mg and 120mg doses demonstrated a statistically significant improvement in the PANSS total score compared with placebo based on the primary endpoint [Perseris™ 90mg vs. placebo: difference = -6.50 (95% CI: -10.87, -2.13); Perseris™ 120mg vs. placebo: difference = -10.24 (95% CI: -14.64, -5.85)].

Cost Comparison:

Medication	Cost Per Unit	Cost Per Month	Cost Per Year
Perseris™ (risperidone ER sub-Q injectable suspension) 90mg	**$1,710.00**	**$1,710.00**	**$20,520.00**
Perseris™ (risperidone ER sub-Q injectable suspension) 120mg	**$2,280.00**	**$2,280.00**	**$27,360.00**
risperidone 4mg oral tablets[¥]	$0.07	$4.20	$50.40
Risperdal Consta® (risperidone IM) 50mg/2mL syringe[±]	$929.00	$1,858.00	$24,154.00

ER = extended-release; sub-Q = subcutaneous; IM = intramuscular
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.
[¥]Risperidone oral tablets dose based on maximum recommended maintenance dose for treatment of schizophrenia of 8mg per day.
[±]Risperdal Consta® dose based on maximum dose of 50mg every 2 weeks for treatment of schizophrenia. Cost per year for Risperdal Consta® based on a total of 26 injections per year.

Recommendations

The College of Pharmacy recommends the following changes to the Atypical Antipsychotic Medications PBPA category:

1. The placement of Aristada Initio® (aripiprazole lauroxil) into Tier-3. Aristada Initio® (aripiprazole lauroxil) is currently in Tier-1 due to supplemental rebate participation. If

the manufacturer chooses not to participate in supplemental rebates, Aristada Initio® may be moved up to the higher tier.

2. The placement of Perseris™ (risperidone ER sub-Q injection) into Tier-3. Current Tier-3 criteria will apply.
3. The placement of Abilify MyCite® (aripiprazole tablets with sensor) into Tier-3 with the following criteria:

Abilify MyCite® (Aripiprazole Tablets with Sensor) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must not have dementia-related psychosis; and
3. A patient-specific, clinically significant reason why the member cannot use all oral or injectable Tier-1 or Tier-2 medications. Tier structure rules continue to apply. Please note, the ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established; and
4. Previous use of aripiprazole tablets and a reason why the Tier-1 tablets are no longer appropriate for the member must be provided; and
5. The prescriber agrees to closely monitor patient adherence; and
6. Patients should be capable and willing to use the MyCite® App and follow the *Instructions for Use* and ensure the MyCite® App is compatible with their specific smartphone; and
7. Initial approval will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance greater than 80% with prescribed therapy must be provided.

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

ER = extended-release; IM = intramuscular; 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.

◊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.
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and will require a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
^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.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).

Utilization Details of Atypical Antipsychotic Medications: Calendar Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
ARIPIPRAZOLE INJECTABLE PRODUCTS						
ABILIFY MAIN INJ 400MG	1,252	230	$2,559,386.59	$71.86	$2,044.24	5.72%
ABILIFY MAIN INJ 400MG	508	120	$1,031,446.99	$70.57	$2,030.41	2.31%
ABILIFY MAIN INJ 300MG	196	56	$300,719.53	$53.34	$1,534.28	0.67%
ABILIFY MAIN INJ 300MG	75	27	$114,794.78	$53.05	$1,530.60	0.26%
SUBTOTAL	**2,031**	**433**	**$4,006,347.89**	**$69.03**	**$1,972.60**	**8.96%**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS						
ARISTADA INJ 882MG	416	92	$955,744.52	$77.53	$2,297.46	2.14%
ARISTADA INJ 662MG	125	30	$210,456.36	$57.88	$1,683.65	0.47%
ARISTADA INJ 1064MG	87	47	$246,061.56	$47.70	$2,828.29	0.55%
ARISTADA INJ 441MG	43	16	$49,094.43	$39.91	$1,141.73	0.11%
ARISTADA INJ INITIO 675MG	6	6	$11,270.26	$53.92	$1,878.38	0.03%
SUBTOTAL	**677**	**191**	**$1,472,627.13**	**$65.28**	**$2,175.22**	**3.30%**
ARIPIPRAZOLE ORAL PRODUCTS						
ARIPIPRAZOLE TAB 5MG	12,318	3,950	$282,911.63	$0.73	$22.97	0.63%
ARIPIPRAZOLE TAB 10MG	9,352	2,872	$215,208.90	$0.72	$23.01	0.48%
ARIPIPRAZOLE TAB 15MG	5,684	1,645	$128,546.48	$0.71	$22.62	0.29%
ARIPIPRAZOLE TAB 2MG	4,356	1,521	$102,282.54	$0.75	$23.48	0.23%
ARIPIPRAZOLE TAB 20MG	3,783	927	$116,452.36	$0.96	$30.78	0.26%
ARIPIPRAZOLE TAB 30MG	2,113	450	$63,225.52	$0.90	$29.92	0.14%
ARIPIPRAZOLE SOL 1MG/ML	209	46	$112,260.32	$15.73	$537.13	0.25%
ABILIFY TAB 20MG	14	2	$26,721.84	$40.49	$1,908.70	0.06%
ABILIFY TAB 5MG	13	1	$11,251.75	$28.85	$865.52	0.03%
ARIPIPRAZOLE TAB 15MG ODT	3	2	$2,294.49	$25.49	$764.83	0.01%
SUBTOTAL	**37,845**	**11,416**	**$1,061,155.83**	**$0.88**	**$28.04**	**2.38%**
CLOZAPINE PRODUCTS						
CLOZAPINE TAB 100MG	5,282	437	$324,110.13	$2.71	$61.36	0.72%
CLOZAPINE TAB 200MG	2,051	177	$160,990.86	$3.90	$78.49	0.36%
CLOZAPINE TAB 50MG	1,680	161	$70,542.05	$2.06	$41.99	0.16%
CLOZAPINE TAB 25MG	955	114	$27,101.24	$1.30	$28.38	0.06%
CLOZARIL TAB 100MG	21	3	$27,315.60	$44.49	$1,300.74	0.06%
SUBTOTAL	**9,989**	**892**	**$610,059.88**	**$2.82**	**$61.07**	**1.36%**
OLANZAPINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
OLANZAPINE TAB 20MG	6,411	1,175	$108,585.74	$0.52	$16.94	0.24%
OLANZAPINE TAB 10MG	5,918	1,598	$83,702.05	$0.45	$14.14	0.19%
OLANZAPINE TAB 5MG	3,528	1,169	$47,108.17	$0.42	$13.35	0.11%
OLANZAPINE TAB 15MG	2,609	677	$44,939.46	$0.53	$17.22	0.10%
OLANZAPINE TAB 2.5MG	1,055	360	$14,033.20	$0.44	$13.30	0.03%
OLANZAPINE TAB 7.5MG	497	149	$7,452.79	$0.48	$15.00	0.02%
OLANZAPINE TAB 10MG ODT	387	120	$16,749.19	$1.38	$43.28	0.04%
OLANZAPINE TAB 20MG ODT	340	90	$19,352.79	$1.54	$56.92	0.04%
OLANZAPINE TAB 5MG ODT	246	97	$8,718.06	$1.22	$35.44	0.02%
OLANZAPINE TAB 15MG ODT	193	50	$10,294.95	$1.48	$53.34	0.02%
ZYPREXA TAB 15MG	12	1	$9,741.16	$27.06	$811.76	0.02%
ZYPREXA TAB 5MG	11	2	$6,125.34	$12.01	$556.85	0.01%
ZYPREXA TAB 10MG	6	2	$8,230.78	$19.60	$1,371.80	0.02%
OLANZAPINE INJ 10MG	1	1	$176.55	$88.28	$176.55	0.00%
ZYPREXA TAB 20MG	1	1	$1,068.58	$35.62	$1,068.58	0.00%
SUBTOTAL	**21,215**	**5,492**	**$386,278.81**	**$0.57**	**$18.21**	**0.86%**
PALIPERIDONE INJECTABLE PRODUCTS						
INVEGA SUST INJ 234MG/1.5ML	3,782	760	$9,130,162.57	$84.53	$2,414.11	20.40%
INVEGA SUST INJ 156MG/ML	1,741	518	$2,806,827.25	$56.53	$1,612.19	6.27%
INVEGA TRINZ INJ 819MG	698	232	$5,006,646.82	$82.50	$7,172.85	11.19%
INVEGA SUST INJ 117MG/0.75ML	406	110	$486,995.97	$42.03	$1,199.50	1.09%
INVEGA TRINZ INJ 546MG	293	102	$1,411,538.20	$55.42	$4,817.54	3.15%
INVEGA TRINZ INJ 410MG	91	36	$336,049.51	$42.50	$3,692.85	0.75%
INVEGA TRINZ INJ 273MG	31	12	$77,771.84	$29.26	$2,508.77	0.17%
INVEGA SUST INJ 39MG/0.25ML	31	5	$12,680.17	$14.12	$409.04	0.03%
INVEGA SUST INJ 78MG/0.5ML	29	8	$24,298.89	$29.00	$837.89	0.05%
SUBTOTAL	**7,102**	**1,783**	**$19,292,971.22**	**$72.07**	**$2,716.55**	**43.10%**
QUETIAPINE PRODUCTS						
QUETIAPINE TAB 100MG	11,255	3,044	$149,243.91	$0.42	$13.26	0.33%
QUETIAPINE TAB 50MG	8,720	2,642	$112,394.29	$0.41	$12.89	0.25%
QUETIAPINE TAB 200MG	7,833	1,934	$120,575.11	$0.48	$15.39	0.27%
QUETIAPINE TAB 300MG	6,888	1,473	$124,262.72	$0.56	$18.04	0.28%
QUETIAPINE TAB 400MG	5,972	1,141	$110,836.05	$0.57	$18.56	0.25%
QUETIAPINE TAB 25MG	5,244	1,733	$65,578.74	$0.40	$12.51	0.15%
QUETIAPINE TAB 400MG ER	811	159	$38,114.40	$1.42	$47.00	0.09%
QUETIAPINE TAB 300MG ER	757	187	$33,381.99	$1.35	$44.10	0.07%
QUETIAPINE TAB 150MG ER	521	178	$16,808.80	$0.95	$32.26	0.04%
QUETIAPINE TAB 50MG ER	519	199	$15,596.89	$0.93	$30.05	0.03%
QUETIAPINE TAB 200MG ER	306	103	$10,368.36	$1.03	$33.88	0.02%
SEROQUEL TAB 400MG	12	1	$13,553.80	$37.65	$1,129.48	0.03%
SEROQUEL XR TAB 400MG	12	2	$16,714.64	$46.43	$1,392.89	0.04%
SUBTOTAL	**48,850**	**12,796**	**$827,429.70**	**$0.53**	**$16.94**	**1.85%**
RISPERIDONE INJECTABLE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
RISPERDAL INJ 50MG	266	34	$408,264.11	$60.55	$1,534.83	0.91%
RISPERDAL INJ 25MG	96	14	$62,689.82	$31.07	$653.02	0.14%
RISPERDAL INJ 37.5MG	94	16	$114,122.39	$45.87	$1,214.07	0.26%
RISPERDAL INJ 12.5MG	32	7	$12,646.04	$15.55	$395.19	0.03%
SUBTOTAL	**488**	**71**	**$597,722.36**	**$49.55**	**$1,224.84**	**1.34%**
RISPERIDONE ORAL PRODUCTS						
RISPERIDONE TAB 1MG	11,919	2,724	$144,412.73	$0.39	$12.12	0.32%
RISPERIDONE TAB 0.5MG	10,357	2,425	$127,001.89	$0.40	$12.26	0.28%
RISPERIDONE TAB 2MG	7,047	1,490	$85,167.95	$0.39	$12.09	0.19%
RISPERIDONE TAB 0.25MG	5,119	1,350	$61,656.23	$0.39	$12.04	0.14%
RISPERIDONE TAB 3MG	3,296	638	$40,474.51	$0.39	$12.28	0.09%
RISPERIDONE TAB 4MG	1,894	332	$24,341.56	$0.40	$12.85	0.05%
RISPERIDONE SOL 1MG/ML	890	151	$32,577.50	$1.10	$36.60	0.07%
RISPERIDONE TAB 0.5MG OD	174	53	$7,342.28	$1.50	$42.20	0.02%
RISPERIDONE TAB 1MG ODT	151	39	$8,309.95	$1.91	$55.03	0.02%
RISPERIDONE TAB 2MG ODT	113	24	$8,197.50	$2.25	$72.54	0.02%
RISPERIDONE TAB 0.25MG ODT	64	17	$9,978.94	$5.25	$155.92	0.02%
RISPERIDONE TAB 3MG ODT	27	12	$2,765.07	$4.00	$102.41	0.01%
RISPERIDONE TAB 4MG ODT	24	4	$3,798.18	$4.70	$158.26	0.01%
RISPERDAL SOL 1MG/ML	20	2	$10,722.79	$17.87	$536.14	0.02%
RISPERDAL TAB 2MG	12	1	$10,601.76	$29.45	$883.48	0.02%
RISPERDAL TAB 3MG	12	1	$12,562.80	$34.90	$1,046.90	0.03%
SUBTOTAL	**41,119**	**9,263**	**$589,911.64**	**$0.46**	**$14.35**	**1.31%**
ZIPRASIDONE PRODUCTS						
ZIPRASIDONE CAP 80MG	2,266	396	$80,649.71	$1.15	$35.59	0.18%
ZIPRASIDONE CAP 40MG	2,194	629	$67,515.90	$0.98	$30.77	0.15%
ZIPRASIDONE CAP 20MG	2,039	640	$64,069.35	$1.05	$31.42	0.14%
ZIPRASIDONE CAP 60MG	1,672	379	$64,421.20	$1.23	$38.53	0.14%
GEODON INJ 20MG	4	3	$1,731.32	$69.25	$432.83	0.00%
SUBTOTAL	**8,175**	**2,047**	**$278,387.48**	**$1.10**	**$34.05**	**0.61%**
TIER-1 SUBTOTAL	**177,491**	**44,384**	**$29,122,891.94**	**$5.25**	**$164.08**	**65.07%**
TIER-2 PRODUCTS						
LURASIDONE PRODUCTS						
LATUDA TAB 40MG	2,477	779	$2,935,744.94	$38.84	$1,185.20	6.56%
LATUDA TAB 20MG	1,751	612	$2,070,917.07	$38.93	$1,182.71	4.63%
LATUDA TAB 80MG	1,726	416	$2,342,027.29	$43.47	$1,356.91	5.23%
LATUDA TAB 60MG	1,420	398	$1,710,600.73	$37.83	$1,204.65	3.82%
LATUDA TAB 120MG	882	178	$1,634,386.15	$58.07	$1,853.05	3.65%
SUBTOTAL	**8,256**	**2,383**	**$10,693,676.18**	**$41.77**	**$1,295.26**	**23.89%**
ASENAPINE PRODUCTS						
SAPHRIS SUB 10MG	573	125	$551,569.76	$31.48	$962.60	1.23%
SAPHRIS SUB 5MG	403	126	$366,955.30	$28.70	$910.56	0.82%
SAPHRIS SUB 2.5MG	138	41	$108,188.09	$26.03	$783.97	0.24%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SUBTOTAL	**1,114**	**292**	**$1,026,713.15**	**$29.79**	**$921.65**	**2.29%**
TIER-2 SUBTOTAL	**9,370**	**2,675**	**$11,720,389.33**	**$40.35**	**$1,250.84**	**26.18%**
TIER-3 PRODUCTS						
BREXPIPRAZOLE PRODUCTS						
REXULTI TAB 2MG	233	77	$251,296.44	$33.29	$1,078.53	0.56%
REXULTI TAB 4MG	123	29	$160,406.12	$34.83	$1,304.11	0.36%
REXULTI TAB 3MG	96	31	$106,215.49	$34.23	$1,106.41	0.24%
REXULTI TAB 1MG	90	39	$91,867.67	$35.39	$1,020.75	0.21%
REXULTI TAB 0.5MG	44	13	$43,587.70	$34.73	$990.63	0.10%
REXULTI TAB 0.25MG	3	1	$3,160.11	$35.11	$1,053.37	0.01%
SUBTOTAL	**589**	**190**	**$656,533.53**	**$34.20**	**$1,114.66**	**1.48%**
CARIPRAZINE PRODUCTS						
VRAYLAR CAP 3MG	321	112	$390,433.23	$38.54	$1,216.30	0.87%
VRAYLAR CAP 6MG	170	45	$199,837.06	$37.80	$1,175.51	0.45%
VRAYLAR CAP 4.5MG	140	43	$166,098.62	$38.49	$1,186.42	0.37%
VRAYLAR CAP 1.5MG	107	47	$130,724.06	$38.18	$1,221.72	0.29%
SUBTOTAL	**738**	**247**	**$887,092.97**	**$38.31**	**$1,202.02**	**1.98%**
CLOZAPINE ORALLY DISINTEGRATING PRODUCTS						
CLOZAPINE TAB 100MG ODT	168	17	$99,846.14	$21.22	$594.32	0.22%
CLOZAPINE TAB 150MG ODT	93	10	$88,752.46	$32.31	$954.33	0.20%
CLOZAPINE TAB 200MG ODT	64	7	$80,642.93	$44.36	$1,260.05	0.18%
CLOZAPINE TAB 25MG ODT	43	5	$8,808.87	$7.84	$204.86	0.02%
FAZACLO TAB 100MG ODT	23	4	$33,124.94	$52.58	$1,440.21	0.07%
FAZACLO TAB 150MG ODT	10	1	$19,646.96	$65.49	$1,964.70	0.04%
FAZACLO TAB 200MG ODT	7	2	$15,564.12	$77.43	$2,223.45	0.03%
FAZACLO TAB 25MG ODT	7	1	$4,949.35	$23.57	$707.05	0.01%
CLOZAPINE TAB 12.5MG ODT	2	1	$443.33	$7.39	$221.67	0.00%
SUBTOTAL	**417**	**48**	**$351,779.10**	**$29.82**	**$843.59**	**0.77%**
ILOPERIDONE PRODUCTS						
FANAPT TAB 6MG	193	32	$220,310.82	$38.15	$1,141.51	0.49%
FANAPT TAB 12MG	177	20	$321,038.74	$60.90	$1,813.78	0.72%
FANAPT TAB 8MG	108	15	$112,651.69	$40.42	$1,043.07	0.25%
FANAPT TAB 10MG	86	13	$156,181.12	$60.77	$1,816.06	0.35%
FANAPT TAB 4MG	83	11	$68,433.47	$28.65	$824.50	0.15%
FANAPT TAB 2MG	58	9	$43,289.35	$23.30	$746.37	0.10%
FANAPT TAB 1MG	5	3	$5,486.08	$36.57	$1,097.22	0.01%
SUBTOTAL	**710**	**103**	**$927,391.27**	**$44.58**	**$1,306.18**	**2.07%**
OLANZAPINE/FLUOXETINE COMBINATION PRODUCTS						
OLANZA/FLUOX CAP 12-50MG	21	2	$10,372.15	$16.46	$493.91	0.02%
OLANZA/FLUOX CAP 3-25MG	12	1	$2,462.67	$6.84	$205.22	0.01%
OLANZA/FLUOX CAP 6-25MG	12	2	$3,400.20	$9.45	$283.35	0.01%
OLANZA/FLUOX CAP 12-25MG	11	1	$5,512.74	$16.71	$501.16	0.01%
OLANZA/FLUOX CAP 6-50MG	9	1	$3,029.03	$11.22	$336.56	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SUBTOTAL	**65**	**7**	**$24,776.79**	**$12.71**	**$381.18**	**0.06%**
PALIPERIDONE ORAL PRODUCTS						
PALIPERIDONE TAB ER 6MG	1,074	190	$506,982.40	$14.89	$472.05	1.13%
PALIPERIDONE TAB ER 9MG	615	104	$341,875.04	$17.09	$555.89	0.76%
PALIPERIDONE TAB ER 3MG	469	109	$184,135.64	$11.76	$392.61	0.41%
PALIPERIDONE TAB ER 1.5MG	62	15	$23,644.97	$11.94	$381.37	0.05%
SUBTOTAL	**2,220**	**418**	**$1,056,638.05**	**$14.74**	**$475.96**	**2.35%**
TIER-3 SUBTOTAL	**4,739**	**1,013**	**$3,904,211.71**	**$26.27**	**$823.85**	**8.71%**
TOTAL	**191,600**	**27,070***	**$44,747,492.98**	**$7.47**	**$233.55**	**100%**

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

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Appendix N

Calendar Year 2018 Annual Review of ADHD and Narcolepsy Medications and 30-Day Notice to Prior Authorize Jornay PM™ [Methylphenidate Extended-Release (ER) Capsule], Evekeo ODT™ [Amphetamine Orally Disintegrating Tablet (ODT)], Adhansia XR™ (Methylphenidate ER Capsule), and Sunosi™ (Solriamfetol Tablet)

Oklahoma Health Care Authority
June 2019

Current Prior Authorization Criteria

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			Adzenys ER™ (amphetamine ER susp) Adzenys XR-ODT® (amphetamine ER-ODT) Cotempla XR-ODT™ (methylphenidate ER ODT) Daytrana® (methylphenidate ER) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) Dexedrine Spansules® (dextroamphetamine ER) Dyanavel® XR (amphetamine ER susp) Evekeo® (amphetamine) Methylin® (methylphenidate soln & chew tabs)
Short-Acting			
Adderall® (amphetamine/ dextroamphetamine)			
Long-Acting			
Vyvanse® (lisdexamfetamine caps and chew tabs)+	Adderall XR® (amphetamine/ dextroamphetamine ER)		
Methylphenidate			
Short-Acting			
Focalin® (dexmethylphenidate) Methylin® (methylphenidate) Ritalin® (methylphenidate)			
Long-Acting			
Aptensio XR® (methylphenidate ER) Focalin XR® brand name only (dexmethylphenidate ER) Metadate CD® (methylphenidate ER)	dexmethylphenidate ER (generic Focalin XR®) Quillivant XR® (methylphenidate ER susp)	Concerta® (methylphenidate ER) Metadate ER® (methylphenidate ER) Methylin ER® (methylphenidate ER) methylphenidate ER 72mg	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
QuilliChew ER® (methylphenidate ER chew tabs) Ritalin LA® (methylphenidate ER)		Ritalin SR® (methylphenidate ER)	Mydayis® (amphetamine/ dextroamphetamine ER) ProCentra® (dextroamphetamine) Zenzedi® (dextroamphetamine)
Non-Stimulants			
Intuniv® (guanfacine ER) Strattera® (atomoxetine)		Kapvay® (clonidine ER)$^{\Delta}$	

*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.
$^{+}$Unique criteria applies for the diagnosis of binge eating disorder (BED).
$^{\Delta}$Unique criteria applies in addition to tier trial requirements.
ADHD = attention deficit hyperactivity disorder; PA= prior authorization; ER = extended-release; SR = sustained-release; caps = capsules; ODT = orally disintegrating tablet; chew tabs = chewable tablets; soln = solution; susp = suspension

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 180 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. For Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician.

4. A clinical exception may apply for special formulation products when there is a patient-specific, clinically significant reason why the member cannot use the available long-acting lower tiered formulations.
5. Use of Kapvay® (clonidine extended-release tablets) requires:
    a. An FDA approved diagnosis; and
    b. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, a long-acting Tier-2 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
    c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.

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®, and Dyanavel® XR 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 must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Mydayis® Approval Criteria:
    a. A covered diagnosis; and
    b. Member must be 13 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members

younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)-contracted psychiatrist.

3. 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 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.

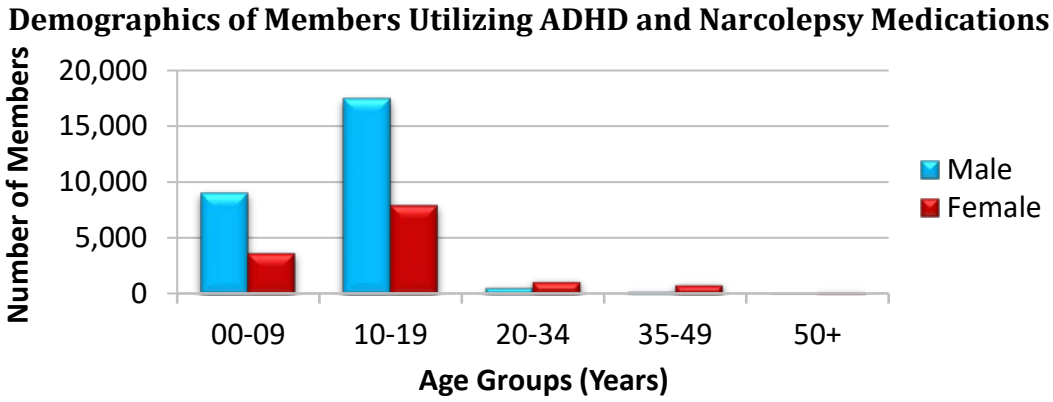
Utilization of ADHD and Narcolepsy Medications: Calendar Year 2018

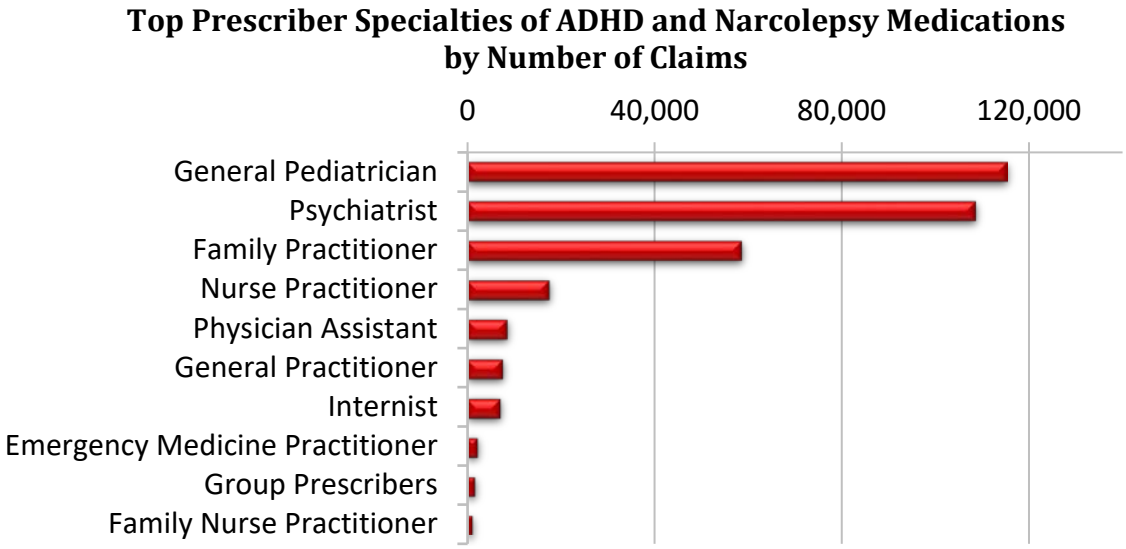
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	42,104	344,510	$55,679,838.15	$161.62	$5.45	12,149,954	10,224,670
2018	41,146	335,114	$50,744,547.72	$151.42	$5.10	11,715,348	9,952,684
% Change	**-2.30%**	**-2.70%**	**-8.90%**	**-6.30%**	**-6.40%**	**-3.60%**	**-2.70%**
Change	**-958**	**-9,396**	**-$4,935,290.43**	**-$10.20**	**-$0.35**	**-434,606**	**-271,986**

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

- Aggregate drug rebates collected during calendar year 2018 for ADHD and narcolepsy medications: $30,223,791.33[Δ]

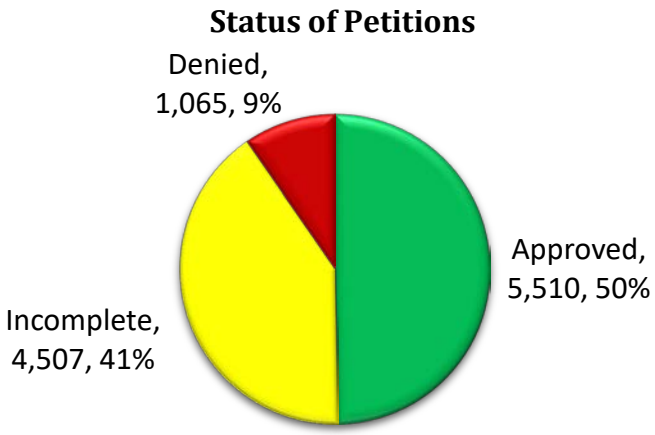




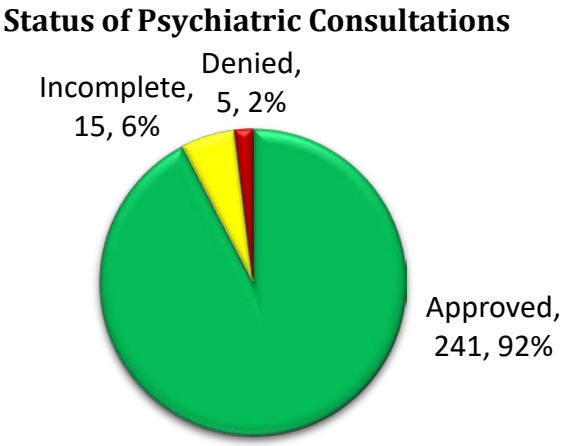
Prior Authorization of ADHD and Narcolepsy Medications

There were 11,082 prior authorization requests submitted for ADHD and narcolepsy medications during calendar year 2018. Computer edits are in place to detect lower tiered ADHD 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 2018.

[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.



There were 261 prior authorization requests submitted for a total of 195 unique members for ADHD and narcolepsy medications during calendar year 2018 that were referred for a psychiatric consultation. Most requests were for children 3 and 4 years of age. The following chart shows the status of the submitted petitions referred for psychiatric consultation for calendar year 2018.



Medicaid Drug Rebate Program[1,2,3]

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). 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. Until 2017, the CPI penalty only applied to brand medications; however, following a Senate vote in October 2015, the Medicaid CPI penalty was extended to generic drugs with an effective date of January 1, 2017. Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. The ADHD and Narcolepsy Medications Product Based Prior Authorization (PBPA) category is heavily influenced by supplemental rebates. The ADHD and narcolepsy brand name products that are preferred over available generic products are preferred due to a lower net cost compared to generics, after taking into account federal and/or supplemental rebate participation. In calendar year 2018, the Oklahoma Health Care Authority (OHCA) collected $30,223,791.33 in aggregate drug rebates for ADHD and narcolepsy medications. 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.

Market News and Updates[4,5,6,7,8,9,10,11,12,13,14,15,16,17,18]

Anticipated Patent Expiration(s):

- Vyvanse® (lisdexamfetamine capsule and chewable tablet): February 2023
- Evekeo ODT™ [amphetamine orally disintegrating tablet (ODT)]: April 2024
- Daytrana® [methylphenidate extended-release (ER) patch]: October 2025
- Dyanavel® XR (amphetamine ER suspension): March 2029
- Mydayis® (amphetamine/dextroamphetamine ER capsule): August 2029
- Quillivant XR® (methylphenidate ER suspension): February 2031
- Jornay PM™ (methylphenidate ER capsule): March 2032
- Adzenys XR-ODT® (amphetamine ER ODT): June 2032
- Adzenys ER™ (amphetamine ER suspension): June 2032
- Cotempla XR-ODT® (methylphenidate ER ODT): June 2032
- QuilliChew ER® (methylphenidate ER chewable tablet): August 2033
- Xyrem® (sodium oxybate solution): September 2033
- Adhansia XR™ (methylphenidate ER capsule): October 2035

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

- **August 2018:** The FDA approved Ironshore Pharmaceuticals' Jornay PM™ (methylphenidate ER capsule) for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years of age and older. Jornay PM™ is a novel formulation of methylphenidate which is taken in the evening and has demonstrated improvement in the severity of ADHD symptoms in the early morning and throughout the day. Jornay PM™ is the first drug utilizing Ironshore's proprietary drug delivery platform, DELEXIS®. DELEXIS® is a novel and proprietary drug delivery technology that contains 2 functional film coatings that act synergistically to achieve a unique pharmacokinetic profile: the first layer delays the initial release of the drug for up to 10 hours while the second layer helps to control the rate of release of the active pharmaceutical ingredient throughout the day. Ironshore plans to initiate the commercial launch of Jornay PM™ in the first half of 2019.
- **October 2018:** The FDA approved an expanded indication for Xyrem® (sodium oxybate oral solution) to include an indication to treat cataplexy or excessive daytime sleepiness

(EDS) in patients with narcolepsy ages 7 years and older. Sodium oxybate is the only product approved by the FDA for both cataplexy and EDS in adult and pediatric patients 7 years of age and older with narcolepsy. Cataplexy is a sudden and uncontrollable muscle weakness or paralysis that is often triggered by a strong emotion, such as laughter, surprise, embarrassment, or anger. The efficacy and safety of sodium oxybate for the treatment of cataplexy or EDS in pediatric patients with narcolepsy were established in the multisite Phase 2/3 EXPRESS study; results from the Phase 2/3 EXPRESS study were published in *The Lancet Child & Adolescent Health* in July 2018 and topline data was presented at the Associated Professional Sleep Societies (APSS) annual meetings in June 2017 and 2018. Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB) and is a central nervous system (CNS) depressant; abuse or misuse of illicit GHB is associated with CNS adverse reactions, including seizures, respiratory depression, decreased consciousness, coma, and death. Sodium oxybate is available only through the Xyrem® REMS program. Sodium oxybate was first FDA approved in 2002 for the treatment of cataplexy in adult patients with narcolepsy and in 2005 for the treatment of EDS in adult patients with narcolepsy.

- **December 2018:** The FDA approved Actavis Elizabeth's marketing of methylphenidate ER capsules (10, 15, 20, 30, 40, 50, and 60mg) for the treatment of ADHD. This is the first generic version of Aptensio XR® capsules; however, it is not yet available on the market. The College of Pharmacy will monitor the net costs of the generic formulation as it becomes available and also as more generic versions of Aptensio XR® become available.
- **January 2019:** The FDA approved Arbor Pharmaceuticals' Evekeo ODT™ (amphetamine ODT) for the treatment of ADHD in pediatric patients 6 to 17 years of age. Evekeo ODT™ is the first short-acting ODT stimulant medication approved by the FDA for the treatment of ADHD. Evekeo ODT™ will be available as 5mg, 10mg, 15mg, and 20mg ODTs. Arbor's launch plans for Evekeo ODT™ are pending; cost information for Evekeo ODT™ is not yet available. Evekeo® tablets were first FDA approved in 2012 and are currently available both as brand and generic formulations.
- **February 2019:** The FDA approved Adlon Therapeutics' Adhansia XR™ (methylphenidate ER capsule) for the treatment of ADHD in patients 6 years of age and older. The efficacy of Adhansia XR™ was demonstrated at 1 hour and at 16 hours post-dose in adult patients. Adlon Therapeutics is a subsidiary of Purdue Pharma. Adhansia XR™ was developed by Purdue Pharma and was granted marketing authorization in Canada in December 2017 (as brand Foquest™) for the treatment of ADHD in adults. Adhansia XR™ ER capsules contain multilayered beads, utilizing Purdue Pharma's MLR® (multi-layer release) technology.
- **March 2019:** The FDA approved Jazz Pharmaceuticals' Sunosi™ (solriamfetol tablet) to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea (OSA). Solriamfetol is the first dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI) approved to treat EDS in adults with narcolepsy or OSA. Solriamfetol is expected to be commercially available in the United States following the final scheduling decision by the U.S. Drug Enforcement Administration (DEA), which is typically within 90 days of FDA approval.

News:

- **ADHD Tied to Short Stature in Early Childhood:** According to a recent study, children with ADHD had a higher chance of having a short stature by the 4th grade, especially if they were on medication. From kindergarten to 4th grade, children diagnosed with ADHD had almost 4 times the odds of having a short stature (height <3rd percentile) versus kids without ADHD [odds ratio 3.88; 95% confidence interval (CI) 1.69-8.88; P<0.01] after adjusting for sex, parental education, and family income. Compared with children without ADHD, those with ADHD demonstrated significantly lower height-for-age z scores (HAZ) from kindergarten to 4th grade (difference 0.26; 95% CI 0.08-0.44; P<0.01) and lower body mass index (BMI) z scores (BMIZ) across the same period (difference 0.26; 95% CI 0.07-0.50; P<0.01), as presented at the Pediatric Academic Societies (PAS) annual meeting. Among the 699 children with ADHD in this study, a longer duration of ADHD medication use was also associated with lower HAZ and BMIZ, compared to children who were not on medication. The current study used data from the Early Childhood Longitudinal Study-Kindergarten cohort, in which children's growth charts were evaluated in kindergarten, 2nd grade, and 4th grade for changes in HAZ and BMIZ; researchers conducted telephone interviews with parents to determine if their child had been diagnosed with ADHD and if so, whether they were taking medication for ADHD. It remains unclear whether the poor growth observed in this study was an isolated childhood event or whether it persisted into adulthood. A 1998 study suggested that ADHD may be associated with temporary deficits in height gain through mid-adolescence that may normalize by late adolescence, and that the height deficits appear to be mediated by ADHD and not by its treatment. A 2014 study found that neither ADHD nor ADHD stimulant treatment were associated with a child's final adult height; however, it did find a positive correlation in males between a longer duration of stimulant use before peak height velocity and the age at which they reached their peak height velocity, which could be explained by a "maturational lag". Researchers concluded that due to the large numbers of children diagnosed with ADHD, further study of children with ADHD, with and without treatment, is warranted to evaluate their growth trajectories and final adult height.
- **FDA Draft Guidance: Developing Stimulant Drugs for the Treatment of ADHD:** In May 2019, the FDA released a draft guidance intended to provide general framework recommendations to sponsors developing stimulant drugs for the treatment of ADHD in pediatric and adult patients. The guidance does not address development programs for non-stimulant drugs. The guidance includes sections on general considerations (i.e., clinical pharmacology, trial design, and pregnancy), methylphenidate and amphetamine development programs, and new molecular entities. The guidance document was released for comment purposes only; comments and suggestions are to be submitted to the FDA within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance (by July 5, 2019).

Pipeline:

- **Dasotraline:** Sunovion Pharmaceuticals is currently developing dasotraline, a novel DNRI, for the treatment of ADHD and binge eating disorder (BED). Sunovion received a

Complete Response Letter (CRL) from the FDA in August 2018 regarding the New Drug Application (NDA) for dasotraline for the treatment of ADHD, indicating that additional clinical data are needed to further evaluate the efficacy and tolerability of dasotraline for the treatment of ADHD.

- **Fasoracetam (AEVI-001, AEVI-004):** Aevi Genomic Medicine is currently developing AEVI-001 and AEVI-004, both fasoracetam products, for the treatment of ADHD in patients with genetic mutations that disrupt the metabotropic glutamate receptor (mGluR) network. AEVI-001 is an oral non-stimulant pan selective activator/modulator of mGluRs. AEVI-004 is a co-crystal formulation of AEVI-001, with enhanced physical and chemical properties; AEVI-004 has comparatively greater stability and a higher melting point than AEVI-001. AEVI-004 was engineered to maintain solubility, dissolution, and pharmacokinetics similar to AEVI-001, and as such, Aevi believes that AEVI-004 may progress directly to Phase 3 studies with only minimal bridging preclinical and clinical pharmacological studies. In January 2019, Aevi announced that the ASCEND Phase 2 trial of AEVI-001 in children 6 to 17 years of age with ADHD with or without an mGluR copy number variant did not achieve its primary endpoint, but was safe and well tolerated. Aevi plans to conduct a full review of the trial data with their scientific advisors and consider their options going forward.
- **Viloxazine (SPN-812):** Supernus Pharmaceuticals is currently developing SPN-812 for the treatment of ADHD. The active ingredient in SPN-812, viloxazine hydrochloride, is a norepinephrine reuptake inhibitor that has an extensive safety record in Europe, where it was marketed for many years as an antidepressant. SPN-812 could represent a well-differentiated, once daily, non-stimulant treatment option for patients with ADHD. In March 2019, Supernus announced positive topline results from the second Phase 3 study (P304) of SPN-812 in adolescents for the treatment of ADHD. P304 is the fourth clinical trial in the SPN-812 Phase 3 program; positive data from 3 successful pivotal Phase 3 trials (P301, P302, and P303) were reported in December 2018. The data are consistent in showing a clinically meaningful reduction in the symptoms of ADHD, with a favorable safety and tolerability profile. Supernus plans to submit a NDA for SPN-812 to the FDA in the second half of 2019.
- **Molindone (SPN-810):** Supernus is also currently developing SPN-810 as a novel treatment for impulsive aggression (IA) in patients who have ADHD. The active ingredient of SPN-810, molindone hydrochloride, was previously marketed in the United States for the treatment of schizophrenia under the brand name Moban® at higher strengths and different dosage forms than Supernus is using in their development program. SPN-810 is currently in Phase 3 clinical trials; the Phase 3 program consists of 2 clinical studies in children 6 to 11 years of age and 1 clinical trial in adolescents 12 to 17 years of age. If successful in demonstrating the effectiveness of SPN-810 for IA in patients with ADHD, Supernus plans on developing it for the treatment of IA across other CNS disorders where IA is widely present.
- **JZP-258:** Jazz Pharmaceuticals is currently developing JZP-258 for the treatment of cataplexy and EDS in adult patients with narcolepsy and for the treatment of idiopathic hypersomnia. JZP-258 is a novel oxybate product candidate with a unique composition of cations resulting in 92% less sodium than Xyrem® (sodium oxybate). The safety profile

of JZP-258 is consistent with sodium oxybate. In March 2019, Jazz announced positive topline results from the Phase 3 trial of JZP-258 for the treatment of cataplexy and EDS in adult patients with narcolepsy and plans to meet with the FDA to discuss the Phase 3 results and the NDA submission plans for JZP-258. JZP-258 is also currently in Phase 3 clinical trials for the treatment of idiopathic hypersomnia. It is hypothesized that the therapeutic effects of JZP-258 on sleep/wake symptoms are mediated through modulation of $GABA_B$ during sleep. Jazz is also developing a once nightly formulation of oxybate, which is currently in pre-clinical trials.

Jornay PM™ (Methylphenidate Hydrochloride ER Capsule) Product Summary[19]

Indication(s): Jornay PM™ (methylphenidate hydrochloride ER capsule) is indicated for the treatment of ADHD in patients 6 years of age and older.

Dosing:

- Prior to treating patients with CNS stimulants, including Jornay PM™, patients should be assessed for the presence of cardiac disease. Use of CNS stimulants should be avoided in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease (CAD), and other serious cardiac problems.
- Patients should also be assessed for the risk of abuse prior to prescribing Jornay PM™ (refer to the following *Boxed Warning*). Careful prescription records should be maintained, patients should be educated about abuse and monitored for signs of abuse and overdose, and patients should be periodically re-evaluated for the need of Jornay PM™.
- Jornay PM™ should be taken only in the evening. The recommended starting dose of Jornay PM™ is 20mg daily in the evening, taken consistently either with or without food.
- Dosing of Jornay PM™ should be initiated at 8:00pm, and the timing of administration between 6:30pm and 9:30pm should be adjusted to optimize the tolerability and efficacy the next morning and throughout the day. Following the determination of the optimal administration time, patients should be advised to maintain a consistent dosing time.
    - In clinical trials of patients 6 to 12 years of age, the most common dosing time (>70% of patients) was 8:00pm, with an allowed range between 6:30pm and 9:30pm.
- Patients who miss their dose of Jornay PM™ at the regularly scheduled time should take it as soon as they remember that same evening. If a patient remembers the missed dose the following morning, they should skip the missed dose and wait until their next scheduled evening administration.
- The dosage of Jornay PM™ may be increased in weekly increments of 20mg per day up to a maximum daily dose of 100mg.
- Jornay PM™ is available as 20mg, 40mg, 60mg, 80mg, and 100mg ER capsules, which exhibit both delayed-release (DR) and ER properties. Jornay PM™ ER capsules contain beads with the 2 functional film coatings (outer DR and inner ER) surrounding a drug core coated with methylphenidate hydrochloride.

- Jornay PM™ capsules may be swallowed whole, or the capsule may be opened and the entire contents sprinkled on applesauce to be consumed immediately without chewing.
- Jornay PM™ should not be substituted for other methylphenidate products on a milligram-per-milligram basis, as other methylphenidate products have different pharmacokinetic profiles from Jornay PM™ and may have different methylphenidate base composition.

Boxed Warning: Abuse and Dependence

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

Contraindication(s):

- Patients with a history of hypersensitivity to methylphenidate or other components of Jornay PM™; hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate products
- Patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of a MAOI, because of the risk of hypertensive crisis

Wholesale Acquisition Cost (WAC): The WAC of Jornay PM™ is $12.33 per ER capsule, regardless of strength, which results in a monthly cost of $369.90, based on once daily dosing.

Adhansia XR™ (Methylphenidate Hydrochloride ER Capsule) Product Summary[20]

Indication(s): Adhansia XR™ (methylphenidate hydrochloride ER capsule) is indicated for the treatment of ADHD in patients 6 years of age and older.

Dosing:

- Prior to treating patients with Adhansia XR™, patients should be assessed for the presence of cardiac disease. Use of CNS stimulants should be avoided in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, CAD, and other serious cardiac problems.
- Patients should also be assessed for the risk of abuse prior to prescribing Adhansia XR™ (refer to the following *Boxed Warning*). Careful prescription records should be maintained, patients should be educated about abuse and monitored for signs of abuse and overdose, and patients should be periodically re-evaluated for the need of Adhansia XR™.
- Adhansia XR™ should be administered once daily in the morning with or without food.
- The recommended starting dose of Adhansia XR™ is 25mg once daily.
- In the event of a missed dose, Adhansia XR™ should not be administered later in the day, and additional medication to make up for the missed dose should not be administered.

- The dosage of Adhansia XR™ may be titrated in increments of 10 to 15mg at intervals of no less than 5 days; dosages higher than 100mg daily in adults and 85mg daily in pediatric patients have not been evaluated in clinical trials and are not recommended.
- Adhansia XR™ is available as 25mg, 35mg, 45mg, 55mg, 70mg, and 85mg ER capsules. Adhansia XR™ ER capsules contain multilayered beads, which are comprised of an immediate-release (IR) layer, which contains approximately 20% of the methylphenidate dose, and a controlled-release layer, which contains approximately 80% of the methylphenidate dose.
- Adhansia XR™ capsules may be swallowed whole, or the capsule may be opened and the entire contents sprinkled on a tablespoon of applesauce or yogurt to be consumed immediately (or within 10 minutes after mixing) without chewing.
- Adhansia XR™ should not be substituted for other methylphenidate products on a milligram-per-milligram basis because of different methylphenidate base compositions and differing pharmacokinetic profiles.

Boxed Warning: Abuse and Dependence

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

Contraindication(s):

- Patients with a history of hypersensitivity to methylphenidate or other components of Adhansia XR™; hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other methylphenidate products
- Patients receiving concomitant treatment with MAOIs, and also within 14 days following discontinuation of treatment with a MAOI, because of the risk of hypertensive crisis

Cost: Cost information for Adhansia XR™ is not yet available.

Sunosi™ (Solriamfetol Tablet) Product Summary[21]

Indication(s): Sunosi™ (solriamfetol tablet) is indicated to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA.

Limitations of Use:

- Solriamfetol is not indicated to treat the underlying airway obstruction in OSA. The underlying airway obstruction should be treated [e.g., with continuous positive airway pressure (CPAP)] for at least 1 month prior to initiating solriamfetol for EDS. Modalities to treat the underlying airway obstruction should be continued during treatment with solriamfetol; solriamfetol is not a substitute for these modalities.

Dosing:

- Prior to initiating treatment with solriamfetol, the patient's blood pressure (BP) should be adequately controlled.

- Sunosi™ is supplied as oral tablets in 2 strengths: 75mg and 150mg. Sunosi™ 75mg tablets are functionally scored tablets that can be split in half.
- Solriamfetol should be administered upon awakening with or without food. Patients should avoid taking solriamfetol within 9 hours of planned bedtime because of the potential to interfere with sleep if taken too late in the day.
- For adult patients with narcolepsy, the recommended starting dose of solriamfetol is 75mg once daily. Based on efficacy and tolerability, the dosage of solriamfetol may be doubled at intervals of at least 3 days. The recommended dosage range for solriamfetol in patients with narcolepsy is 75 to 150mg once daily; the maximum recommended dose is 150mg once daily.
- For adult patients with OSA, the recommended starting dose of solriamfetol is 37.5mg once daily. Based on efficacy and tolerability, the dosage of solriamfetol may be doubled at intervals of at least 3 days. The recommended dosage range for solriamfetol in patients with OSA is 37.5 to 150mg once daily; the maximum recommended dose is 150mg once daily.
- Dosages above 150mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions.
- The dose of solriamfetol should be adjusted in patients with moderate [estimated glomerular filtration rate (eGFR) 30-59mL/min/1.73m^2] or severe (eGFR 15-29mL/min/1.73m^2) renal impairment (*refer to Sunosi™ prescribing information for recommended dose adjustments*). Solriamfetol is not recommended for use in patients with end stage renal disease (ESRD; eGFR <15mL/min/1.73m^2).

Mechanism of Action: The mechanism of action of solriamfetol to improve wakefulness in patients with EDS associated with narcolepsy or OSA is unclear; however, its efficacy could be mediated through its activity as a DNRI.

Contraindication(s):

- Patients receiving concomitant treatment with MAOIs, or within 14 days following discontinuation of a MAOI, because of the risk of hypertensive crisis

Warnings and Precautions:

- **BP and Heart Rate (HR) Increases:** Solriamfetol increases systolic BP, diastolic BP, and HR in a dose-dependent fashion. Epidemiological data show that chronic elevations in BP increase the risk of major adverse cardiovascular events (MACE), including stroke, heart attack, and cardiovascular (CV) death. The magnitude of the increase in absolute risk is dependent on the increase in BP and the underlying risk of MACE in the population being treated. Many patients with narcolepsy and OSA have multiple risk factors for MACE, including hypertension (HTN), diabetes, hyperlipidemia, and high body mass index (BMI). BP should be assessed and HTN should be controlled before initiating treatment with solriamfetol. BP should be monitored regularly during treatment with solriamfetol, and new-onset HTN and exacerbations of pre-existing HTN should be treated. Caution should be used when treating patients at higher risk of MACE, particularly patients with known CV and cerebrovascular disease, pre-existing HTN, and advanced age. Caution should be used with other drugs that increase BP and

HR. The need for continued treatment with solriamfetol should be periodically reassessed. If a patient experiences increases in BP or HR that cannot be managed with dose reduction of solriamfetol or other appropriate medical intervention, discontinuation of solriamfetol should be considered. Patients with moderate or severe renal impairment may be at a higher risk of increases in BP and HR because of the prolonged half-life of solriamfetol.

- **Psychiatric Symptoms:** Psychiatric adverse reactions have been observed in clinical trials with solriamfetol, including anxiety, insomnia, and irritability. Solriamfetol has not been evaluated in patients with psychosis or bipolar disorders. Caution should be used when treating patients with solriamfetol who have a history of psychosis or bipolar disorders. Patients with moderate or severe renal impairment may be at a higher risk of psychiatric symptoms because of the prolonged half-life of solriamfetol. Patients treated with solriamfetol should be observed for the possible emergence or exacerbation of psychiatric symptoms. If psychiatric symptoms develop in association with the administration of solriamfetol, dose reduction or discontinuation of solriamfetol should be considered.

Adverse Reactions: The most common adverse reactions (incidence ≥5% and greater than placebo) in patients treated with solriamfetol in clinical trials included: headache, tension headache, and head discomfort; nausea and vomiting; decreased appetite; anxiety, nervousness, and panic attack; and insomnia, initial insomnia, middle insomnia, and terminal insomnia.

Efficacy:

- **Narcolepsy:** The efficacy of solriamfetol in improving wakefulness and reducing EDS in patients with narcolepsy was demonstrated in a 12-week, multi-center, randomized, double-blind, placebo-controlled, parallel-group study (Study 1) in adult patients diagnosed with narcolepsy (diagnosis based on the ICSD-3 or DSM-5 criteria).
  - Wakefulness and sleepiness were assessed using the Maintenance of Wakefulness Test (MWT) and the Epworth Sleepiness Scale (ESS).
    - The MWT measures a patient's ability to remain awake during the daytime in a darkened, quiet environment. Patients were instructed to remain awake for as long as possible during 40-minute test sessions, and sleep latency was determined as the mean number of minutes patients could remain awake in the first 4 test sessions.
    - The ESS is an 8-item questionnaire by which patients rate their perceived likelihood of falling asleep during usual daily life activities.
  - Change in overall symptom severity was assessed using the Patient Global Impression of Change (PGIc) scale. The PGIc is a 7-point patient-reported scale by which patients rate their symptom change since the beginning of the study. Responses range from "very much improved" to "very much worse".
  - The co-primary efficacy endpoints were change from baseline in MWT and ESS at week 12. A pre-specified secondary endpoint was the percentage of patients

reported as improved (minimally, much, or very much) at week 12 by the PGIc scale.

- A total of 239 patients with narcolepsy were randomized to receive solriamfetol 75mg, 150mg, or 300mg (2 times the maximum recommended daily dose), or placebo once daily. Patients randomized to the 150mg dose received 75mg for the first 3 days before increasing to 150mg.
- Compared to the placebo group, patients randomized to solriamfetol 150mg showed significant improvements on the MWT (treatment effect difference: 7.7 minutes) and on the ESS (treatment effect difference: 3.8 points) at week 12. These effects were apparent at week 1 and consistent with the results at week 12. The change in the percentage of patients reported as improved by the PGIc scale was also statistically significant compared with placebo.
- At week 12, solriamfetol 150mg demonstrated improvements in wakefulness compared to placebo as assessed in test sessions 1 (approximately 1 hour post-dose) through 5 (approximately 9 hours post-dose) of the MWT. Nighttime sleep as measured with polysomnography was not affected by the use of solriamfetol in Study 1.

- **OSA:** The efficacy of solriamfetol in improving wakefulness and reducing EDS in patients with OSA was demonstrated in a 12-week, multi-center, randomized, double-blind, placebo-controlled study (Study 2) in adult patients diagnosed with OSA (diagnosis based on ICSD-3 criteria).
  - The co-primary efficacy endpoints were change from baseline in MWT and ESS at week 12. A pre-specified secondary endpoint was the percentage of patients reported as improved (minimally, much, or very much) at week 12 by the PGIc scale.
  - A total of 476 patients with OSA were randomized to receive solriamfetol 37.5mg, 75mg, 150mg, or 300mg (2 times the maximum recommended daily dose), or placebo once daily. Patients randomized to the 150mg dose received 75mg for the first 3 days before increasing to 150mg.
  - Compared to the placebo group, patients randomized to solriamfetol 37.5mg, 75mg, and 150mg showed statistically significant improvements on the MWT (treatment effect difference: 4.5 minutes, 8.9 minutes, and 10.7 minutes, respectively) and on the ESS (treatment effect difference: 1.9 points, 1.7 points, and 4.5 points, respectively) at week 12. The change in the percentage of patients reported as improved by the PGIc scale was also statistically significant compared with placebo.
  - At week 12, solriamfetol 37.5mg, 75mg, and 150mg all demonstrated improvements in wakefulness compared to placebo as assessed in test sessions 1 (approximately 1 hour post-dose) through 5 (approximately 9 hours post-dose) of the MWT. Nighttime sleep as measured with polysomnography was not affected by the use of solriamfetol in Study 2. Patients' compliance with a primary OSA therapy device was similar across the placebo and solriamfetol treatment groups at

baseline and did not change during the 12-week study period in any treatment group.

Cost: Cost information for Sunosi™ is not yet available.

Recommendations

The College of Pharmacy recommends the following changes to the ADHD and Narcolepsy Medications PBPA category:

1. The placement of Jornay PM™ (methylphenidate ER capsule) and Adhansia XR™ (methylphenidate ER capsule) into Tier-3. Current Tier-3 criteria will apply.
2. The placement of Evekeo ODT™ (amphetamine ODT) into the Special Prior Authorization (PA) Tier. Current Special PA criteria will apply.
3. Updating the current Special PA approval criteria for Methylin® chewable tablets and solution to prefer the brand formulation of Methylin® solution based on net costs.
4. The prior authorization of Sunosi™ (solriamfetol tablet) in the Narcolepsy Medications category. Criteria similar to the current approval criteria for Xyrem® (sodium oxybate) will apply.

Proposed changes are shown in red in the following Tier Chart and approval criteria:

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			Adzenys ER™ (amphetamine ER susp) Adzenys XR-ODT® (amphetamine ER-ODT) Cotempla XR-ODT™ (methylphenidate ER ODT) Daytrana® (methylphenidate ER) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) Dexedrine Spansules® (dextroamphetamine ER) Dyanavel® XR (amphetamine ER susp) Evekeo® (amphetamine) **Evekeo ODT™ (amphetamine ODT)**
Short-Acting			
Adderall® (amphetamine/ dextroamphetamine)			
Long-Acting			
Vyvanse® (lisdexamfetamine caps and chew tabs)+	Adderall XR® (amphetamine/ dextroamphetamine ER)		
Methylphenidate			
Short-Acting			
Focalin® (dexmethylphenidate) Methylin® (methylphenidate) Ritalin® (methylphenidate)			
Long-Acting			
Aptensio XR® (methylphenidate ER) Focalin XR® brand name only	dexmethylphenidate ER (generic Focalin XR®)	**Adhansia XR™ (methylphenidate ER)** Concerta® (methylphenidate ER)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
(dexmethylphenidate ER) Metadate CD® (methylphenidate ER) QuilliChew ER® (methylphenidate ER chew tabs) Ritalin LA® (methylphenidate ER)	Quillivant XR® (methylphenidate ER susp)	**Jornay PM™ (methylphenidate ER)** Metadate ER® (methylphenidate ER) Methylin ER® (methylphenidate ER) methylphenidate ER 72mg Ritalin SR® (methylphenidate ER)	Methylin® (methylphenidate soln & chew tabs) Mydayis® (amphetamine/ dextroamphetamine ER) ProCentra® (dextroamphetamine) Zenzedi® (dextroamphetamine)
Non-Stimulants			
Intuniv® (guanfacine ER) Strattera® (atomoxetine)		Kapvay® (clonidine ER)[Δ]	

*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.
[+]Unique criteria applies for the diagnosis of binge eating disorder (BED).
[Δ]Unique criteria applies in addition to tier trial requirements.
ADHD = attention deficit hyperactivity disorder; PA= prior authorization; ER = extended-release; SR = sustained-release; caps = capsules; ODT = orally disintegrating tablet; chew tabs = chewable tablets; 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 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.

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) 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.

Utilization Details of ADHD and Narcolepsy Medications: Calendar Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LISDEXAMFETAMINE PRODUCTS						
VYVANSE CAP 30MG	21,896	5,609	$6,002,895.32	$274.15	3.9	11.83%
VYVANSE CAP 40MG	18,007	3,993	$4,942,097.79	$274.45	4.5	9.74%
VYVANSE CAP 20MG	17,344	5,144	$4,759,826.85	$274.44	3.4	9.38%
VYVANSE CAP 50MG	11,574	2,461	$3,180,614.44	$274.81	4.7	6.27%
VYVANSE CAP 60MG	7,431	1,408	$2,024,773.30	$272.48	5.3	3.99%
VYVANSE CAP 70MG	6,754	1,122	$1,875,635.17	$277.71	6.0	3.70%
VYVANSE CAP 10MG	6,071	2,423	$1,647,599.44	$271.39	2.5	3.25%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VYVANSE CHW 20MG	1,071	431	$290,666.84	$271.40	2.5	0.57%
VYVANSE CHW 10MG	1,035	491	$288,600.15	$278.84	2.1	0.57%
VYVANSE CHW 30MG	616	231	$174,314.85	$282.98	2.7	0.34%
VYVANSE CHW 40MG	195	77	$57,317.86	$293.94	2.5	0.11%
VYVANSE CHW 50MG	132	38	$36,277.11	$274.83	3.5	0.07%
VYVANSE CHW 60MG	40	15	$12,077.95	$301.95	2.7	0.02%
SUBTOTAL	**92,166**	**23,443**	**$25,292,697.07**	**$274.43**	**3.9**	**49.84%**
METHYLPHENIDATE PRODUCTS						
METHYLPHENID TAB 10MG	9,418	2,209	$214,542.48	$22.78	4.3	0.42%
METHYLPHENID CAP 20MG CD	8,090	2,324	$771,677.61	$95.39	3.5	1.52%
METHYLPHENID TAB 5MG	7,627	2,191	$148,905.45	$19.52	3.5	0.29%
METHYLPHENID CAP 30MG CD	7,158	1,812	$688,527.63	$96.19	4.0	1.36%
METHYLPHENID TAB 36MG ER	6,224	1,240	$1,720,631.47	$276.45	5.0	3.39%
METHYLPHENID TAB 54MG ER	5,683	1,012	$1,210,653.61	$213.03	5.6	2.39%
METHYLPHENID CAP 40MG CD	4,937	1,095	$594,792.31	$120.48	4.5	1.17%
METHYLPHENID TAB 20MG	4,110	851	$113,961.52	$27.73	4.8	0.22%
METHYLPHENID CAP 10MG CD	3,457	1,314	$327,406.20	$94.71	2.6	0.65%
METHYLPHENID CAP 50MG CD	2,131	448	$328,831.48	$154.31	4.8	0.65%
METHYLPHENID TAB 27MG ER	1,939	501	$350,349.36	$180.69	3.9	0.69%
METHYLPHENID CAP 60MG CD	1,682	296	$244,767.81	$145.52	5.7	0.48%
APTENSIO XR CAP 20MG	1,474	569	$329,264.37	$223.38	2.6	0.65%
APTENSIO XR CAP 30MG	1,329	483	$297,039.64	$223.51	2.8	0.59%
METHYLPHENID TAB 18MG ER	1,276	350	$234,144.19	$183.50	3.6	0.46%
APTENSIO XR CAP 10MG	1,153	620	$261,561.26	$226.85	1.9	0.52%
METHYLPHENID CAP 20MG LA	1,031	391	$121,654.32	$118.00	2.6	0.24%
METHYLPHENID TAB 20MG ER	1,025	197	$96,243.37	$93.90	5.2	0.19%
APTENSIO XR CAP 40MG	955	351	$209,356.44	$219.22	2.7	0.41%
METHYLPHENID CAP 30MG LA	862	264	$112,368.89	$130.36	3.3	0.22%
APTENSIO XR CAP 60MG	825	199	$186,548.87	$226.12	4.1	0.37%
APTENSIO XR CAP 15MG	706	276	$159,363.58	$225.73	2.6	0.31%
APTENSIO XR CAP 50MG	590	187	$129,455.85	$219.42	3.2	0.26%
METHYLPHENID CAP 40MG LA	584	149	$74,297.22	$127.22	3.9	0.15%
QUILLICHEW CHW 20MG ER	488	192	$129,118.39	$264.59	2.5	0.25%
METHYLPHENID SOL 5MG/5ML	352	131	$36,355.78	$103.28	2.7	0.07%
METHYLPHENID CHW 5MG	332	111	$58,913.79	$177.45	3.0	0.12%
METHYLPHENID TAB 10MG ER	287	60	$24,278.47	$84.59	4.8	0.05%
METHYLPHENID SOL 10MG/5ML	252	66	$49,054.00	$194.66	3.8	0.10%
METHYLPHENID CAP 10MG LA	244	122	$57,746.77	$236.67	2.0	0.11%
RITALIN LA CAP 30MG	232	65	$76,111.68	$328.07	3.6	0.15%
RITALIN LA CAP 10MG	211	83	$61,369.64	$290.85	2.5	0.12%
QUILLICHEW CHW 30MG ER	190	67	$58,405.28	$307.40	2.8	0.12%
RITALIN LA CAP 40MG	168	29	$52,892.45	$314.84	5.8	0.10%
DAYTRANA DIS 30MG/9HR	160	21	$45,494.82	$284.34	7.6	0.09%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
METHYLIN SOL 5MG/5ML	158	43	$10,423.99	$65.97	3.7	0.02%
METHYLPHENIDA CHW 2.5MG	156	79	$22,717.42	$145.62	2.0	0.04%
RITALIN LA CAP 20MG	134	49	$39,595.47	$295.49	2.7	0.08%
CONCERTA TAB 36MG	128	59	$36,022.58	$281.43	2.2	0.07%
CONCERTA TAB 54MG	109	45	$27,971.58	$256.62	2.4	0.06%
QUILLIVANT SUS 25MG/5ML	108	51	$33,832.10	$313.26	2.1	0.07%
METHYLPHENID CHW 10MG	95	29	$31,173.06	$328.14	3.3	0.06%
QUILLICHEW CHW 40MG ER	85	24	$26,555.39	$312.42	3.5	0.05%
METHYLIN SOL 10MG/5ML	71	21	$5,538.23	$78.00	3.4	0.01%
METADATE CD CAP 20MG	61	35	$13,503.64	$221.37	1.7	0.03%
METADATE TAB 20MG ER	57	23	$3,854.44	$67.62	2.5	0.01%
DAYTRANA DIS 20MG/9HR	56	13	$17,306.98	$309.05	4.3	0.03%
METADATE CD CAP 10MG	52	42	$11,768.53	$226.32	1.2	0.02%
METADATE CD CAP 30MG	43	30	$9,365.83	$217.81	1.4	0.02%
DAYTRANA DIS 10MG/9HR	26	11	$7,112.07	$273.54	2.4	0.01%
CONCERTA TAB 27MG	25	11	$5,275.10	$211.00	2.3	0.01%
METHYLPHENID TAB 72MG ER	24	8	$10,458.12	$435.76	3.0	0.02%
METADATE CD CAP 40MG	20	18	$6,032.71	$301.64	1.1	0.01%
METADATE CD CAP 50MG	16	8	$5,438.20	$339.89	2.0	0.01%
DAYTRANA DIS 15MG/9HR	13	7	$4,296.67	$330.51	1.9	0.01%
RITALIN TAB 10MG	12	1	$1,207.73	$100.64	12.0	0.00%
METHYLPHENID CAP 60MG LA	10	5	$3,074.72	$307.47	2.0	0.01%
METADATE CD CAP 60MG	6	5	$1,934.40	$322.40	1.2	0.00%
CONCERTA TAB 18MG	5	1	$819.23	$163.85	5.0	0.00%
COTEMPLA TAB 25.9MG	5	1	$1,676.70	$335.34	5.0	0.00%
RITALIN TAB 20MG	4	1	$642.38	$160.60	4.0	0.00%
COTEMPLA TAB 8.6MG	3	1	$1,018.98	$339.66	3.0	0.00%
SUBTOTAL	**78,664**	**20,897**	**$9,914,702.25**	**$126.04**	**3.8**	**19.54%**
GUANFACINE EXTENDED-RELEASE (ER) PRODUCTS						
GUANFACINE TAB 2MG ER	16,973	3,928	$421,806.07	$24.85	4.3	0.83%
GUANFACINE TAB 1MG ER	12,275	4,013	$298,975.90	$24.36	3.1	0.59%
GUANFACINE TAB 3MG ER	11,585	2,233	$282,465.47	$24.38	5.2	0.56%
GUANFACINE TAB 4MG ER	9,622	1,476	$237,597.69	$24.69	6.5	0.47%
INTUNIV TAB 3MG	67	7	$19,450.18	$290.30	9.6	0.04%
INTUNIV TAB 4MG	39	4	$11,554.21	$296.26	9.8	0.02%
INTUNIV TAB 2MG	29	5	$8,462.44	$291.81	5.8	0.02%
INTUNIV TAB 1MG	22	3	$6,399.42	$290.88	7.3	0.01%
SUBTOTAL	**50,612**	**11,669**	**$1,286,711.38**	**$25.42**	**4.3**	**2.54%**
AMPHETAMINE/DEXTROAMPHETAMINE PRODUCTS						
AMPHET/DEXTR TAB 10MG	11,746	2,763	$340,930.30	$29.03	4.3	0.67%
AMPHET/DEXTR TAB 20MG	8,504	1,639	$293,848.29	$34.55	5.2	0.58%
AMPHET/DEXTR TAB 5MG	8,359	2,254	$241,219.53	$28.86	3.7	0.48%
AMPHET/DEXTR TAB 30MG	3,941	655	$137,762.74	$34.96	6.0	0.27%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADDERALL XR CAP 30MG	3,775	573	$797,764.80	$211.33	6.6	1.57%
AMPHET/DEXTR TAB 15MG	3,607	813	$111,932.94	$31.03	4.4	0.22%
ADDERALL XR CAP 20MG	3,579	721	$797,987.56	$222.96	5.0	1.57%
ADDERALL XR CAP 10MG	1,838	465	$376,616.86	$204.91	4.0	0.74%
ADDERALL XR CAP 15MG	1,644	419	$344,148.85	$209.34	3.9	0.68%
ADDERALL XR CAP 25MG	1,247	250	$263,228.23	$211.09	5.0	0.52%
AMPHET/DEXTR TAB 7.5MG	1,000	285	$41,145.93	$41.15	3.5	0.08%
ADDERALL XR CAP 5MG	300	102	$62,775.85	$209.25	2.9	0.12%
AMPHET/DEXTR TAB 12.5MG	270	66	$10,879.25	$40.29	4.1	0.02%
AMPHET/DEXTR CAP 20MG ER	50	9	$2,962.86	$59.26	5.6	0.01%
AMPHET/DEXTR CAP 30MG ER	32	11	$2,175.09	$67.97	2.9	0.00%
AMPHET/DEXTR CAP 15MG ER	13	2	$437.87	$33.68	6.5	0.00%
AMPHET/DEXTR CAP 25MG ER	9	4	$483.01	$53.67	2.3	0.00%
MYDAYIS CAP 12.5MG	7	2	$1,655.43	$236.49	3.5	0.00%
MYDAYIS CAP 37.5MG	6	1	$1,624.09	$270.68	6.0	0.00%
MYDAYIS CAP 25MG	2	2	$542.42	$271.21	1.0	0.00%
MYDAYIS CAP 50MG	2	1	$539.50	$269.75	2.0	0.00%
AMPHET/DEXTR CAP 10MG ER	2	2	$125.04	$62.52	1.0	0.00%
SUBTOTAL	**49,933**	**11,039**	**$3,830,786.44**	**$76.72**	**4.5**	**7.55%**
DEXMETHYLPHENIDATE PRODUCTS						
DEXMETHYLPH TAB 10MG	7,239	1,350	$305,020.36	$42.14	5.4	0.60%
DEXMETHYLPH TAB 5MG	5,481	1,299	$169,220.17	$30.87	4.2	0.33%
FOCALIN XR CAP 20MG	3,852	907	$1,385,302.50	$359.63	4.2	2.73%
FOCALIN XR CAP 10MG	2,819	895	$984,037.56	$349.07	3.1	1.94%
FOCALIN XR CAP 30MG	2,740	516	$956,323.98	$349.02	5.3	1.88%
FOCALIN XR CAP 15MG	2,665	696	$954,606.23	$358.20	3.8	1.88%
FOCALIN XR CAP 25MG	1,770	371	$665,885.71	$376.21	4.8	1.31%
DEXMETHYLPH TAB 2.5MG	1,262	388	$32,344.26	$25.63	3.3	0.06%
FOCALIN XR CAP 5MG	1,063	445	$362,069.08	$340.61	2.4	0.71%
FOCALIN XR CAP 40MG	1,048	178	$411,052.31	$392.23	5.9	0.81%
FOCALIN XR CAP 35MG	477	87	$188,818.63	$395.85	5.5	0.37%
DEXMETHYLPHE CAP ER 20MG	135	39	$21,848.84	$161.84	3.5	0.04%
DEXMETHYLPHE CAP ER 15MG	132	42	$15,401.83	$116.68	3.1	0.03%
FOCALIN TAB 10MG	107	31	$7,712.88	$72.08	3.5	0.02%
DEXMETHYLPHE CAP ER 30MG	102	21	$12,570.51	$123.24	4.9	0.02%
FOCALIN TAB 5MG	80	29	$4,041.64	$50.52	2.8	0.01%
DEXMETHYLPHE CAP ER 10MG	52	28	$8,042.34	$154.66	1.9	0.02%
DEXMETHYLPHE CAP ER 25MG	23	4	$1,660.98	$72.22	5.8	0.00%
DEXMETHYLPHE CAP ER 40MG	19	8	$3,143.65	$165.46	2.4	0.01%
DEXMETHYLPHE CAP ER 35MG	10	1	$1,631.39	$163.14	10.0	0.00%
DEXMETHYLPHE CAP ER 5MG	8	5	$1,114.66	$139.33	1.6	0.00%
FOCALIN TAB 2.5MG	8	6	$207.21	$25.90	1.3	0.00%
SUBTOTAL	**31,092**	**7,346**	**$6,492,056.72**	**$208.80**	**4.2**	**12.79%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ATOMOXETINE PRODUCTS						
ATOMOXETINE CAP 40MG	8,124	2,255	$862,036.01	$106.11	3.6	1.70%
ATOMOXETINE CAP 25MG	7,165	2,172	$725,248.64	$101.22	3.3	1.43%
ATOMOXETINE CAP 60MG	5,025	1,071	$519,469.75	$103.38	4.7	1.02%
ATOMOXETINE CAP 18MG	3,651	1,338	$379,044.23	$103.82	2.7	0.75%
ATOMOXETINE CAP 80MG	3,064	649	$336,418.20	$109.80	4.7	0.66%
ATOMOXETINE CAP 10MG	2,850	1,118	$305,762.16	$107.28	2.5	0.60%
ATOMOXETINE CAP 100MG	926	182	$104,233.48	$112.56	5.1	0.21%
STRATTERA CAP 40MG	31	5	$13,027.58	$420.24	6.2	0.03%
STRATTERA CAP 10MG	25	4	$10,610.11	$424.40	6.3	0.02%
STRATTERA CAP 25MG	20	4	$7,493.36	$374.67	5.0	0.01%
STRATTERA CAP 60MG	11	2	$4,629.11	$420.83	5.5	0.01%
STRATTERA CAP 18MG	6	2	$4,461.05	$743.51	3.0	0.01%
STRATTERA CAP 100MG	5	1	$2,270.35	$454.07	5.0	0.00%
SUBTOTAL	**30,903**	**8,803**	**$3,274,704.03**	**$105.97**	**3.5**	**6.45%**
CLONIDINE ER ORAL PRODUCTS						
CLONIDINE TAB 0.1MG ER	816	126	$137,158.95	$168.09	6.5	0.27%
KAPVAY TAB 0.1 MG	21	3	$17,639.72	$839.99	7.0	0.03%
SUBTOTAL	**837**	**129**	**$154,798.67**	**$184.94**	**6.5**	**0.31%**
AMPHETAMINE PRODUCTS						
ADZENYS XR TAB 6.3MG	77	17	$24,298.78	$315.57	4.5	0.05%
ADZENYS XR TAB 12.5MG	76	15	$24,055.08	$316.51	5.1	0.05%
ADZENYS XR TAB 9.4MG	66	16	$19,143.82	$290.06	4.1	0.04%
ADZENYS XR TAB 15.7 MG	39	10	$12,343.67	$316.50	3.9	0.02%
ADZENYS XR TAB 18.8MG	14	3	$4,450.93	$317.92	4.7	0.01%
ADZENYS XR TAB 3.1MG	10	1	$3,140.37	$314.04	10.0	0.01%
EVEKEO TAB 5MG	3	1	$1,126.22	$375.41	3.0	0.00%
EVEKEO TAB 10MG	3	1	$1,128.50	$376.17	3.0	0.00%
DYANAVEL XR SUS 2.5MG/ML	1	1	$275.88	$275.88	1.0	0.00%
SUBTOTAL	**289**	**65**	**$89,963.25**	**$311.29**	**4.4**	**0.18%**
MODAFINIL PRODUCTS						
MODAFINIL TAB 200MG	240	33	$12,732.14	$53.05	7.3	0.03%
PROVIGIL TAB 200MG	7	1	$19,861.27	$2,837.32	7.0	0.04%
MODAFINIL TAB 100MG	5	4	$295.56	$59.11	1.3	0.00%
SUBTOTAL	**252**	**38**	**$32,888.97**	**$130.51**	**6.6**	**0.06%**
DEXTROAMPHETAMINE PRODUCTS						
DEXTROAMPHET CAP 15MG ER	64	7	$11,691.81	$182.68	9.1	0.02%
DEXTROAMPHET TAB 10MG	37	5	$2,366.13	$63.95	7.4	0.00%
DEXTROAMPHET CAP 5MG ER	21	3	$1,107.77	$52.75	7.0	0.00%
DEXTROAMPHET CAP 10MG ER	20	3	$396.82	$19.84	6.7	0.00%
DEXTROAMPHET TAB 5MG	18	4	$693.09	$38.51	4.5	0.00%
ZENZEDI TAB 30MG	10	1	$4,028.16	$402.82	10.0	0.01%
DEXTROAMPHET SOL 5MG/5ML	3	1	$5,269.95	$1,756.65	3.0	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**173**	**24**	**$25,553.73**	**$147.71**	**7.2**	**0.05%**
ARMODAFINIL PRODUCTS						
NUVIGIL TAB 250MG	69	13	$46,594.69	$675.29	5.3	0.09%
ARMODAFINIL TAB 150MG	32	5	$1,420.23	$44.38	6.4	0.00%
NUVIGIL TAB 150MG	31	9	$27,841.16	$898.10	3.4	0.05%
ARMODAFINIL TAB 250MG	17	3	$763.89	$44.93	5.7	0.00%
NUVIGIL TAB 200MG	6	3	$4,142.63	$690.44	2.0	0.01%
NUVIGIL TAB 50MG	4	1	$1,237.84	$309.46	4.0	0.00%
SUBTOTAL	**159**	**34**	**$82,000.44**	**$515.73**	**4.7**	**0.16%**
SODIUM OXYBATE PRODUCTS						
XYREM SOL 500MG/ML	24	2	$259,080.40	$10,795.02	12.0	0.51%
SUBTOTAL	**24**	**2**	**$259,080.40**	**$10,795.02**	**12.0**	**0.51%**
METHAMPHETAMINE PRODUCTS						
METHAMPHETAM TAB 5MG	9	1	$6,906.16	$767.35	9.0	0.01%
DESOXYN TAB 5MG	1	1	$1,698.21	$1,698.21	1.0	0.00%
SUBTOTAL	**10**	**2**	**$8,604.37**	**$860.44**	**5.0**	**0.02%**
TOTAL	**335,114**	**41,146***	**$50,744,547.72**	**$151.42**	**8.1**	**100%**

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

[1] Peters CP. The Basics: The Medicaid Drug Rebate Program. National Health Policy Forum. Available online at: https://www.nhpf.org/library/the-basics/Basics_MedicaidDrugRebate_04-13-09.pdf. Issued 04/13/2009. Last accessed 05/23/2019.
[2] Office of Inspector General (OIG). Department of Health and Human Services. States' Collection of Offset and Supplemental Medicaid Rebates. Available online at: http://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf. Issued 12/2014. Last accessed 05/23/2019.
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Appendix O

Calendar Year 2018 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System), Bijuva™ (Estradiol/Progesterone Capsule), Cequa™ (Cyclosporine 0.09% Ophthalmic Solution), Corlanor® (Ivabradine Oral Solution), Crotan™ (Crotamiton 10% Lotion), Gloperba® (Colchicine Oral Solution), Glycate® (Glycopyrrolate Tablet), Khapzory™ (Levoleucovorin Injection), Qmiiz™ ODT [Meloxicam Orally Disintegrating Tablet (ODT)], Seconal Sodium™ (Secobarbital Sodium Capsule), TaperDex™ (Dexamethasone Tablet), Tiglutik™ (Riluzole Oral Suspension), TobraDex® ST (Tobramycin/Dexamethasone 0.3%/0.05% Ophthalmic Suspension), Tolsura™ (Itraconazole Capsule), and Yutiq™ (Fluocinolone Acetonide Intravitreal Implant)

Oklahoma Health Care Authority
June 2019

Introduction

Multiple formulations of medications are made for ease of administration, to increase bioavailability, or as new technologies are created to provide a more efficient treatment response. Some of the new formulations incur greater costs for production resulting in greater costs for the payer and consumer. A clinical review of each product and its comparative cost to other formulations is provided in the following report for reference.

Current Prior Authorization Criteria

Erythromycin 2% Swabs Approval Criteria:

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

Erythromycin 2% Topical Gel Approval Criteria:

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

GoNitro™ (Nitroglycerin Sublingual Powder) Approval Criteria:

1. An FDA approved indication of acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease; and
2. A patient-specific, clinically significant reason why the member cannot use nitroglycerin sublingual tablets or nitroglycerin lingual spray must be provided.

Gralise® (Gabapentin Extended-Release Tablet) Approval Criteria:

1. An FDA approved indication of postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
    a. Tricyclic antidepressants; or
    b. Anticonvulsants; or
    c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Horizant® (Gabapentin Enacarbil Extended-Release Tablet) Approval Criteria:

1. For the FDA approved indication of restless leg syndrome:
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts at recommended dosing with at least 2 of the following medications that did not yield adequate relief:
        i. Carbidopa/levodopa; or
        ii. Pramipexole; or
        iii. Ropinirole; and
    c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.
2. For the FDA approved indication of postherpetic neuralgia (PHN):
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
        i. Tricyclic antidepressants; or
        ii. Anticonvulsants; or
        iii. Topical or oral analgesics; and
    c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Klor-Con® 20mEq Packet (Potassium Chloride) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the potassium chloride tablet formulation must be provided.

Kristalose® (Lactulose Packet for Oral Solution) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the liquid lactulose formulation must be provided.

Lyrica® CR (Pregabalin Extended-Release Capsule) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Neuropathic pain associated with diabetic peripheral neuropathy (DPN); or
    b. Neuropathic pain associated with postherpetic neuralgia (PHN); and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation must be provided; and
3. Requests exceeding once daily dosing will not be approved.

Metozolv® ODT [Metoclopramide Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the metoclopramide oral tablet formulation must be provided.

MetroGel 1%® (Metronidazole 1% Gel) Approval Criteria:

1. Approval consideration requires a trial of metronidazole 0.75% gel.

Nuvessa™ (Metronidazole Vaginal 1.3% Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis in non-pregnant women; and
2. A patient-specific, clinically significant reason why the member cannot use MetroGel-Vaginal® 0.75% (metronidazole vaginal 0.75% gel) or the generic metronidazole oral tablets 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.

Purixan® (Mercaptopurine Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of acute lymphoblastic leukemia (ALL); and
2. An age restriction for members older than 10 years of age applies. Purixan® does not require prior authorization for members 10 years of age and younger; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Rasuvo® (Methotrexate Injection) and Otrexup® (Methotrexate Injection) Approval Criteria:

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

Rayos® (Prednisone Delayed-Release Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use immediate-release corticosteroid medications must be provided.

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Restasis® in the individual dosage formulation (single-use vials) must be provided.

Sinuva™ (Mometasone Furoate Sinus Implant) Approval Criteria:

1. An FDA approved indication of nasal polyps in adults 18 years of age and older who have had ethmoid sinus surgery; and

2. Date of ethmoid sinus surgery must be provided; and
3. Sinuva™ must be prescribed and implanted by a physician specializing in otolaryngology; and
4. Failure of intranasal corticosteroids after at least a 3 month trial at the maximum recommended dose in combination with a 14-day trial of oral corticosteroids within the last 6 months (if not contraindicated); and
5. Prescriber must confirm the member has recurrent nasal obstruction/congestion symptoms and recurrent bilateral sinusitis or chronic sinusitis due to nasal polyps; and
6. A quantity limit of 2 implants per member will apply.

Soltamox® (Tamoxifen Citrate 10mg/5mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of metastatic breast cancer in women and men; or
    b. Adjuvant treatment of node-positive breast cancer in postmenopausal women and for the adjuvant treatment of axillary node-negative breast cancer in women following total mastectomy or segmental mastectomy, axillary dissection, and breast irradiation; or
    c. The reduction in risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS), following breast surgery and radiation; or
    d. To reduce the incidence of breast cancer in women at high risk for breast cancer; and
2. A patient-specific, clinically significant reason why the member cannot use tamoxifen oral tablets must be provided.

Taytulla® (Norethindrone Acetate/Ethinyl Estradiol Capsule and Ferrous Fumarate Capsule) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use all other generic formulations of norethindrone acetate/ethinyl estradiol tablets with ferrous fumarate tablets must be provided.

Tirosint®-SOL (Levothyroxine Sodium 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 sodium in the place of the oral solution, even when the tablets are crushed, must be provided.

Xatmep® (Methotrexate 2.5mg/mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:

a. Treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen; or
b. Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy; and

2. A patient-specific, clinically significant reason why the oral tablets or generic injectable formulation cannot be used must be provided.

ZTlido™ (Lidocaine 1.8% Topical System) Approval Criteria:

1. An FDA approved diagnosis of pain due to postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that failed to provide adequate relief or contraindication(s) to all of the following classes:
   a. Tricyclic antidepressants; or
   b. Anticonvulsants; or
   c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot use lidocaine 5% topical patch(es), which are available without prior authorization, must be provided; and
4. A quantity limit of 3 patches per day with a maximum of 90 patches per month will apply.

Utilization of Special Formulations: Calendar Year 2018

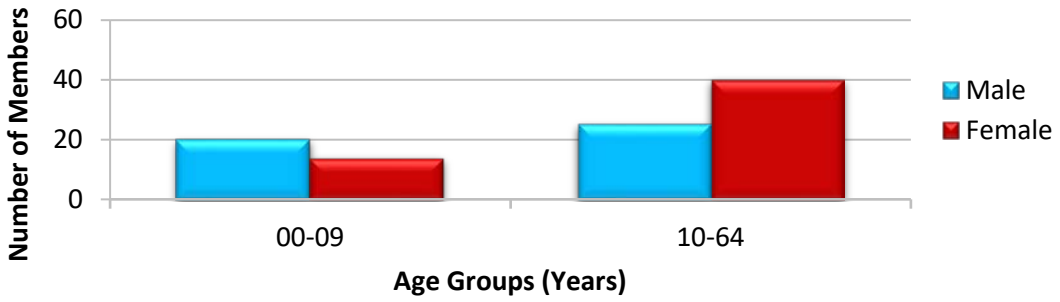
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	47	162	$118,284.48	$730.15	$26.54	10,314	4,456
2018	99	265	$153,400.72	$578.87	$20.04	15,092	7,653
% Change	**110.60%**	**63.60%**	**29.70%**	**-20.70%**	**-24.50%**	**46.30%**	**71.70%**
Change	**52**	**103**	**$35,116.24**	**-$151.28**	**-$6.50**	**4,778**	**3,197**

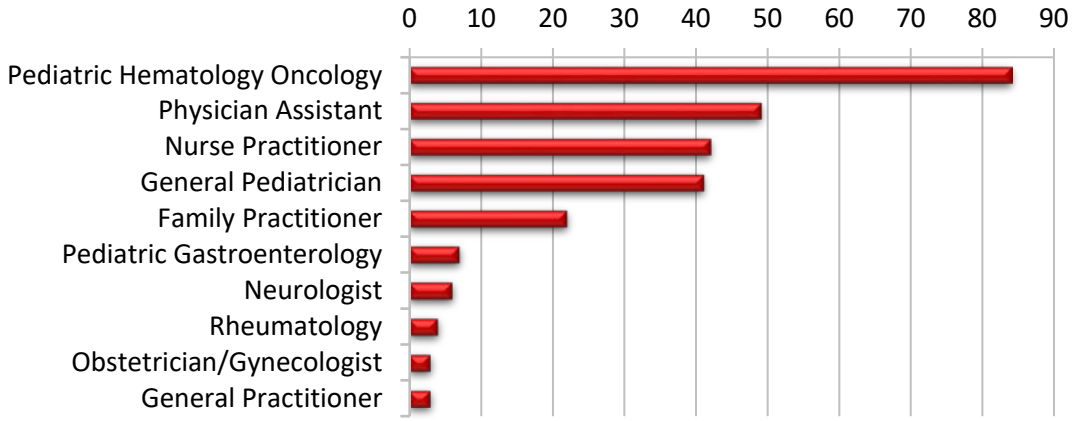
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- Due to the evolving nature of this category, calendar year comparisons may not reflect the same product utilization from year to year.

Demographics of Members Utilizing Special Formulations



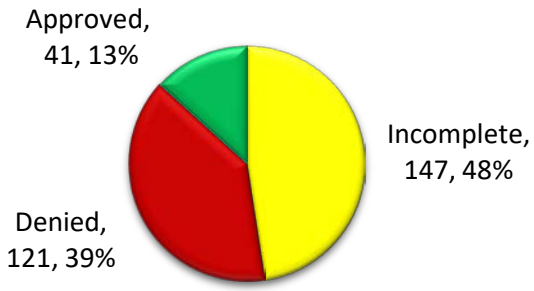
Top Prescriber Specialties of Special Formulations by Number of Claims



Prior Authorization of Special Formulations

There were 309 prior authorization requests submitted for special formulations during calendar year 2018. The following chart shows the status of the submitted petitions for calendar year 2018.

Status of Petitions



Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) Product Summary[1,2]

Indication(s): Annovera™ [segesterone acetate (SA)/ethinyl estradiol (EE) vaginal system] is a progestin/estrogen combination hormonal contraceptive indicated for use by females of reproductive potential to prevent pregnancy.

Limitation(s) of Use: Annovera™ has not been adequately evaluated in females with a body mass index (BMI) of >29kg/m^2.

Dosing and Administration:

- Annovera™ is a silicone elastomer vaginal system containing 103mg SA and 17.4mg EE, which releases on average 0.15mg/day of SA and 0.013mg/day of EE.
- Annovera™ is inserted in the vagina, and must remain in place continuously for 3 weeks (21 days) followed by a 1-week (7-day) vaginal system-free interval.
- One vaginal system provides contraception for (13) 28-day cycles (1 year).

Boxed Warning: Cigarette Smoking and Serious Cardiovascular (CV) Events

- Cigarette smoking increases the risk of serious CV events from combination hormonal contraceptive (CHC) use. This risk increases with age, particularly in females over 35 years of age, and with the number of cigarettes smoked. For this reason, CHCs should not be used by females who are over 35 years of age and smoke.

Other Formulation(s) Available:

- NuvaRing® (Etonogestrel/EE Vaginal Ring):
  - The indication, dosing, and administration for NuvaRing® are the same as Annovera™ with the exception of NuvaRing® requiring a new ring to be inserted after a 1-week break from use. NuvaRing® also has the same boxed warning as Annovera™.
  - NuvaRing® is a polymeric vaginal ring containing 11.7mg etonogestrel and 2.7mg EE, which releases on average 0.12mg/day of etonogestrel and 0.015mg/day of EE.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days	Cost Per Year
Annovera™ (SA/EE) vaginal system	**Unavailable**	**Unavailable**	**Unavailable**
NuvaRing® (etonogestrel/EE) vaginal ring	$148.81	$148.81	$1,934.53

Unit = vaginal 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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Annovera™ during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
NUVARING MIS	3,936	1,502	$1,090,966.66	$5.42	2.62	$277.18
TOTAL	**3,936**	**1,502***	**$1,090,966.66**	**$5.42**	**2.62**	**$277.18**

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

Bijuva™ (Estradiol/Progesterone Capsule) Product Summary[3,4]

Indication(s): Bijuva™ (estradiol/progesterone capsule) is a combination of estrogen and progesterone indicated for women with a uterus for the treatment of moderate-to-severe vasomotor symptoms due to menopause.

Dosing and Administration:

- Bijuva™ is supplied as a capsule containing 1mg of estradiol and 100mg of progesterone.
- Bijuva™ is available in a blister package of 30 capsules.
- The recommended dosage is 1 capsule every evening with food.

Boxed Warning: CV Disorders, Breast Cancer, Endometrial Cancer, and Probable Dementia

- Estrogen plus progestin therapy should not be used for the prevention of CV disease or dementia. The Women's Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of stroke, deep vein thrombosis (DVT), pulmonary embolism (PE), and myocardial infarction (MI).
- The WHI substudy also reported increased risks of invasive breast cancer with estrogen plus progestin.
- The WHI estrogen plus progestin ancillary study reported increased risk of probable dementia in postmenopausal women 65 years of age of older.
- There is an increased risk of endometrial cancer in women with an intact uterus who use unopposed estrogens.
- Estrogen-alone therapy should not be used for the prevention of CV disease or dementia.
- The WHI estrogen-alone substudy reported increased risks of stroke and DVT.
- The WHI estrogen-alone ancillary report indicated an increased risk of probable dementia in postmenopausal women 65 years of age or older.

Other Formulation(s) Available:

- Estradiol/Norethindrone Tablets (Activella®):
  - Estradiol/norethindrone tablet (Activella®) has the same indication as Bijuva™. Both strengths of Activella® are also indicated for prevention of postmenopausal osteoporosis and for the treatment of moderate-to-severe symptoms of vulvar and vaginal atrophy due to menopause in women with an intact uterus.
  - Activella® has the same boxed warning as Bijuva™. Additionally, Activella® has the following limitations of use:
    - When prescribing solely for the treatment of moderate-to-severe symptoms of vulvar and vaginal atrophy due to menopause, topical vaginal products should be considered.
    - When prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and non-estrogen medication should be carefully considered.
  - Activella® is dosed once daily and supplied in 2 strengths: 1mg/0.5mg and 0.5mg/0.1mg estradiol/norethindrone. Either strength can be used for each indication with the exception of the treatment of moderate-to-severe symptoms of vulvar and vaginal atrophy due to menopause in women with an intact uterus, with the recommended dose being Activella® 1mg/0.5mg once daily.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Pack*
Bijuva™ (estradiol/progesterone) 1mg/100mg capsules	**$7.15**	**$214.50**
estradiol/norethindrone tablets (Activella®) both strengths	$2.32	$64.96

Unit = capsule or tablet

*Cost per pack for Bijuva™ is a 30-day supply, while cost per pack for generic Activella® is a 28-day supply.

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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Bijuva™ during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ESTRA/NORETH TAB 1-0.5MG	52	7	$4,882.03	$2.72	7.43	$93.89
MIMVEY TAB 1-0.5MG	22	6	$2,822.67	$2.65	3.67	$128.30
TOTAL	**74**	**11***	**$7,704.70**	**$2.70**	**6.73**	**$104.12**

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

Cequa™ (Cyclosporine 0.09% Ophthalmic Solution) Product Summary[5,6]

Indication(s): Cequa™ (cyclosporine 0.09% ophthalmic solution) is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

Dosing and Administration:

- Cequa™ is supplied in sterile, preservative-free, single-use vials containing 0.25mL of cyclosporine 0.09% ophthalmic solution in 0.9mL vials. The vials are packaged in a polyfoil aluminum pouch containing 10 vials. Each box contains 6 pouches. The entire contents of each box of 60 vials must be dispensed intact.
- The recommended dosing is 1 drop twice daily [(BID), approximately 12 hours apart] into each eye.
- The vial should be discarded immediately after use in both eyes.

Other Formulation(s) Available:

- Restasis® (Cyclosporine 0.05% Ophthalmic Emulsion):
  - The indication for Restasis® is essentially the same as Cequa™, as follows:
    - To increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.
  - The recommended dosing of Restasis® is the same as that of Cequa™.
  - Restasis® is packaged in sterile, preservative-free, single-use vials. Each vial contains 0.4mL in a 0.9mL vial. The vials are packaged in trays containing either 30 or 60 vials. The entire contents of each tray must be dispensed intact.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Cequa™ (cyclosporine) 0.09% ophthalmic solution	**$8.45**	**$507.00**
Restasis® (cyclosporine) 0.05% ophthalmic emulsion	$8.93	$535.80

Unit = single-use vial
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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Cequa™ during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
RESTASIS EMU 0.05%	755	281	$317,769.78	$15.36	2.69	$420.89
TOTAL	**755**	**281***	**$317,769.78**	**$15.36**	**2.69**	**$420.89**

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

Corlanor® (Ivabradine Oral Solution) Product Summary[7,8,9]

Indication(s): Corlanor® (ivabradine oral solution) is a hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated for the following:

- To reduce the risk of hospitalization for worsening heart failure (HF) in patients with stable, symptomatic chronic HF with reduced left ventricular ejection fraction.
- For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in patients 6 months of age and older.

Dosing and Administration:

- Corlanor® [5mg/5mL (1mg/mL)] oral solution is a colorless liquid supplied in an opaque, plastic ampule. Each 5mL ampule is individually packaged in a foil pouch and supplied in cartons containing 28 foil pouches.
- The recommended starting dose for adult and pediatric patients >40kg is 2.5mg or 5mg BID with food.
- The recommended starting dose for pediatric patients <40kg is 0.05mg/kg BID with food.
- It is recommended to adjust the dose at 2-week intervals based on heart rate (*refer to Corlanor® prescribing information for recommended dose adjustments*).

Other Formulation(s) Available:

- Corlanor® (Ivabradine Tablets), Carvedilol Tablets, and Carvedilol Extended-Release (ER) Capsules:
  - Corlanor® tablets have the same indications as Corlanor® solution.
    - Corlanor® tablets are supplied in 2 strengths: 5mg and 7.5mg. The recommended dosing is the same as Corlanor® solution.
  - Carvedilol tablets and carvedilol ER capsules are indicated for mild-to-severe chronic HF, left ventricular dysfunction following MI in clinically stable patients, and hypertension.
    - Carvedilol tablets are supplied in 4 strengths: 3.125mg, 6.25mg, 12.5mg, and 25mg. The recommended dosing varies depending on diagnosis. For HF, it is recommended to start at 3.125mg BID and increase to 6.25, 12.5, and then 25mg BID over intervals of at least 2 weeks.
    - Carvedilol ER capsules are supplied in 4 strengths: 10mg, 20mg, 40mg, and 80mg. The recommended dosing varies depending on diagnosis. For HF, it is recommended to start at 10mg once daily and increase to 20, 40, and then 80mg once daily over intervals of at least 2 weeks.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Corlanor® (ivabradine) 5mg/5mL oral solution	**Unavailable**	**Unavailable**
Corlanor® (ivabradine) 7.5mg tablets	$7.05	$423.00
carvedilol 25mg tablets	$0.03	$1.80
carvedilol 80mg ER capsules	$5.74	$172.20

Unit = mL, tablet, or capsule
*Cost per 30 days based on maximum recommended dose for heart failure.
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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Corlanor® (ivabradine oral solution) during calendar year 2018. For other products including Corlanor® (ivabradine tablets), carvedilol tablets, and carvedilol ER capsules, there were 15,951 claims for 3,584 unduplicated members with a total cost of $232,926.44. The cost per day was $0.46 with a cost per claim of $14.60. For Corlanor® tablets, there were 102 claims for 20 unduplicated members for a total cost of $43,145.11. These costs do not reflect rebated prices or net costs.

Crotan™ (Crotamiton 10% Lotion) Product Summary[10,11,12,13]

Indication(s): Crotan™ (crotamiton 10% lotion) is indicated for eradication of scabies (*Sarcoptes scabiei*) and for symptomatic treatment of pruritic skin.

Dosing and Administration:

- Crotan™ is supplied as 10% crotamiton lotion in 3 bottle sizes: 2oz, 8oz, and 16oz.
- For scabies, the recommended dosing is to thoroughly massage Crotan™ into the skin of the whole body, from the chin down, paying particular attention to all folds and creases and including fingernails. A second application is advisable 24 hours later. Clothing and bed linens should be changed the next morning. A cleansing bath should be taken 48 hours after the last application.
- For pruritus, the recommended dosing is to gently massage Crotan™ into affected areas until medication is completely absorbed and repeat as needed.
- Crotan™ should be shaken well before use.

Other Formulation(s) Available:

- <u>Permethrin 5% Cream, Eurax® (Crotamiton 10% Lotion/Cream), and Hydrocortisone 2.5% Cream:</u>
  - Permethrin 5% cream is indicated for the treatment of infestation with scabies.
    - Permethrin 5% cream is to be thoroughly massaged into the skin from the head to the soles of the feet. The cream should be removed by washing after 8 to 14 hours. One application is generally curative.
    - Permethrin 5% cream is supplied in a 60g tube.
  - Eurax® has the same indications and same recommended dosing as Crotan™.
    - Eurax® is supplied as a cream in a 60g tube and lotion in 2oz and 16oz bottles.

- Hydrocortisone 2.5% cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
    - o Hydrocortisone 2.5% cream is to be applied as a thin film 2 to 4 times daily depending on severity of dermatoses.
    - o Hydrocortisone 2.5% cream is supplied in various sizes including 30g tubes and 454g jars.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Crotan™ (crotamiton) 10% lotion	**$4.06**	**$1,838.70**
permethrin 5% cream	$0.44	$26.40
Eurax® (crotamiton) 10% lotion	$4.56	$2,070.24
hydrocortisone 2.5% cream	$0.13	$59.20

Unit = gram
*Cost per treatment based on largest package size available.
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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Crotan™ or Eurax® during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PERMETHRIN CRE 5%	8,671	6,742	$397,716.66	$4.88	1.29	$45.87
HYDROCORT CRE 2.5%	4,345	3,423	$52,135.04	$0.86	1.27	$12.00
TOTAL	**13,016**	**10,165***	**$449,851.70**	**$3.16**	**1.28**	**$34.56**

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

Gloperba® (Colchicine Oral Solution) Product Summary[14,15,16,17,18]

Indication(s): Gloperba® (colchicine oral solution) is indicated for prophylaxis of gout flares in adults.

Limitation(s) of Use: The safety and effectiveness of Gloperba® for acute treatment of gout flares during prophylaxis has not been studied. Gloperba® is not an analgesic medication and should not be used to treat pain from other causes.

Dosing and Administration:

- Gloperba® is supplied as a red, 0.6mg/5mL colchicine oral solution with a cherry odor. It is available in a 150mL white, high density polyethylene bottle with a child-resistant cap.
- The recommended dosing is 0.6mg (5mL) once or twice daily with a maximum dose of 1.2mg/day.

Other Formulation(s) Available:

- Allopurinol Tablets, Probenecid/Colchicine Tablets, and Colchicine Capsules/Tablets:
    - Allopurinol tablets are indicated for 1) the management of patients with signs and symptoms of primary or secondary gout (acute attacks, tophi, joint destruction,

uric acid lithiasis, and/or nephropathy), 2) the management of patients with leukemia, lymphoma, and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels, and 3) the management of patients with recurrent calcium oxalate calculi whose daily uric acid excretion exceeds 800mg/day in male patients and 750mg/day in female patients.
    - Allopurinol tablets are dosed 200 to 300mg/day for mild gout and 400 to 600mg/day for moderately severe tophaceous gout. The minimum effective dose is 100 to 200mg/day and the maximum recommended dose is 800mg/day. Dosing for other indications is available in the full *Prescribing Information*.
    - Allopurinol tablets are supplied in 2 strengths: 100mg and 300mg.
- Probenecid/colchicine tablets are indicated for the treatment of chronic gouty arthritis when complicated by frequent, recurrent acute attacks of gout.
    - Probenecid/colchicine tablets are started after an acute gouty attack has subsided and dosed as 1 tablet daily for 1 week, followed by 1 tablet BID thereafter.
    - Probenecid/colchicine tablets are supplied as 500mg/0.5mg capsule-shaped tablets.
- Colchicine capsules/tablets have the same indication as Gloperba®. Additionally, colchicine tablets are indicated for familial Mediterranean fever (FMF).
    - Colchicine capsules and tablets are dosed as 0.6mg once or twice daily with a maximum dose of 1.2mg/day for the indication for gout prophylaxis. For FMF, colchicine tablets are dosed based on age.
    - Colchicine capsules and tablets are supplied in 1 strength, 0.6mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Gloperba® (colchicine) 0.6mg/5mL oral solution	**Unavailable**	**Unavailable**
allopurinol 300mg tablets	$0.11	$3.30
probenecid/colchicine 500mg/0.5mg tablets	$0.73	$43.80
colchicine 0.6mg capsules	$4.24	$254.40
colchicine 0.6mg tablets	$4.50	$270.00

Unit = mL, tablet, or capsule
*Cost per 30 days based on recommended dosing for gout.
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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Gloperba® during calendar year 2018. For other products including allopurinol tablets, colchicine/probenecid tablets, and colchicine tablets/capsules, there were 5,361 claims for 1,302 unduplicated members with a total cost of $100,574.25. The cost per day was $0.47 with a cost per claim of $18.76. These costs do not reflect rebated prices or net costs.

Glycate® (Glycopyrrolate Tablet) Product Summary[19,20]

Indication(s): Glycate® (glycopyrrolate tablet) is an anticholinergic indicated for use as adjunctive therapy in the treatment of peptic ulcer disease (PUD) in patients 12 years of age and older.

Dosing and Administration:

- Glycate® is supplied as 1.5mg glycopyrrolate compressed, white tablets available in a 100-count bottle.
- Glycate® is used with glycopyrrolate 1mg or 2mg tablets to provide intermediate titration doses. The recommended dosing is based on patient response.

Other Formulation(s) Available:

- Glycopyrrolate 1mg and 2mg Tablets:
  - Glycopyrrolate 1mg and 2mg tablets have the same indication as Glycate®.
  - Dosing for glycopyrrolate 1mg and 2mg tablets should be adjusted based on patient response.
  - The recommended initial dosing for glycopyrrolate 1mg tablet is 1 tablet 3 times daily. For maintenance dosing, 1 tablet BID may be adequate. For glycopyrrolate 2mg tablet, the recommended dosing is 1 tablet 2 or 3 times daily. The maximum recommended dose is 8mg/day.
  - Glycopyrrolate tablets are scored and supplied in 2 strengths: 1mg and 2mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*
Glycate® (glycopyrrolate) 1.5mg tablets	**$5.19**	**$467.10**
glycopyrrolate 1mg tablets	$0.17	$15.30
glycopyrrolate 2mg tablets	$0.31	$27.90

Unit = tablet

*Cost per 30 days based on 1 tablet 3 times daily. Please note, the maximum recommended dosing is 8mg/day; therefore, with use of adjunctive, intermittent titration costs may vary.

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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Glycate® during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
GLYCOPYRROL TAB 1MG	1,238	241	$32,805.65	$0.89	5.14	$26.50
GLYCOPYRROL TAB 2MG	756	105	$30,573.91	$1.36	7.2	$40.44
TOTAL	**1,994**	**335***	**$63,379.56**	**$1.07**	**5.95**	**$31.79**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

Khapzory™ (Levoleucovorin Injection) Product Summary[21,22,23]

Indication(s): Khapzory™ (levoleucovorin injection) is a folate analog indicated for the following:

- Rescue after high-dose methotrexate (MTX) therapy in patients with osteosarcoma.
- Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination.
- Treatment of patients with metastatic colorectal cancer in combination with fluorouracil.

Limitation(s) of Use: Khapzory™ is not indicated for the treatment of pernicious anemia and megaloblastic anemia secondary to lack of vitamin B_{12} because of the risk of progression of neurologic manifestations despite hematologic remission.

Dosing and Administration:

- Khapzory™ is supplied as a sterile, preservative-free, lyophilized powder in a single-dose vial (SDV). The vials are available in 2 strengths: 175mg and 300mg.
- Khapzory™ is for intravenous (IV) administration only.
- The recommended dosing is based on diagnosis, as follows (additional information available in the full *Prescribing Information*):
  - Rescue After High-Dose MTX Therapy for Osteosarcoma: Based on a MTX dose of 12g/m^2 administered by IV infusion over 4 hours, the rescue dose is initiated at 7.5mg (approximately 5mg/m^2) every 6 hours, 24 hours after the beginning of the MTX infusion. Dosing should be continued until MTX level is $<5x10^{-8}$M.
  - Overdosage of Folic Acid Antagonists or Impaired MTX Elimination: Khapzory™ should be started as soon as possible after MTX overdosage, or within 24 hours of delayed MTX elimination. The dosing is 7.5mg (approximately 5mg/m^2) IV every 6 hours, until MTX level is $<5x10^{-8}$M.
  - Metastatic Colorectal Cancer in Combination with Fluorouracil: One of the following regimens are recommended: 1) Khapzory™ 100mg/m^2 by IV injection over a minimum of 3 minutes, followed by fluorouracil 370mg/m^2 once daily for 5 consecutive days or 2) Khapzory™ 10mg/m^2 by IV injection followed by fluorouracil 425mg/m^2 once daily for 5 consecutive days. The 5-day courses may be repeated every 4 weeks for 2 courses, then every 4-5 weeks.

Other Formulation(s) Available:

- Levoleucovorin Calcium Injection and Leucovorin Injection:
  - The indications for levoleucovorin calcium and leucovorin are the same as Khapzory™, with the indication for advanced colorectal cancer in combination with fluorouracil defined as use in palliative care. Leucovorin has an additional indication for treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible.
  - The recommended dosing for levoleucovorin calcium is the same as that of Khapzory™. The recommended dosing for leucovorin is double that of

levoleucovorin for all overlapping indications. For megaloblastic anemia due to folic acid deficiency, the dose is up to 1mg daily.

- Levoleucovorin calcium solution is supplied as 175mg/17.5mL and 250mg/25mL (10mg/mL) SDVs that should be refrigerated at 36 to 46°F (2 to 8°C) prior to use.
- Leucovorin is supplied as 50mg, 100mg, 200mg, and 350mg SDVs for reconstitution that should be stored at 68 to 77°F (20 to 25°C).

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Khapzory™ (levoleucovorin) 175mg injection	**$700.00**	**$3,500.00**
levoleucovorin calcium 175mg/17.5mL injection	$6.52	$570.50
leucovorin 350mg injection	$18.95	$94.75

*Cost per treatment based on recommended dosing for metastatic colorectal cancer in combination with fluorouracil at 100mg/m^2 for a patient with an approximate weight of 70kg and height of 165cm.
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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Khapzory™ during calendar year 2018.

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
LEUCOVORIN INJ J0640	347	74	$8,011.60	$23.09
LEVOLEUCOVRIN INJ J0641	10	3	$1,122.60	$112.26
TOTAL	**357**	**77***	**$9,134.20**	**$25.59**

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

- There were no SoonerCare pharmacy claims for levoleucovorin calcium injection or leucovorin injection for calendar year 2018

Qmiiz™ ODT [Meloxicam Orally Disintegrating Tablet (ODT)] Product Summary[24,25]

Indication(s): Qmiiz™ ODT [meloxicam orally disintegrating tablet (ODT)] is a non-steroidal anti-inflammatory drug (NSAID) indicated for osteoarthritis (OA) in adults, rheumatoid arthritis (RA) in adults, and juvenile rheumatoid arthritis (JRA) pauciarticular and polyarticular course, in pediatric patients who weigh ≥60kg.

Dosing and Administration:

- Qmiiz™ ODT is supplied as orange flavored, yellow tablets packaged in blister packs containing 10 tablets each. Blister packs are packed into cartons containing 30, 90, or 100 tablets.
- Qmiiz™ ODT is available in 2 strengths: 7.5mg and 15mg.
- The lowest effective dosage for the shortest duration consistent with individual patient treatment goals is recommended.
- For OA and RA, the recommended starting dose is 7.5mg once daily and may be increased to 15mg once daily.

- For JRA in children ≥60kg, the recommended dose is 7.5mg once daily.

Boxed Warning: Risk of Serious CV and Gastrointestinal (GI) Events

- NSAIDs cause an increased risk of serious CV thrombotic events, including MI and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- Qmiiz™ ODT is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.
- NSAIDs cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of PUD and/or GI bleeding are at greater risk for serious GI events.

Other Formulation(s) Available:

- Meloxicam 7.5mg and 15mg Tablets:
  - Meloxicam 7.5mg and 15mg tablets have essentially the same indication as Qmiiz™ ODT.
  - Meloxicam 7.5mg and 15mg tablets have the same boxed warning as Qmiiz™ ODT.
  - The recommended dosing is the same as Qmiiz™ ODT for OA, RA, and JRA.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Qmiiz™ ODT (meloxicam ODT) both strengths	**$6.75**	**$202.50**
meloxicam tablets both strengths	$0.02	$0.60

Unit = ODT 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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Qmiiz™ ODT during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
MELOXICAM TAB 15MG	18,216	8,434	$154,734.15	$0.22	2.16	$8.49
MELOXICAM TAB 7.5MG	8,794	4,632	$78,252.67	$0.28	1.9	$8.90
TOTAL	**27,010**	**12,581***	**$232,986.82**	**$0.24**	**2.15**	**$8.63**

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

Seconal Sodium™ (Secobarbital Sodium Capsule) Product Summary[26,27,28,29]

Indication(s): Seconal Sodium™ (secobarbital sodium capsule) is a barbiturate indicated as a hypnotic for the short-term treatment of insomnia and as a preanesthetic.

Dosing and Administration:

- Seconal Sodium™ is supplied as 100mg capsules.
- For insomnia, the recommended dosing for adults is 100mg at bedtime for no more than 2 weeks. For preoperative use, the recommended dosing is 200 to 300mg 1 to 2 hours before surgery.
- The recommended dosing for children preoperatively is 2 to 6mg/kg with a maximum dosage of 100mg.

Other Formulation(s) Available:

- Zolpidem Tablets, Lorazepam Tablets, and Lorazepam Injection:
  - Zolpidem tablets are indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
    - The recommended dose for zolpidem tablets is 5mg for women and 5 to 10mg for men, initially. The lowest effective dose is recommended and the maximum daily dose is 10mg.
    - Zolpidem is supplied as immediate-release tablets in 2 strengths: 5mg and 10mg.
  - Lorazepam tablets are indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms.
    - The recommended dose for lorazepam tablets is 2 to 3mg/day given 2 times a day or 3 times a day for anxiety and a single daily dose of 2 to 4mg at bedtime, for insomnia due to anxiety or transient situational stress.
    - Lorazepam tablets are supplied in 3 strengths: 0.5mg, 1mg, and 2mg.
  - Lorazepam injection is indicated for the treatment of status epilepticus and, in adult patients, as a preanesthetic medication.
    - The recommended dose for lorazepam injection is 4mg given IV for status epilepticus, and for preanesthetic use the recommended dosing is 0.05mg/kg up to 4mg given intramuscularly (IM). Alternatively, an initial dose of 2mg IV is recommended for preanesthetic use.
    - Lorazepam injection is supplied as 2mg/mL and 4mg/mL in vials containing 1mL or 10mL of solution.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Seconal Sodium™ (secobarbital sodium) 100mg capsules	**$35.62**	**$498.68**
zolpidem 10mg tablets	$0.03	$0.42
lorazepam 2mg tablets	$0.06	$1.68
lorazepam 4mg/mL injection	$2.63	$2.63

Unit = capsule, tablet, or mL

*Cost per treatment based on a 14-day supply at maximum recommended dose for insomnia for oral dosage formulations and as a single dose for preanesthetic for injectable formulation.

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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Seconal Sodium™ during calendar year 2018. For other products including zolpidem tablets, lorazepam tablets, and lorazepam injection, there were 27,350 claims for 6,280 unduplicated members with a total cost of $263,350.95. The cost per day was $0.34 with a cost per claim of $9.63. These costs do not reflect rebated prices or net costs.

TaperDex™ (Dexamethasone Tablet) Product Summary[30,31,32]

Indication(s): TaperDex™ (dexamethasone tablet) is a corticosteroid indicated for various diagnoses including allergic states, dermatologic diseases, endocrine disorders, GI diseases, hematologic disorders, neoplastic diseases, nervous system disorders, ophthalmic diseases, renal diseases, respiratory diseases, rheumatic disorders, and miscellaneous diagnostic testing.

Dosing and Administration:

- TaperDex™ is supplied as 1.5mg dexamethasone tablets in fixed 6-day, 7-day, or 12-day dose packages.
- The tablets are available in unit-dose, tapered blister packs with the dosage printed on the right side of the blister card. The 6-day pack contains 21 tablets, the 7-day pack contains 27 tablets, and the 12-day pack contains 49 tablets.
- The recommended dosing is variable and must be individualized based on diagnosis and the response of the patient.

Other Formulation(s) Available:

- Dexamethasone 1.5mg Tablets:
  - Dexamethasone 1.5mg tablets have the same indications as TaperDex™.
  - The initial dosage varies from 0.75 to 9mg a day depending on the disease being treated. Like TaperDex™, the recommended dosing is variable and must be individualized based on diagnosis and the response of the patient.
  - Dexamethasone 1.5mg tablets are bisected on 1 side to allow for functional scoring to ensure accurate splitting.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment
TaperDex™ 6-Day (dexamethasone 1.5mg tablets)	**$9.00**	**$189.00**
TaperDex™ 7-Day (dexamethasone 1.5mg tablets)	**$7.22**	**$194.94**
TaperDex™ 12-Day (dexamethasone 1.5mg tablets)	**$4.73**	**$231.77**
dexamethasone 1.5mg tablets	$0.36	$17.64*

Unit = tablet

*Cost per treatment for generic dexamethasone 1.5mg tablets equivalent to TaperDex™ 12-Day treatment or #49 tablets. 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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of TaperDex™ during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
DEXAMETHASON TAB 1.5MG	46	31	$496.23	$2.46	1.48	$10.79
TOTAL	**46**	**31***	**$496.23**	**$2.46**	**1.48**	**$10.79**

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

Tiglutik™ (Riluzole Suspension) Product Summary[33,34]

Indication(s): Tiglutik™ (riluzole suspension) is a benzothiazole indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Dosing and Administration:

- Tiglutik™ is supplied as a 50mg/10mL (5mg/mL) riluzole oral suspension in a 300mL amber, glass bottle with a child-resistant, tamper-evident screw cap.
- Tiglutik™ is available in a carton containing (2) 300mL bottles, (2) 10mL oral syringes, (2) syringe bottle adapters, (2) syringe tip caps, and prescribing information.
- The recommended dosing is 50mg (10mL) BID, every 12 hours at least 1 hour before or 2 hours after a meal.

Other Formulation(s) Available:

- Riluzole 50mg Tablets:
  - Riluzole 50mg tablets have the same indication as Tiglutik™.
  - The recommended dosing is also the same, 50mg (1 tablet) every 12 hours at least 1 hour before or 2 hours after a meal.
  - Riluzole tablets are supplied as 50mg film-coated, capsule-shaped tablets.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
Tiglutik™ (riluzole) 50mg/10mL suspension	**$5.25**	**$3,150.00**
riluzole 50mg oral tablets	$0.89	$53.40

Unit = mL 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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Tiglutik™ during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
RILUZOLE TAB 50MG	15	3	$1,584.83	$3.52	5	$105.66
TOTAL	**15**	**3***	**$1,584.83**	**$3.52**	**5**	**$105.66**

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

TobraDex® ST (Tobramycin/Dexamethasone 0.3%/0.05% Ophthalmic Suspension) Product Summary[35,36,37]

Indication(s): TobraDex® ST (tobramycin/dexamethasone 0.3%/0.05% ophthalmic suspension) is a topical antibiotic and corticosteroid combination for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Dosing and Administration:

- TobraDex® ST is supplied as 3mg/mL tobramycin and 0.5mg/mL dexamethasone ophthalmic suspension. It is available as 2.5mL, 5mL, or 10mL in a Drop-Tainer® bottle with a dispenser tip and an overcap.
- The recommended dosing is to instill 1 drop into the conjunctival sac(s) every 4 to 6 hours. During the initial 24 to 48 hours, dosage may be increased to 1 drop every 2 hours.
- Dosing frequency should be decreased gradually as warranted by improvement in clinical signs.

Other Formulation(s) Available:

- Neomycin/Polymyxin B/Dexamethasone Ophthalmic Suspension and TobraDex® (Tobramycin/Dexamethasone) Ophthalmic Suspension:
  - Both neomycin/polymyxin B/dexamethasone ophthalmic suspension and TobraDex® ophthalmic suspension have the same indication as TobraDex® ST.
  - Neomycin/polymyxin B/dexamethasone ophthalmic suspension is dosed as 1 to 2 drops hourly in severe disease, tapered as inflammation subsides. In mild disease, the recommended dose is 1 to 2 drops up to 4 to 6 times daily.
    - Neomycin/polymyxin B/dexamethasone ophthalmic suspension is supplied as 3.5mg/mL neomycin, 10,000 units/mL polymyxin B, and 1mg/mL dexamethasone in a 5mL bottle.
  - TobraDex® ophthalmic suspension is dosed as 1 to 2 drops every 4 to 6 hours. During the initial 24 to 48 hours, dosage may be increased to 1 to 2 drops every 2 hours.
    - TobraDex® ophthalmic suspension is supplied as 3mg/mL tobramycin and 1mg/mL dexamethasone in 2.5mL, 5mL, and 10mL Drop-Tainer® bottles.

Formulation Cost Comparison:

Product	Cost Per Unit*	Cost Per Treatment*
TobraDex® ST (tobramycin/dexamethasone) 0.3%/0.05%	**$39.62**	**$198.10**
TobraDex® (tobramycin/dexamethasone) 0.3%/0.1%	$30.31	$151.55
neomycin/polymyxin B/dexamethasone (Maxitrol®)	$2.60	$13.00

Unit = mL

*Cost per unit and treatment is based on pricing for the 5mL bottle.

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.

Calendar Year 2018 Utilization: There were 9 claims for 9 unduplicated members utilizing TobraDex® ST with a total cost of $2,107.61 for calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
NEO/POLY/DEX SUS 0.1% OP	2,137	1,931	$43,020.94	$1.51	1.11	$20.13
TOBRA/DEXAME SUS 0.3-0.1%	469	438	$34,664.82	$4.86	1.07	$73.91
TOBRADEX SUS 0.3-0.1%	32	24	$4,685.38	$11.83	1.33	$146.42
TOTAL	**2,638**	**2,382***	**$82,371.14**	**$2.28**	**1.11**	**$31.22**

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

Tolsura™ (Itraconazole Capsule) Product Summary[38,39]

Indication(s): Tolsura™ (itraconazole capsule) is an azole antifungal indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:

- Blastomycosis, pulmonary and extrapulmonary;
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis;
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Limitation(s) of Use: Tolsura™ is not indicated for the treatment of onychomycosis. Tolsura™ is not interchangeable or substitutable with other itraconazole products.

Dosing and Administration:

- Tolsura™ is supplied as a hard, gelatin capsule containing 65mg of itraconazole. It is available in a 60-count bottle.
- For blastomycosis, histoplasmosis, and aspergillosis, the recommended dosage is 130mg to 260mg daily.
- Additional dosing information for life-threatening situations is available in the full *Prescribing Information*.
- Tolsura™ must be administered with food. The capsules should be swallowed whole and should not be crushed, chewed, or broken.

Boxed Warning: Congestive Heart Failure (CHF) and Drug Interactions

- Tolsura™ can cause or exacerbate CHF. If signs or symptoms of CHF occur or worsen during administration of Tolsura™, the benefit-risk of continuing treatment should be reassessed.
- Co-administration of certain drugs that are metabolized by human CYP3A4 enzymes are contraindicated with Tolsura™ because plasma concentrations of such drugs are increased.
- Co-administration with colchicine, fesoterodine, and solifenacin is contraindicated in patients with varying degrees of renal or hepatic impairment.
- Co-administration with eliglustat is contraindicated in poor or intermediate metabolizers of CYP2D6 and in patients taking strong or moderate CYP2D6 inhibitors.
- Increased plasma concentrations of some of these drugs can lead to QT prolongation and ventricular tachyarrhythmias including occurrences of *torsades de pointes*.

Other Formulation(s) Available:

- Itraconazole 100mg Capsules:
  - Itraconazole 100mg capsules have the same indications as Tolsura™. Additionally, itraconazole 100mg capsules are indicated for onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes, and onychomycosis of the fingernail due to dermatophytes in non-immunocompromised patients.
  - Itraconazole 100mg capsules have a *Boxed Warning* similar to Tolsura™. The following information includes the differences for itraconazole 100mg capsules:
    - With regard to CHF, itraconazole 100mg capsules should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as CHF or a history of CHF. If signs or symptoms of CHF occur during administration of itraconazole 100mg capsules, administration should be discontinued
    - With regard to drug interactions, the interactions for Tolsura™ are the same as itraconazole 100mg capsules. Additional drug interactions are also included for itraconazole 100mg capsules. The following drugs are specifically listed and are contraindicated with itraconazole 100mg capsules: methadone, disopyramide, dofetilide, dronedarone, quinidine, isavuconazole, ergot alkaloids [such as dihydroergotamine, ergometrine (ergonovine), ergotamine, methylergometrine (methylergonovine)], irinotecan, lurasidone, oral midazolam, pimozide, triazolam, felodipine, nisoldipine, ivabradine, ranolazine, eplerenone, cisapride, naloxegol, lomitapide, lovastatin, simvastatin, avanafil, and ticagrelor.
  - For blastomycosis and histoplasmosis, the recommended dose is 200mg once daily up to a maximum of 400mg daily.
  - For aspergillosis, the recommended dose is 200 to 400mg daily.
  - Additional dosing information for life-threatening situations is available in the full *Prescribing Information*.

- For onychomycosis of toenails with or without fingernail involvement, the recommended dose is 200mg once daily for 12 consecutive weeks.
- For onychomycosis of fingernails only, the recommended dosing regimen is 2 treatment pulses, each consisting of 200mg BID (400mg/day) for 1 week. The pulses are separated by a 3-week period without treatment.
- Itraconazole 100mg capsules should be taken with a full meal to ensure maximal absorption. Capsules should be swallowed whole.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Tolsura™ (itraconazole) 65mg capsules	**$34.48**	**$6,206.40**
itraconazole 100mg capsules	$1.78	$320.40

Unit = capsule
*Cost per treatment based on recommended dosing for blastomycosis and histoplasmosis for 3 months.
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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Tolsura™ during calendar year 2018.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ITRACONAZOLE CAP 100MG	216	113	$38,314.36	$7.18	1.91	$177.38
TOTAL	**216**	**113***	**$38,314.36**	**$7.18**	**1.91**	**$177.38**

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

Yutiq™ (Fluocinolone Acetonide Intravitreal Implant) Product Summary[40,41,42]

Indication(s): Yutiq™ (fluocinolone acetonide intravitreal implant) contains a corticosteroid and is indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye.

Dosing and Administration:

- Yutiq™ is supplied as a 0.18mg fluocinolone acetonide intravitreal implant in a sterile single-dose preloaded applicator with a 25-gauge needle.
- Yutiq™ is a non-bioerodible intravitreal implant in a drug delivery system designed to release fluocinolone acetonide at an initial rate of 0.25mcg/day and last 36 months.
- For implant administration, the needle of the applicator is inserted through the conjunctiva and sclera. The applicator is then fully depressed to deliver the implant into the back of the eye. After implant placement, the applicator is removed and discarded.
- Following the injection, patients should be monitored for change in intraocular pressure and for endophthalmitis.

Other Formulation(s) Available:

- Retisert® (Fluocinolone Acetonide Intravitreal Implant) and Ozurdex® (Dexamethasone Intravitreal Implant):
  - Retisert® has the same indication as Yutiq™.
    - Retisert® is supplied as a 0.59mg fluocinolone acetonide intravitreal implant. The implant consists of a tablet encased in a silicone elastomer cup containing a release orifice, stored in a clear polycarbonate case within a foil pouch.
    - Retisert® 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.
    - Retisert® is implanted into the posterior segment of the affected eye through a pars plana incision.
  - Ozurdex® is indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion, the treatment of non-infectious uveitis affecting the posterior segment of the eye, and the treatment of diabetic macular edema.
    - Ozurdex® is supplied as a 0.7mg dexamethasone intravitreal implant in a foil pouch with 1 single-use plastic applicator.
    - For implant administration, the needle of the applicator is advanced into the sclera until the vitreous cavity is entered. The actuator button is then fully depressed to deliver the implant.

Formulation Cost Comparison:

Product	Cost Per Unit*	Cost Per 30 Days*
Yutiq™ (fluocinolone acetonide) 0.18mg intravitreal implant	**$8,340.00**	**$231.67**
Retisert® (fluocinolone acetonide) 0.59mg intravitreal implant	$19,025.00	$634.17
Ozurdex® (dexamethasone) 0.7mg intravitreal implant	$1,333.00	$333.25

Unit = intravitreal implant

*Please note duration of treatments vary. Yutiq™ is intended to last 36 months per implant, Retisert® 30 months per implant, and Ozurdex® 3 to 4 months per implant.

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.

Calendar Year 2018 Utilization: There was no SoonerCare utilization of Yutiq™ during calendar year 2018.

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM
OZURDEX J7312	16	13	$19,970.73	$1,248.17
TOTAL	**16**	**13***	**$19,970.73**	**$1,248.17**

*Total number of unduplicated members.

Costs do not reflect rebated prices or net costs.

- There were no paid medical claims for Retisert® during calendar year 2018.

Recommendations

The College of Pharmacy recommends the prior authorization of Annovera™ (segesterone acetate/ethinyl estradiol vaginal system), Bijuva™ (estradiol/progesterone capsule), and Cequa™ (cyclosporine 0.09% ophthalmic solution) with the following criteria:

Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) or all other available formulations of estrogen/progestin contraception must be provided; and
3. A quantity limit of 1 vaginal system per 365 days will apply.

Bijuva™ (Estradiol/Progesterone Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause in women with an intact uterus; and
2. A patient-specific, clinically significant reason why the member cannot use all other available estrogen/progestin products indicated for vasomotor symptoms of menopause must be provided; and
3. A quantity limit of 30 capsules (1 pack) per 30 days will apply.

Cequa™ (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in patients with keratoconjunctivitis sicca (dry eye); and
2. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion), which is available without a prior authorization, must be provided; and
3. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

The College of Pharmacy also recommends the prior authorization of Corlanor® (ivabradine oral solution) and to update the current Corlanor® (ivabradine tablet) approval criteria to be consistent with package labeling (proposed changes shown in red).

Corlanor® (Ivabradine Tablet and Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. To reduce the risk of hospitalization for worsening heart failure (HF) in adult patients with stable, symptomatic chronic HF with reduced left ventricular ejection fraction; or
    b. For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in patients 6 months of age and older; and
2. For a diagnosis of worsening HF in adults:
    a. The prescriber must verify that the member has left ventricular ejection fraction ≤35%; and
    b. The prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute; and

c. The member must be on maximal/maximally tolerated doses of beta-blockers or have a contraindication to beta-blockers; and

3. For a diagnosis of DCM in patients 6 months of age or older:
   a. The prescriber must verify that the member has left ventricular ejection fraction ≤45%; and
   b. The prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:
      i. Age 6 to 12 months, HR ≥105 beats per minute (bpm); or
      ii. Age 1 to 3 years, HR ≥95 bpm; or
      iii. Age 3 to 5 years, HR ≥75 bpm; or
      iv. Age 5 to 18 years, HR ≥70 bpm; and
   c. The prescriber must verify that dose titration will be followed according to package labeling; and
   d. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Authorization of Corlanor® solution for members >40kg, requires a patient-specific, clinically significant reason Corlanor® tablets cannot be used; and
5. For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and
6. For Corlanor® solution, a quantity limit of 56 ampules (2 boxes) per 28 days will apply.

The College of Pharmacy also recommends the addition of Crotan™ (crotamiton 10% lotion) to the current Eurax® (crotamiton lotion/cream) criteria and the addition of Gloperba® (colchicine oral solution) to the current Colcrys® (colchicine tablet) and Mitigare® (colchicine capsule) criteria (proposed changes shown in red).

Eurax® (Crotamiton 10% Lotion/Cream) and Crotan™ (Crotamiton 10% Lotion) Approval Criteria:

1. An FDA approved diagnosis of scabies or pruritic skin; and
2. Member must be at least 18 years of age; and
3. For a diagnosis of scabies, member must have used permethrin 5% cream in the past 7 to 14 days with inadequate results; and
4. For a diagnosis of pruritic skin, a patient-specific, clinically significant reason why the member cannot use other available topical treatments used for pruritic skin must be provided; and
5. For authorization of Crotan™, a patient-specific, clinically significant reason why the member cannot use Eurax® must be provided; and
6. A quantity limit of 1 tube or bottle per 30 days will apply.

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

1. A quantity of 6 tablets/capsules for a 3-day supply is available without prior authorization for treatment of acute gouty attacks; and
2. Failure of allopurinol after 6 months of treatment defined by persistent gouty attacks with serum urate levels greater than 6.0mg/dL; and

3. A patient-specific, clinically significant reason why colchicine/probenecid would not be a viable option for the member must be provided; and
4. For authorization of Gloperba®, a patient-specific, clinically significant reason why the member cannot use colchicine tablets or capsules must be provided; and
5. A quantity limit of 60 tablets/capsules per 30 days or 300mL per 30 days will apply for gout; and
6. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

Additionally, the College of Pharmacy recommends the prior authorization of Glycate® (glycopyrrolate tablet) and Khapzory™ (levoleucovorin injection) with the following criteria:

Glycate® (Glycopyrrolate Tablet) Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in patients 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.

Khapzory™ (Levoleucovorin Injection) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Rescue after high-dose methotrexate (MTX) therapy in patients with osteosarcoma; or
    b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or
    c. Treatment of patients with metastatic colorectal cancer in combination with fluorouracil; and
2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection must be provided.

The College of Pharmacy recommends the placement of Qmiiz™ ODT (meloxicam ODT) into the Special Prior Authorization (PA) Tier of the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) Product Based Prior Authorization (PBPA) category. Current Special PA Criteria will apply. The proposed change is shown in red in the following NSAIDs Tier Chart.

NSAIDs Special Prior Authorization (PA) Approval Criteria:

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

Nonsteroidal 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)	diclofenac sodium/ misoprostol (Arthrotec®)	diclofenac (Zorvolex®)
diclofenac ER (Voltaren® XR)	diclofenac sodium (Voltaren®) 25mg tabs	diclofenac potassium (Cambia®) powder pack
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/famotidine (Duexis®)
ketoprofen (Orudis®)	tolmetin (Tolectin®)	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 ODT (Qmiiz™ ODT)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)

ER = extended-release, EC = enteric coated, caps = capsules, tabs = tablets, susp = suspension, ODT = orally disintegrating tablet, 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.

The College of Pharmacy recommends the prior authorization of Seconal Sodium™ (secobarbital sodium capsule), TaperDex™ (dexamethasone tablet), and Tiglutik™ (riluzole suspension) with the following criteria:

Seconal Sodium™ (Secobarbital Sodium Capsule) Approval Criteria:

1. An FDA approved indication for 1 of the following:
   a. The short-term treatment of insomnia; or
   b. A preanesthetic; and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives must be provided; and
3. For the short-term treatment of insomnia, a quantity limit of 1 capsule per day not to exceed 14 capsules per 30 days will apply.

TaperDex™ (Dexamethasone Tablet) Approval Criteria:

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

Tiglutik™ (Riluzole 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.

The College of Pharmacy recommends the placement of TobraDex® ST (tobramycin/ dexamethasone 0.3%/0.05% ophthalmic suspension) into Tier-2 of the Ophthalmic Antibiotics/Steroid Combination Products PBPA category. Current Tier-2 criteria will apply. The proposed change is shown in red in the following Ophthalmic Antibiotic/Steroid Combination Products Tier Chart.

Ocular Antibiotic/Steroid Combination Tier-2 Approval Criteria:

1. Prescription written by optometrists/ophthalmologists; or
2. When requested medication is being used for pre/post-operative prophylaxis.

Ophthalmic Antibiotic/Steroid Combination Products	
Tier-1	**Tier-2**
neomycin/polymyxin B/dexamethasone (Maxitrol®) susp & oint	bacitracin/polymyxin B/neomycin/HC oint
sulfacetamide/prednisolone sol	gentamicin/prednisolone (Pred-G®) susp & oint
tobramycin/dexamethasone (TobraDex®) susp*	neomycin/polymyxin B/HC (Cortisporin®) susp
	sulfacetamide/prednisolone (Blephamide®) susp & oint
	tobramycin/dexamethasone (TobraDex®) oint
	tobramycin/dexamethasone (TobraDex® ST) susp
	tobramycin/loteprednol (Zylet®) susp

oint = ointment; susp = suspension; HC = hydrocortisone; sol = solution
Tier structure(s) based on supplemental rebate participation, and/or National Average Drug Acquisition Costs (NDAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Brand preferred.

Finally, the College of Pharmacy recommends the prior authorization of Tolsura™ (itraconazole capsule) and Yutiq™ (fluocinolone acetonide intravitreal implant) with the following criteria:

Tolsura™ (Itraconazole Capsule) Approval Criteria:

1. An FDA approved indication of 1 of the following fungal infections in immunocompromised and non-immunocompromised adult patients:
    a. Blastomycosis, pulmonary and extrapulmonary; or
    b. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; or

c. Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy; and

2. A patient-specific, clinically significant reason why the member cannot use itraconazole 100mg capsules, which are available without prior authorization, must be provided.

Yutiq™ (Fluocinolone Acetonide 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 local corticosteroids must be provided; and
5. A quantity limit of 1 implant per eye every 36 months will apply.

Utilization Details of Special Formulations: Calendar Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
ERYTHROMYCIN PRODUCTS						
ERYTHROMYCIN GEL 2%	64	56	$5,115.29	$3.65	1.14	$79.93
SUBTOTAL	**64**	**56**	**$5,115.29**	**$3.65**	**1.14**	**$79.93**
GABAPENTIN PRODUCTS						
HORIZANT TAB 600MG ER	10	3	$3,823.08	$12.74	3.33	$382.31
HORIZANT TAB 300MG ER	1	1	$380.98	$12.70	1	$380.98
SUBTOTAL	**11**	**4**	**$4,204.06**	**$12.74**	**2.75**	**$382.19**
LACTULOSE PRODUCTS						
KRISTALOSE PAK 20GM	14	5	$2,980.68	$7.10	2.8	$212.91
KRISTALOSE PAK 10GM	12	4	$3,811.64	$11.55	3	$317.64
SUBTOTAL	**26**	**9**	**$6,792.32**	**$9.06**	**2.89**	**$261.24**
MERCAPTOPURINE PRODUCTS						
PURIXAN SUS 20MG/ML	116	22	$112,328.15	$31.32	5.27	$968.35
SUBTOTAL	116	22	$112,328.15	$31.32	5.27	$968.35
METHOTREXATE PRODUCTS						
OTREXUP INJ 15MG	2	1	$1,320.66	$23.58	2	$660.33
OTREXUP INJ 17.5MG	1	1	$656.33	$23.44	1	$656.33
RASUVO INJ 15MG	3	1	$1,370.60	$16.32	3	$456.87
XATMEP SOL 2.5MG/ML	34	6	$19,853.54	$16.77	5.67	$583.93
SUBTOTAL	**40**	**9**	**$23,201.13**	**$17.16**	**4.44**	**$580.03**
METRONIDAZOLE PRODUCTS						
METRONIDAZOL GEL 1%	3	2	$450.14	$5.00	1.5	$150.05
SUBTOTAL	**3**	**2**	**$450.14**	**$5.00**	**1.5**	**$150.05**
NORETHINDRONE/ESTRADIOL PRODUCTS						
TAYTULLA CAP 1MG/20MCG	3	2	$522.33	$6.22	1.5	$174.11
SUBTOTAL	**3**	**2**	**$522.33**	**$6.22**	**1.5**	**$174.11**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
PREGABALIN PRODUCTS						
LYRICA CR TAB 165MG	2	1	$787.30	$13.12	2	$393.65
SUBTOTAL	**2**	**1**	**$787.30**	**$13.12**	**2**	**$393.65**
TOTAL	**265**	**99***	**$153,400.72**	**$20.04**	**2.68**	**$578.87**

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

- There were no SoonerCare pharmacy claims for calendar year 2018 for the following special formulation products: erythromycin 2% swabs, GoNitro™ (nitroglycerin sublingual powder), Gralise® (gabapentin extended-release tablets), Klor-Con® 20meq packets (potassium chloride), Metozolv® ODT (metoclopramide ODT), Nuvessa™ (metronidazole 1.3% vaginal gel), potassium chloride 25mEQ packet (Klor-Con®, Epiklor®), Rayos® (prednisone delayed-release tablets), Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion), Sinuva™ (mometasone furoate sinus implant), Soltamox® (tamoxifen citrate 10mg/5ml oral solution), Tirosint®-SOL (levothyroxine sodium oral solution), and ZTlido™ (lidocaine 1.8% topical system).

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Appendix P

Calendar Year 2018 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Cassipa® (Buprenorphine/ Naloxone) and Levorphanol

Oklahoma Health Care Authority
June 2019

Current Prior Authorization Criteria

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting: oxycodone ER 10mg, 15mg, 20mg only (Oxycontin®)◊ **Short-Acting:** ASA/butalbital/caff/cod (Fiorinal with Codeine®) codeine codeine/APAP dihydrocodeine/ASA/caff (Synalgos-DC®) hydrocodone/APAP (Norco®) hydrocodone/IBU (Vicoprofen®, Ibudone®, Reprexain™) hydromorphone (Dilaudid®) morphine IR (MSIR®) oxycodone IR (Oxy IR®) oxycodone/APAP (Percocet®) oxycodone/ASA (Percodan®) oxycodone/IBU (Combunox®) tramadol (Ultram®) tramadol/APAP (Ultracet®)	**Long-Acting:** buprenorphine patch (Butrans®) fentanyl patch (Duragesic®) hydrocodone ER (Hysingla® ER) morphine ER tab (MS Contin®) morphine/naltrexone (Embeda®) oxycodone ER 30mg, 40mg, 60mg, 80mg (Oxycontin®)◊ tramadol ER tab (Ultram ER®, Ryzolt®) **Short-Acting:** oxymorphone IR (Opana®) tapentadol IR (Nucynta®)	**Long-Acting:** buprenorphine ER buccal film (Belbuca®) hydrocodone ER (Vantrela™ ER) hydrocodone ER (Zohydro® ER) hydromorphone ER (Exalgo®) methadone (Dolophine®) morphine ER (Arymo® ER) morphine ER (Avinza®, Kadian®) morphine ER (MorphaBond™) morphine/naltrexone (Troxyca® ER) oxycodone ER (Xtampza® ER) tapentadol ER (Nucynta® ER) **Short-Acting:** benzhydrocodone/APAP (Apadaz®) dihydrocodeine/APAP/caff (Trezix®) hydrocodone/APAP (Xodol®, Zamicet®, Liquicet®) oxycodone (Oxaydo®) oxycodone (Oxecta®) oxycodone (RoxyBond™) oxycodone/APAP (Primlev™, Xolox®)	**Long-Acting:** oxycodone/APAP ER (Xartemis® XR) oxymorphone ER (Opana ER®) tramadol ER cap (ConZip®) **Oncology Only:** fentanyl SL tab (Abstral®) fentanyl transmucosal lozenge (Actiq®) fentanyl buccal tab (Fentora®) fentanyl nasal spray (Lazanda®) fentanyl buccal film (Onsolis®) fentanyl SL spray (Subsys®)

APAP = acetaminophen; ASA = aspirin; IR = immediate-release; ER = extended-release; IBU = ibuprofen; cod = codeine; caff = caffeine; tab = tablet; cap = capsule; SL = sublingual
*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.

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

e. Tier structure rules still apply.

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

1. Members may be approved for greater than 12 claims per year of hydrocodone products if the member has a pain contract with a single prescriber. A copy of the pain contract 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.

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

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

High-Dose Buprenorphine Products Approval Criteria:

1. Each request for >24mg bioequivalent buprenorphine per day will be evaluated on a case-by-case basis.
2. A taper schedule, dates of an attempted taper with reason for failure, or a patient-specific, clinically significant reason why a taper schedule or 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 daily 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
    b. Stability of living environment
    c. Participation in a structured activity/job
    d. Consistency in participation in recommended behavioral therapy/peer support program
    e. Consistency in compliance with clinic visit requirements
    f. Minimal to no desire or need to use illicit opioids
    g. Period without episodes of hospitalizations (addiction or mental health issues), emergency room visits, or crisis interventions
    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. 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
2. An FDA approved diagnosis of moderate-to-severe opioid use disorder; 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.

Utilization of Opioid Analgesics and MAT Medications: Calendar Year 2018

Comparison of Calendar Years: Opioid Analgesics

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	105,823	371,525	$16,451,837.56	$44.28	$2.29	26,186,495	7,194,081
2018	88,217	301,126	$12,512,925.39	$41.55	$2.11	21,021,891	5,917,214
% Change	**-16.60%**	**-18.90%**	**-23.90%**	**-6.20%**	**-7.90%**	**-19.70%**	**-17.70%**
Change	**-17,606**	**-70,399**	**-$3,938,912.17**	**-$2.73**	**-$0.18**	**-5,164,604**	**-1,276,867**

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

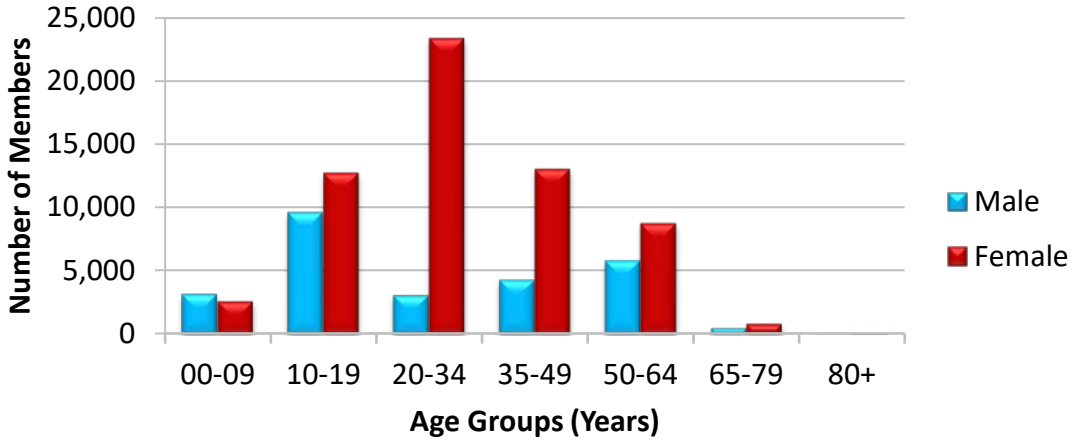
- Aggregate drug rebates collected during calendar year 2018 for opioid analgesics: $5,806,107.97[Δ]

Comparison of Calendar Years: MAT Medications

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	2,196	15,805	$4,710,665.49	$298.05	$11.35	848,919	415,166
2018	2,689	18,978	$5,512,584.51	$290.47	$11.04	1,039,927	499,242
% Change	**22.40%**	**20.10%**	**17.00%**	**-2.50%**	**-2.70%**	**22.50%**	**20.30%**
Change	**493**	**3,173**	**$801,919.02**	**-$7.58**	**-$0.31**	**191,008**	**84,076**

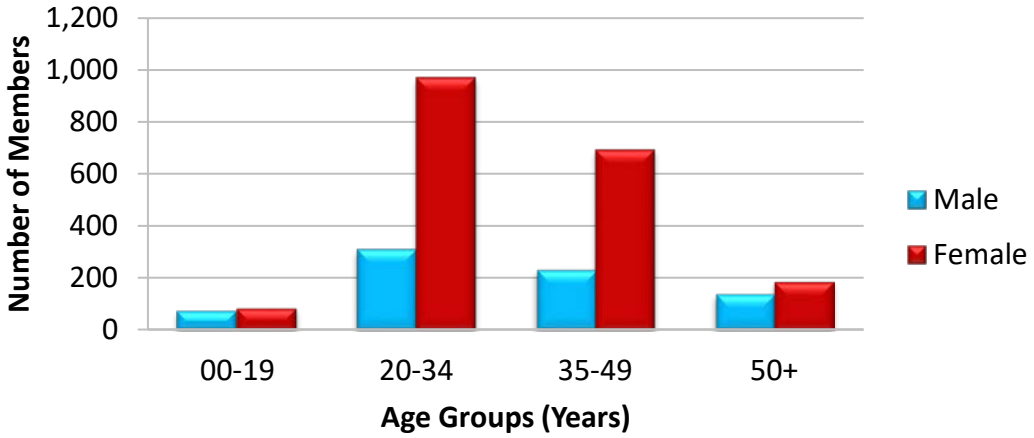
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs. The above MAT medications data does not include Butrans® or Belbuca® claims.

Demographics of Members Utilizing Opioid Analgesics

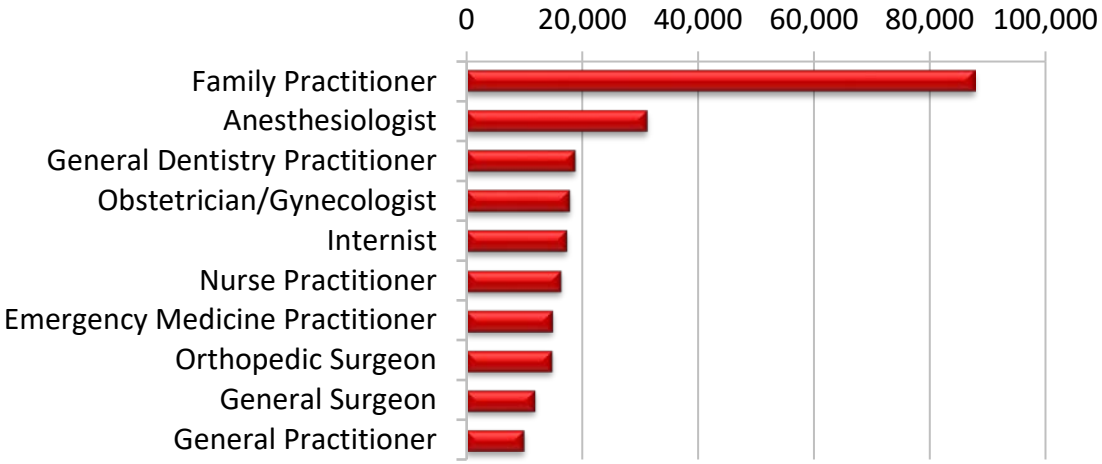


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

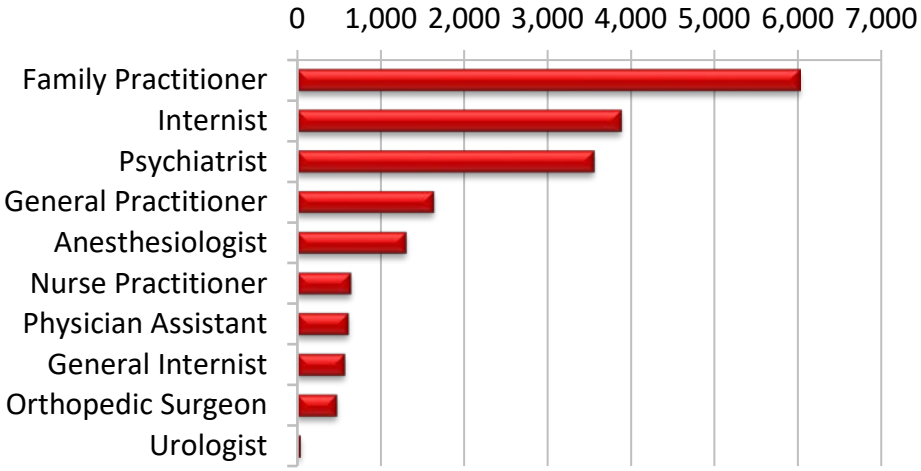
Demographics of Members Utilizing MAT Medications



Top Prescriber Specialties of Opioid Analgesics by Number of Claims



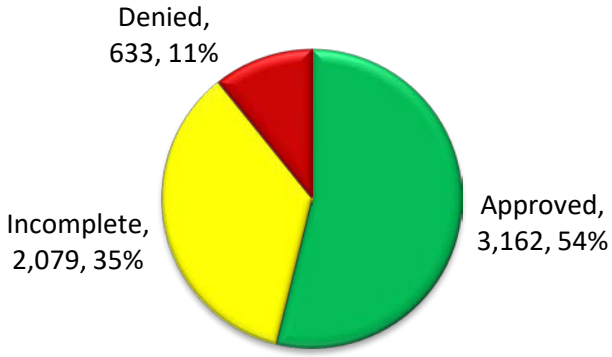
Top Prescriber Specialties of MAT Medications by Number of Claims



Prior Authorization of Opioid Analgesics and MAT Medications

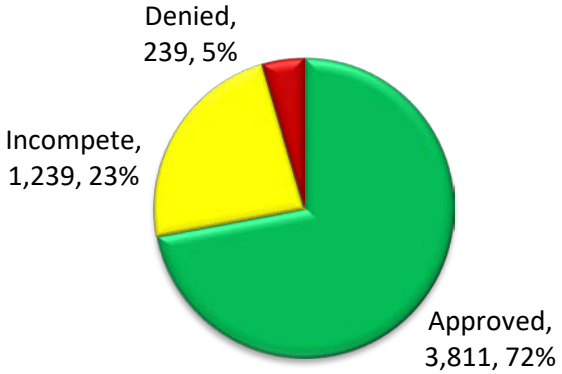
There were 5,874 prior authorizations submitted for the opioid analgesics category during calendar year 2018. Computer edits are in place to detect diagnosis, quantities/day supply, and lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2018.

Status of Petitions: Opioid Analgesics



There were 5,289 prior authorizations submitted for MAT medications during calendar year 2018. Computer edits are in place to detect diagnosis, concomitant opioid claims, and quantities/day supply and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2018.

Status of Petitions: MAT Medications



Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33]

Anticipated Patent Expiration(s):

- Abstral® [fentanyl sublingual (SL) tablet]: September 2019
- 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 SL spray): April 2030
- Apadaz® [benzhydrocodone/acetaminophen (APAP) IR tablet]: February 2031
- Hysingla® ER (hydrocodone bitartrate 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 bitartrate 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):

- **September 2018:** The FDA approved Cassipa® (buprenorphine/naloxone SL film) for the maintenance treatment of opioid dependence. This approval provides a new dosage strength (16mg/4mg) of buprenorphine/naloxone SL film.
- **November 2018:** The FDA approved Dsuvia™ (sufentanil SL tablet) for the management of acute pain, severe enough to require an opioid analgesic and for which alternative treatments are inadequate, in adults. Dsuvia™ is only for use in a certified medically supervised health care setting, such as hospitals, surgical centers, and emergency departments.
- **December 2018:** The FDA tentatively approved Brixadi™ (buprenorphine ER injection) for the treatment of moderate-to-severe opioid use disorder (OUD) in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. The product is administered only by a health care provider in a health care setting and used as part of a complete treatment program that includes counseling and psychosocial support. The tentative approval means the FDA concluded Brixadi™ met all the required safety, efficacy, and quality standards necessary for approval, but it is not eligible for marketing at this time due to exclusivity considerations.
- **January 2019:** KemPharm, Inc. announced that the FDA approved a supplemental New Drug Application (sNDA) for 2 additional strengths of Apadaz® (benzhydrocodone/APAP), 4.08mg/325mg benzhydrocodone/APAP and 8.16mg/325mg benzhydrocodone/APAP. Apadaz® is indicated for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
- **February 2019:** New generic buprenorphine/naloxone SL film products are available for treating opioid dependence, following a new approval from the FDA and resolution of patent litigation. FDA officials approved generic versions of buprenorphine/naloxone SL film in June 2018.

Oklahoma Legislative Update(s):

- **November 2018:** Opioid prescribing laws changed on November 1, 2018 as a result of Oklahoma Senate Bill (SB) 1446. The SB places limits on initial prescriptions for opioids for acute pain and also puts into place other safeguards to help curb the potential for opioid

abuse. The State Board of Osteopathic Examiners, Oklahoma State Medical Association, Oklahoma Hospital Association, and several medical associations endorsed a best practice document released in October 2018 to clarify some of the details in Oklahoma SB 1446 on opioid prescribing.

FDA and Drug Enforcement Administration (DEA) Update(s):

- **August 2018:** Dr. Scott Gottlieb, FDA Commissioner, issued a statement on new steps to advance the development of evidence-based, indication-specific guidelines to help guide appropriate prescribing of opioid analgesics. According to the statement, the FDA's analyses suggest that the first prescription for many common, acute indications could typically be for many fewer pills, possibly just a day or 2 of medication rather than a 30-day supply, which is typically prescribed. The excess pills that are not used by patients may end up being diverted to illicit markets or misused or abused by friends or family members, in some cases. In other circumstances, patients who are prescribed more medication than necessary may find themselves at increased risk for misuse, abuse, and addiction. In the statement, 1 of the ways identified that the FDA can work together with medical professional societies as good stewards of public health is by developing a framework that can assist them in creating evidence-based guidelines on appropriate opioid analgesic prescribing to treat acute pain. The FDA awarded a contract to the National Academies of Sciences, Engineering, and Medicine (NASEM) to help advance the development of these evidence-based guidelines.
- **December 2018:** FDA advisors narrowly voted in favor of adding labeling changes that recommend co-prescription of naloxone for some or all patients who are prescribed opioids. The 12-11 vote during the joint meeting of the FDA's Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee followed questions of whether co-prescribing necessarily addresses the opioid crisis. Some suggested that co-prescribing could help initiate the conversation about the use of naloxone. Among those voting against the recommendation, some questioned whether a label change was needed, as co-prescribing already takes place in vulnerable, high-risk groups, while others pointed out that co-prescribing does not address deaths from illicit opioids.
- **January 2019:** The FDA announced it is moving forward to remove barriers and make it easier for drug manufacturers to develop naloxone over-the-counter (OTC). Dr. Gottlieb stated that the effort is part of an overall strategy to increase access to the opioid overdose antidote and decrease opioid overdose deaths.
- **February 2019:** The FDA announced they will require drug companies to conduct studies of whether opioids help to control pain when used for chronic pain. Dr. Gottlieb stated that "we are going to impose a mandate on existing products…to answer the question that people have been posing for years: whether you have declining efficacy, and whether that declining efficacy can lead to addiction." The new research will be required for all current and future opioids other than short acting opioids used in hospitals. According to Dr. Gottlieb, each manufacturer would be required to sponsor controlled, unbiased research of its products and negative results could lead to further restrictions on prescribing. A recent meta-analysis suggested that opioids have no clear advantage over other analgesics in

controlling chronic pain. In addition, the FDA will also order a second study to determine whether opioids can induce hyperalgesia.

- **April 2019:** The FDA has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include suicide, psychological distress, uncontrolled pain, and serious withdrawal symptoms. As part of the FDA's ongoing monitoring of risks associated with opioid pain medicines, they are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued. Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms and, in turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse. The FDA stated that health care professionals should not abruptly discontinue opioids in a patient who is physically dependent. They noted that there is no standard opioid tapering schedule that is suitable for all patients, and it is recommended to create a patient-specific plan to gradually taper the dose of the opioid and ensure ongoing monitoring and support as needed.

Centers for Medicare and Medicaid Services (CMS) Update(s):

- **January 2019:** CMS finalized new opioid policies for Medicare drug plans, which became effective on January 1, 2019. CMS recommended that residents of long-term care facilities, those in hospice care, patients receiving palliative care or end-of-life care, and patients being treated for active cancer-related pain should be excluded from these interventions. It was also recommended that these policies not impact patient's access to MAT, such as buprenorphine. In addition, it was stated that the morphine milligram equivalent (MME) thresholds and day supply limits are not prescribing limits and the patient or their prescriber can request an expedited or standard coverage determination from the plan for approval of higher amounts or a longer days' supply. The following CMS safety edits became effective on January 1, 2019:
  - 7-day supply limit for opioid naïve patients (hard edit)
  - Opioid care coordination edit at 90 MME which alerts pharmacists to review when the patient's cumulative MME per day reaches or exceeds 90 across all opioid prescriptions. The 90 MME threshold identifies potentially high-risk patients who may benefit from closer monitoring and care coordination.
  - Some plans may implement a hard edit when a patient's cumulative opioid daily dosage reaches 200 MME or greater
  - Concurrent opioid and benzodiazepine use or duplicative long-acting opioid therapy (soft edits)

News:

- **November 2018:** Results of a study to examine whether state-wide medical cannabis legalization was associated with a reduction in opioids received by Medicaid enrollees were published in the journal *Addiction*. At the time of the analysis, 29 states and Washington D.C. had legalized cannabis for medical use. The secondary data-analysis was conducted of

state-level opioid prescription records from 1993-2014 Medicaid State Drug Utilization Data. Linear time-series regressions assessed the associations between medical cannabis legalization and opioid prescriptions, controlling for state-level time-varying policy covariates, such as prescription drug monitoring programs, and socio-economic covariates, such as income. The primary outcomes were population-adjusted number, dosage, and Medicaid spending on opioid prescriptions. Outcomes for Schedule 2 and 3 opioids were analyzed separately. For Schedule 3 opioid prescriptions, medical cannabis legalization was associated with a 29.6% (P=0.03) reduction in the number of prescriptions, 29.9% (P=0.02) reduction in dosage, and 28.8% (P=0.04) reduction in related Medicaid spending. No evidence was found to support the associations between Schedule 2 opioid prescriptions and medical cannabis legalization. It was estimated that, if all the states had legalized medical cannabis by 2014, Medicaid annual spending on opioid prescriptions would be reduced by $17.8 million. The authors concluded that state-wide medical cannabis legalization appears to have been associated with reductions in both prescriptions and dosages of Schedule 3 (but not Schedule 2) opioids for Medicaid enrollees.

- **December 2018:** Results of a meta-analysis that included 96 randomized clinical trials (RCTs) and 26,169 patients with chronic non-cancer pain to review if the use of opioids was associated with greater benefits or harms compared with placebo and alternative analgesics were published in *The Journal of the American Medical Association (JAMA)*. The primary outcomes were pain intensity [score range, 0-10cm on a visual analog scale for pain; lower is better and the minimally important difference (MID) is 1cm], physical functioning [score range, 0-100 points on the 36-item Short Form Physical Component Score (SF-36 PCS); higher is better and the MID is 5 points], and the incidence of vomiting. Compared with placebo, opioid use was associated with reduced pain [weighted mean difference (WMD), −0.69cm (95% CI, −0.82 to −0.56cm) on a 10cm visual analog scale for pain; modeled risk difference for achieving the MID, 11.9% (95% CI, 9.7% to 14.1%)], improved physical functioning [WMD, 2.04 points (95% CI, 1.41 to 2.68 points) on the 100-point SF-36 PCS; modeled risk difference for achieving the MID, 8.5% (95% CI, 5.9% to 11.2%)], and increased vomiting (5.9% with opioids vs. 2.3% with placebo for trials that excluded patients with adverse events during a run-in period). Low- to moderate-quality evidence suggested similar associations of opioids with improvements in pain and physical functioning compared with nonsteroidal anti-inflammatory drugs (NSAIDs), tricyclic antidepressants, and anticonvulsants. The authors of the study concluded that in this meta-analysis of RCTs of patients with chronic non-cancer pain, evidence from high-quality studies showed that opioid use was associated with statistically significant but small improvements in pain and physical functioning and associated with an increased risk of vomiting compared to placebo. Comparisons of opioids with non-opioid alternatives suggested that the benefit for pain and functioning may be similar; however, the evidence was from low- to moderate-quality studies.
- **December 2018:** The Institute for Clinical and Economic Review (ICER) released a Final Evidence Report and Report-at-a-Glance assessing the comparative clinical effectiveness and value of ER medications indicated for the treatment of OUD. The report focused on an ER naltrexone injection (Vivitrol®), a buprenorphine implant (Probuphine®), and 2 ER buprenorphine injections (Sublocade™ and CAM2038). The report was reviewed at the November 2018 public meeting of the New England Comparative Effectiveness Public

Advisory Council (New England CEPAC). During the meeting, a majority of the panel found that the evidence is not adequate to demonstrate that any of these ER products provide superior net health benefit over buprenorphine/naloxone, nor is the evidence adequate to distinguish between the 4 ER treatments. However, it was noted that access to multiple treatment options for patients with OUD is a clinical and policy priority. Nevertheless, Vivitrol®, Probuphine®, and Sublocade™ are all far more expensive than buprenorphine/ naloxone, and at their current prices exceed commonly cited cost-effectiveness thresholds.

- **December 2018:** According to a report released by the CDC's National Center for Health Statistics, deaths from drug overdose in the United States rose by 54% from 2011 to 2016, with opioids, benzodiazepines, and stimulants being the most commonly used drug classes involved. The rate of overdose involving fentanyl or 1 of its analogs doubled each year from 2013 through 2016, when it took the lead in becoming the most mentioned drug in overdose deaths. In 2016, 29% of all overdose deaths involved fentanyl. Cocaine was the second or third most cited drug in overdose death records throughout the entire study period. The CDC's list of the 10 most frequently mentioned drugs in overdose deaths also included methadone, morphine, hydrocodone, alprazolam, diazepam, and methamphetamine. Of all 10 drugs, only methadone was associated with a decreasing overdose death rate from 2011 to 2016.
- **January 2019:** In a draft report released by a Congressional task force, Pain Management Best Practices Inter-Agency, members of the task force stressed that non-opioid medications and non-pharmacologic therapies should be used as first-line treatment for pain management. The task force was created to identify "gaps and inconsistencies" in pain management as part of the Comprehensive Addiction and Recovery Act of 2016. The authors recommended increasing the use of specific clinical practice guidelines (CPG) for individual diagnoses or causes of pain. They also called for increased access to effective pain management treatment. Other recommendations from the authors included to begin opioid therapy only when "benefits outweigh the risk" and to follow evidence-based guidelines; use "procedure-specific, multimodal regimens and therapies" before, during, and after an operation; and primary care clinicians and other non-pain specialists should collaborate early with pain specialists for patients with complex pain to mitigate complications.
- **January 2019:** The president of the American Medical Association (AMA), Barbara McAneny, called on payers to remove prior authorization requirements for MAT for OUD. According to the U.S. Surgeon General, MAT is considered the "gold standard" for treating OUD. Dr. McAneny stated that "if the payers won't do it on their own, then we urge state medical societies to partner with us to help introduce our model legislation –'Ensuring Access to Medication Assisted Treatment'- and work to get it enacted." The focus of the AMA bill is to prohibit utilization management barriers such as prior authorization and step therapy for MAT. The bill will require payers to provide coverage and access to all forms of MAT as well.
- **January 2019:** In a county-by-county analysis, researchers found that when drug companies increased their opioid marketing budgets by $5.29 per 1,000 population, the number of opioid prescriptions went up by 82% and the opioid death rate was 9% higher a year later. According to the lead author, Dr. Scott Hadland, it is not the amount of money paid to individual physicians that is key but the number of small interactions that seems

the most influential. Dr. Hadland's team looked at county-by-county data from 2013 to 2015 that included overdoses, what the companies spent on marketing to physicians, the number of marketing interactions, prescribing rates, and sociodemographic data. Information on marketing costs came from the Open Payments database mandated by the Physician Payments Sunshine Act. It showed that more than 67,000 physicians in the United States received 434,754 payments totaling nearly $40 million, or almost $600 per physician. About 1 in 5 family physicians received opioid-related marketing during the study period.

- **January 2019:** Researchers at Upstate Medical University in Syracuse are working with Walter Reed Army Institute of Health in advancing a novel approach to treating heroin addiction. Researchers are evaluating a heroin vaccine that could be a factor against opioid addiction. In studies on mice, the experimental vaccine essentially creates antibodies that prevent the effects of heroin from reaching the brain; therefore, there is no high. Furthermore, since it is a vaccine, it could last for several weeks.
- **February 2019:** Results of a study published online in the journal *Health Affairs* suggest that the introduction of abuse-deterrent Oxycontin® in 2010 may have played a role in the increase in hepatitis C infections due to some drug abusers switching to injectable heroin from the prescription opioid. Investigators found that states with above average rates of Oxycontin® misuse prior to the reformulation saw hepatitis C infections increase 3 times as fast as in other states. The lead investigator, David Powell, stated that the results suggest efforts to deter misuse of opioids can have "unintended, long-term public health consequences." David Murray, PhD, senior fellow at the Hudson Institute, cautions against concluding that reformulation of Oxycontin® alone is to blame for the rise in hepatitis C infections. He stated that "the issue is very complicated and teasing out what exactly the abuse-resistant formulary did against the backdrop of several major policy changes is very difficult."
- **April 2019:** The CDC issued a clarification letter that states the agency does not want to deny clinically appropriate opioid therapy to cancer and sickle cell disease patients, particularly those who are undergoing cancer treatment and survivors with chronic pain. The issuance was addressed to 3 major cancer organizations [American Society of Clinical Oncology (ASCO), American Society of Hematology (ASH), and National Comprehensive Cancer Network (NCCN)] who met with the CDC to discuss concerns about the impact of the agency's Guideline for Prescribing Opioids for Chronic Pain. The cancer organizations were worried that patients were being denied pain drugs or reimbursement as a result of the guideline, which is aimed at primary care providers. The CDC letter says the guideline "is not intended to deny any patients who suffer from chronic pain from opioid therapy as an option for pain management." Instead, the CDC's intention is to ensure that patients and clinicians "consider all safe and effective treatment options."

Pipeline:

- **July 2018:** Nektar Therapeutics announced that the FDA has accepted the company's New Drug Application (NDA) for review of NKTR-181 for treatment of chronic low back pain in adult patients new to opioid therapy. NKTR-181 is a new molecular entity and the first analgesic opioid molecule to exhibit a low incidence of specific central nervous system (CNS)-mediated side effects, such as euphoria.

- **August 2018:** Regeneron Pharmaceuticals, Inc. and Teva Pharmaceutical Industries Ltd. announced positive topline results from a Phase 3, randomized, double-blind, placebo-controlled study of fasinumab in patients with chronic pain from osteoarthritis (OA) of the knee or hip. The study met both co-primary endpoints and all key secondary endpoints at the week 16 primary efficacy analysis. Fasinumab-treated patients experienced significantly less pain and significantly improved functional ability from baseline compared to placebo.
- **September 2018:** Opiant Pharmaceuticals, Inc. has been awarded the second tranche of $3 million from the total grant of approximately $7.4 million from the National Institutes of Health's (NIH) National Institute on Drug Abuse (NIDA) for the development of OPNT003, nasal nalmefene, a long-acting opioid antagonist for the treatment of opioid overdose. Opiant intends to pursue a 505(b)(2) development path and anticipates the potential to submit a NDA for the drug and intranasal delivery device combination in 2020.
- **December 2018:** Mallinckrodt announced its specialty generics subsidiary, SpecGx, received a Complete Response Letter (CRL) from the FDA regarding the NDA for its investigational abuse-deterrent, IR reformulation of Roxicodone® (oxycodone tablets), MNK-812. The tablets were designed for the management of severe pain where alternative treatments have proven to be inadequate. The FDA said that some parts of the NDA required additional evaluation in order for the company to move forward with the application. The opioid painkiller, MNK-812, was designed to deter intranasal and intravenous abuse. The rejection of MNK-812 comes after the FDA's Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee voted 10 to 7 to approve the opioid painkiller.
- **January 2019:** Pfizer, Inc. and Eli Lilly and Company announced positive top-line results from a Phase 3 study evaluating tanezumab, a humanized monoclonal antibody that is part of an investigational class of non-opioid pain medications known as nerve growth factor (NGF) inhibitors, in patients with moderate-to-severe OA pain. The 5mg treatment arm met all 3 co-primary endpoints at 24 weeks, demonstrating a statistically significant improvement in pain, physical function, and the patients' overall assessment of their OA compared to those receiving placebo. The 2.5mg treatment arm met 2 of the 3 protocol-defined co-primary efficacy endpoints compared to placebo, demonstrating a statistically significant improvement in pain and physical function, while patients' overall assessment of their OA was not statistically different than placebo. Tanezumab is the first NGF inhibitor to receive Fast Track designation from the FDA.
- **January 2019:** Pain Therapeutics, Inc. announced 2 new publications for its drug candidate Remoxy™ ER (oxycodone ER) were published in the *Journal of Opioid Management*. Remoxy™ ER is a new type of abuse-deterrent, twice-daily gel capsule formulation of oxycodone that has physical/chemical properties intended to deter abuse. The first publication concluded that Remoxy™ ER demonstrated robust, meaningful abuse-deterrence relative to OxyContin® and Xtampza® ER. The second publication concluded that Remoxy™ ER demonstrated significantly lower nasal abuse potential compared to oxycodone IR or Oxycontin®. In August 2018, the FDA issued a CRL for Remoxy™ ER. Pain Therapeutics disagrees with the FDA's conclusions regarding the abuse-deterrent properties of Remoxy™ ER and has requested a neutral re-examination of its data.
- **March 2019:** In November 2018, the FDA declined to approve oliceridine, a mu-opioid receptor modulator, for moderate-to-severe pain. In March 2019, the FDA also removed

the Breakthrough Therapy designation from oliceridine. The agency said that Trevena had not submitted adequate safety data to support its proposed dosing, and it said the drug had abuse and overdose potential similar to other opioid drugs. It also asked for additional information regarding QT prolongation. The FDA has agreed that Trevena can refile for oliceridine at a maximum daily dose of 27mg, provided they complete a Phase 1 study in healthy volunteers to address the potential for QT interval prolongation.

Cassipa® (Buprenorphine/Naloxone) Product Summary[2,34]

Indication(s): Cassipa® film contains buprenorphine, a partial-opioid agonist, and naloxone, an opioid antagonist, and is indicated for the maintenance treatment of opioid dependence. Cassipa® should be used as part of a complete treatment plan to include counseling and psychological support.

Dosing:

- Cassipa® is supplied as a SL film containing 16mg buprenorphine and 4mg naloxone.
- It is recommended to administer Cassipa® SL as a single daily dose by placing 1 film under the tongue, close to the base on the left or right side, and allowing the film to completely dissolve.
- Cassipa® should only be used after induction and stabilization of the patient, and the patient has been titrated to a dose of 16mg buprenorphine using another marketed product.
- Cassipa® must be administered whole and should not be cut, chewed, or swallowed.
- Prescription use of Cassipa® is limited under the Drug Addiction Treatment Act.

Efficacy: Cassipa® was approved through an abbreviated approval pathway, 505(b)(2). The application for Cassipa® relied, in part, on the FDA's finding of safety and effectiveness for Suboxone® SL film to support approval. The applicant demonstrated that reliance on the FDA's finding of safety and effectiveness for Suboxone® was scientifically justified and provided Cassipa®-specific pharmacokinetic data to establish the drug's safety and efficacy for its approved uses.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Month
Cassipa® (buprenorphine/naloxone) 16mg/4mg SL films	**Not Available**	**Not Available**
Suboxone® (buprenorphine/naloxone) 8mg/2mg SL films	$8.21	$492.60*^
buprenorphine/naloxone 8mg/2mg SL tablets	$1.75	$105.00^

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.
SL = sublingual; Unit = SL film or SL tablet
*Supplementally rebated product.
^Dosing based on buprenorphine 16mg/naloxone 4mg daily.

Levorphanol Product Summary[35]

Indication(s): Levorphanol tartrate tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

- Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, levorphanol should be reserved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics, opioid combination products):
  - Have not been tolerated, or are not expected to be tolerated;
  - Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Dosing:

- Levorphanol is supplied as 1mg, 2mg, and 3mg tablets. It is recommended to use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals. It is recommended to initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse. Patients should be closely monitored for respiratory depression, especially within the first 24 to 72 hours of initiating therapy and following dosage increases and the dose should be adjusted accordingly.
- For use as the first opioid analgesic, the recommended dose of levorphanol is 1 to 2mg every 6 to 8 hours as needed for pain, provided the patient is assessed for signs of hypoventilation and excessive sedation. If necessary, the dose may be increased up to 3mg every 6 to 8 hours, after adequate evaluation of the patient's response. Higher doses may be appropriate in opioid-tolerant patients.
- There is inter-patient variability in the potency of opioid drugs and opioid formulations. Therefore, a conservative approach is advised when determining the total daily dosage of levorphanol. It is safer to underestimate a patient's 24-hour levorphanol dosage than to overestimate the dosage and manage an adverse reaction due to overdose. Levorphanol is 4 to 8 times as potent as morphine and has a longer half-life. Because there is incomplete cross-tolerance among opioids, when converting a patient from morphine to levorphanol, the total daily dose of levorphanol should begin at approximately 1/15 to 1/12 of the total daily dose of oral morphine that such patients had previously required, and then the dose should be adjusted to the patient's clinical response.
- Elderly patients (65 years of age or older) may have increased sensitivity to levorphanol. In general, caution should be exercised when selecting a dosage for an elderly patient, usually starting at the lower end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. The initial dose of levorphanol should be reduced by 50% or more in the infirm elderly patient.
- When a patient who has been taking levorphanol regularly and may be physically dependent no longer requires therapy with levorphanol, it is recommended to taper the dose gradually, by 25% to 50% every 2 to 4 days, while monitoring carefully for signs and symptoms of withdrawal.

Boxed Warning: Addiction, abuse, and misuse; Risk Evaluation and Mitigation Strategy (REMS); life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; and risks from concomitant use with benzodiazepines or other CNS depressants

Efficacy: Clinical trials have been reported in the medical literature that investigated the use of levorphanol as a preoperative medication, postoperative analgesic, and in the management of chronic pain due primarily to malignancy. In these clinical settings, levorphanol has been shown to be an effective analgesic of the mu-opioid type and similar to morphine, meperidine, or fentanyl. Levorphanol has been studied in chronic cancer patients. It is recommended to individualize dosage to each patient's level of opioid tolerance. A study of levorphanol tablets indicates that the relative potency is approximately 4 to 8 times that of morphine, depending on the specific circumstances of use. In postoperative patients, intramuscular (IM) levorphanol was determined to be about 8 times as potent as IM morphine, whereas in cancer patients with chronic pain, it was found to be about 4 times as potent.

Cost Comparison:

Medication	Cost Per Unit	Cost Per Day*
levorphanol 2mg tablet	**$44.50**	**$178.00**
morphine 15mg tablet	$0.35	$1.40

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 per day based on maximum of 4 tablets per day. Please note, these are not equianalgesic doses.

Recommendations

The College of Pharmacy, in partnership with the Oklahoma Health Care Authority (OHCA), recommends the implementation of a daily MME limit of 90 to coincide with CMS safety alerts.

1. Prior authorization would be required for members exceeding the 90 MME limit per day. Prior authorizations would require patient-specific, clinically significant reasoning for daily doses of 90 MME or greater. Prescribers must provide reasoning for why tapering to below the MME limit is not appropriate for the member.
2. 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. Oncology, sickle cell disease, and hemophilia diagnoses would also be excluded from the MME limit.

Furthermore, the College of Pharmacy, in partnership with the OHCA, recommends that select MAT products no longer require prior authorization. In addition, it is recommended to update the quantity limit for buprenorphine-containing medications used for MAT to 16mg bioequivalent buprenorphine per day (proposed changes noted in red). Each request for greater than 16mg bioequivalent buprenorphine per day will be evaluated on a case-by-case basis.

The College of Pharmacy recommends the following:

1. The placement of levorphanol tartrate into the Special Prior Authorization (PA) Tier of the Opioid Analgesics Product Based Prior Authorization (PBPA) category with the following criteria listed in red.
2. The prior authorization of Cassipa® (buprenorphine/naloxone SL films) with the following criteria (proposed changes noted in red).

Levorphanol Tartrate Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use alternative lower tiered short-acting opioid analgesics must be provided.

Suboxone® [Buprenorphine/Naloxone Sublingual (SL) Tablets and Films], Subutex® (Buprenorphine SL Tablets), Zubsolv® (Buprenorphine/Naloxone SL Tablets), Bunavail® (Buprenorphine/Naloxone Buccal Films), and Cassipa® (Buprenorphine/Naloxone SL Films) 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.
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.
3. For Cassipa®, the member must have been titrated to a dose of 16mg buprenorphine using another buprenorphine product prior to approval.
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 opioids (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, 4mg/1mg~~, and 8mg/2mg~~ 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 ~~60~~ SL films per 30 days will apply.
    d. **Subutex®** 2mg ~~and 8mg~~ 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, 2.9mg/0.71mg~~, and 5.7mg/1.4mg~~ SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. **Zubsolv®** 5.7mg/1.4mg ~~and 8.6mg/2.1mg~~ 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 ~~and 4.2mg/0.7mg~~ 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 ~~60~~ 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 >16 ~~24~~mg bioequivalent buprenorphine per day will be evaluated on a case-by-case basis.
2. A taper schedule, dates of an attempted taper with reason for failure, or a patient-specific, clinically significant reason why a taper schedule or 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.

Utilization Details of Opioid Analgesics: Calendar Year 2018

Short-Acting Opioid Analgesics

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
IMMEDIATE-RELEASE HYDROCODONE PRODUCTS					
HYDROCO/APAP TAB 10-325MG	54,931	10,133	$1,169,924.74	5.42	$21.30
HYDROCO/APAP TAB 7.5-325MG	43,607	21,429	$688,226.13	2.03	$15.78
HYDROCO/APAP TAB 5-325MG	34,522	23,951	$435,263.53	1.44	$12.61
HYDROCO/APAP SOL 7.5-325MG	7,635	7,089	$184,195.23	1.08	$24.13
HYDROCOD/IBU TAB 7.5-200MG	777	296	$19,105.91	2.63	$24.59
LORCET HD TAB 10-325MG	257	81	$5,864.73	3.17	$22.82
HYDROCOD/IBU TAB 10-200MG	85	14	$18,380.26	6.07	$216.24
LORCET PLUS TAB 7.5-325MG	67	41	$1,475.76	1.63	$22.03
IBUDONE TAB 10-200MG	56	8	$6,282.55	7	$112.19
LORCET TAB 5-325MG	20	13	$259.31	1.54	$12.97
HYDROCOD/IBU TAB 5-200MG	16	6	$3,353.80	2.67	$209.61
HYDROCO/APAP TAB 2.5-325MG	7	4	$420.13	1.75	$60.02
IBUDONE TAB 5-200MG	3	3	$135.87	1	$45.29
SUBTOTAL	**141,983**	**55,948***	**$2,532,887.95**	**2.54**	**$17.84**
IMMEDIATE-RELEASE OXYCODONE PRODUCTS					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
OXYCOD/APAP TAB 10-325MG	20,307	4,386	$723,332.20	4.63	$35.62
OXYCOD/APAP TAB 5-325MG	15,637	12,361	$201,845.65	1.27	$12.91
OXYCOD/APAP TAB 7.5-325	9,255	4,085	$219,338.53	2.27	$23.70
OXYCODONE TAB 15MG	6,427	1,201	$156,539.25	5.35	$24.36
OXYCODONE TAB 10MG	5,757	1,411	$120,591.76	4.08	$20.95
OXYCODONE TAB 30MG	3,560	599	$130,027.25	5.94	$36.52
OXYCODONE TAB 20MG	3,252	619	$107,078.76	5.25	$32.93
OXYCODONE TAB 5MG	2,615	1,560	$35,368.56	1.68	$13.53
OXYCODONE SOL 5MG/5ML	675	602	$14,628.47	1.12	$21.67
OXYCODONE TAB HCL 30MG	229	72	$8,243.31	3.18	$36.00
ENDOCET TAB 10-325MG	115	43	$4,756.80	2.67	$41.36
OXYCODONE CAP 5MG	38	26	$2,170.41	1.46	$57.12
ENDOCET TAB 5-325MG	37	25	$462.98	1.48	$12.51
OXYCOD/APAP TAB 2.5-325MG	25	3	$3,307.28	8.33	$132.29
OXYCODONE CAP HCL 5MG	17	14	$933.48	1.21	$54.91
OXYCOD/ASA TAB 4.8355-325MG	15	14	$401.52	1.07	$26.77
OXYCODONE CON 100/5ML	11	5	$3,593.67	2.2	$326.70
OXYCODONE CON 20MG/ML	11	2	$10,102.04	5.5	$918.37
ENDOCET TAB 7.5-325MG	8	7	$220.09	1.14	$27.51
OXYCODONE POW HCL	2	2	$93.72	1	$46.86
SUBTOTAL	**67,993**	**23,357***	**$1,743,035.73**	**2.91**	**$25.64**
CODEINE PRODUCTS					
APAP/CODEINE TAB 300-30MG	14,595	9,918	$187,184.44	1.47	$12.83
APAP/CODEINE TAB 300-60MG	7,569	2,183	$190,756.83	3.47	$25.20
BUT/APAP/CAF/COD 50/325/40/30MG	485	205	$27,874.80	2.37	$57.47
BUT/ASA/CAF/COD 50/325/40/30MG	242	64	$28,393.90	3.78	$117.33
ASCOMP/COD 50/325/40/30MG	104	31	$8,355.86	3.35	$80.34
APAP/CODEINE SOL 120-12MG/5ML	55	34	$888.09	1.62	$16.15
APAP/CODEINE TAB 300-15MG	43	36	$605.71	1.19	$14.09
CODEINE SULF TAB 30MG	20	12	$797.37	1.67	$39.87
CODEINE SULF TAB 60MG	14	2	$1,251.47	7	$89.39
CODEINE SULF TAB 15MG	12	4	$687.00	3	$57.25
SUBTOTAL	**23,139**	**11,958***	**$446,795.47**	**1.94**	**$19.31**
IMMEDIATE-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHON TAB 4MG	1,069	263	$18,520.15	4.06	$17.32
HYDROMORPHON TAB 2MG	491	278	$6,470.74	1.77	$13.18
HYDROMORPHON TAB 8MG	368	77	$13,090.04	4.78	$35.57
HYDROMORPHON LIQ 1MG/ML	28	4	$12,232.46	7	$436.87
DILAUDID TAB 8MG	11	1	$8,901.03	11	$809.18
HYDROMORPHON INJ 500/50ML	11	2	$3,565.39	5.5	$324.13
SUBTOTAL	**1,978**	**569***	**$62,779.81**	**3.48**	**$31.74**
IMMEDIATE-RELEASE MORPHINE PRODUCTS					
MORPHINE SUL TAB 15MG	1,969	446	$48,769.21	4.41	$24.77
MORPHINE SUL TAB 30MG	608	109	$19,707.00	5.58	$32.41
MORPHINE SUL SOL 10MG/5ML	143	104	$1,956.46	1.38	$13.68
MORPHINE SUL SOL 100/5ML	90	54	$4,429.23	1.67	$49.21
MORPHINE SUL SOL 20MG/5ML	12	9	$278.75	1.33	$23.23
MORPHINE SUL INJ 50MG/ML	2	1	$45.72	2	$22.86
MORPHINE SUL INJ 25MG/ML	1	1	$45.80	1	$45.80
MORPHINE SUL INJ 4MG/ML	1	1	$48.17	1	$48.17

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
DURAMORPH INJ 1MG/ML	1	1	$27.87	1	$27.87
SUBTOTAL	**2,827**	**679***	**$75,308.21**	**4.16**	**$26.64**
IMMEDIATE-RELEASE TRAMADOL PRODUCTS					
TRAMADOL HCL TAB 50MG	34,507	13,122	$345,658.27	2.63	$10.02
TRAMADL/APAP TAB 37.5-325MG	409	306	$6,371.18	1.34	$15.58
SUBTOTAL	**34,916**	**13,374***	**$352,029.45**	**2.61**	**$10.08**
IMMEDIATE-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA TAB 50MG	63	16	$28,924.80	3.94	$459.12
NUCYNTA TAB 100MG	7	2	$6,597.36	3.5	$942.48
NUCYNTA TAB 75MG	5	2	$3,486.57	2.5	$697.31
SUBTOTAL	**75**	**19***	**$39,008.73**	**3.95**	**$520.12**
IMMEDIATE-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB HCL 10MG	213	26	$35,672.68	8.19	$167.48
OXYMORPHONE TAB HCL 5MG	43	8	$3,067.39	5.38	$71.33
SUBTOTAL	**256**	**30***	**$38,740.07**	**8.53**	**$151.33**
IMMEDIATE-RELEASE FENTANYL PRODUCTS					
FENTANYL OT LOZ 400MCG	3	1	$2,703.80	3	$901.27
SUBSYS SPR 100MCG	2	2	$7,085.78	1	$3,542.89
SUBSYS SPR 200MCG	1	1	$9,048.30	1	$9,048.30
FENTANYL CIT INJ 100MCG	1	1	$6.65	1	$6.65
SUBTOTAL	**7**	**4***	**$18,844.53**	**1.75**	**$2,692.08**
PENTAZOCINE PRODUCTS					
PENTAZ/NALOX TAB 50-0.5MG	461	185	$65,942.71	2.49	$143.04
SUBTOTAL	**461**	**185***	**$65,942.71**	**2.49**	**$143.04**
MEPERIDINE PRODUCTS					
MEPERIDINE SOL 50MG/5ML	383	280	$3,723.58	1.37	$9.72
MEPERIDINE TAB 50MG	307	237	$7,986.87	1.3	$26.02
MEPERIDINE TAB 100MG	30	9	$1,527.02	3.33	$50.90
MEPERIDINE INJ 100MG/ML	3	3	$39.80	1	$13.27
SUBTOTAL	**723**	**526***	**$13,277.27**	**1.37**	**$18.36**
TOTAL	**274,358**	**87,883***	**$5,388,649.93**	**3.12**	**$19.64**

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

Long-Acting Opioid Analgesics

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
EXTENDED-RELEASE HYDROCODONE PRODUCTS					
HYSINGLA ER TAB 40 MG	585	119	$283,869.35	4.92	$485.25
HYSINGLA ER TAB 30 MG	476	111	$172,196.22	4.29	$361.76
HYSINGLA ER TAB 20 MG	469	151	$115,647.43	3.11	$246.58
HYSINGLA ER TAB 60 MG	199	44	$134,738.36	4.52	$677.08
HYSINGLA ER TAB 80 MG	103	15	$93,409.72	6.87	$906.89
HYSINGLA ER TAB 120 MG	14	3	$18,447.32	4.67	$1,317.67
HYSINGLA ER TAB 100 MG	14	6	$16,938.81	2.33	$1,209.92
ZOHYDRO ER CAP 10MG	11	2	$5,497.86	5.5	$499.81
ZOHYDRO ER CAP 40MG	4	2	$2,349.68	2	$587.42
ZOHYDRO ER CAP 30MG	1	1	$571.37	1	$571.37
ZOHYDRO ER CAP 15MG	1	1	$270.37	1	$270.37

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
SUBTOTAL	**1,877**	**369***	**$843,936.49**	**5.09**	**$449.62**
EXTENDED-RELEASE OXYCODONE PRODUCTS					
OXYCONTIN TAB 20MG CR	2,298	507	$858,020.12	4.53	$373.38
OXYCONTIN TAB 10MG CR	1,715	442	$335,074.29	3.88	$195.38
OXYCONTIN TAB 15MG CR	1,202	284	$356,094.38	4.23	$296.25
OXYCONTIN TAB 30MG CR	1,133	244	$598,419.32	4.64	$528.17
OXYCONTIN TAB 40MG CR	817	162	$544,767.26	5.04	$666.79
OXYCONTIN TAB 80MG CR	577	72	$816,499.12	8.01	$1,415.08
OXYCONTIN TAB 60MG CR	547	107	$522,192.47	5.11	$954.65
XTAMPZA ER CAP 18MG	23	5	$10,091.11	4.6	$438.74
XTAMPZA ER CAP 36MG	10	3	$6,802.78	3.33	$680.28
XTAMPZA ER CAP 13.5MG	8	3	$2,823.78	2.67	$352.97
XTAMPZA ER CAP 9MG	7	4	$1,647.38	1.75	$235.34
XTAMPZA ER CAP 27MG	4	2	$2,468.12	2	$617.03
SUBTOTAL	**8,341**	**1,331***	**$4,054,900.13**	**6.27**	**$486.14**
EXTENDED-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHON TAB 8MG ER	26	5	$5,434.05	5.2	$209.00
HYDROMORPHON TAB 32MG ER	19	4	$27,431.68	4.75	$1,443.77
HYDROMORPHON TAB 12MG ER	11	4	$5,554.83	2.75	$504.98
HYDROMORPHON TAB 16MG ER	1	1	$432.79	1	$432.79
SUBTOTAL	**57**	**14***	**$38,853.35**	**4.07**	**$681.64**
EXTENDED-RELEASE MORPHINE PRODUCTS					
MORPHINE SUL TAB 15MG ER	3,528	683	$75,278.02	5.17	$21.34
MORPHINE SUL TAB 30MG ER	3,080	536	$97,548.37	5.75	$31.67
MORPHINE SUL TAB 60MG ER	1,124	188	$60,944.37	5.98	$54.22
MORPHINE SUL TAB 100MG ER	262	43	$21,463.08	6.09	$81.92
EMBEDA CAP 20-0.8MG	104	29	$33,355.06	3.59	$320.72
EMBEDA CAP 30-1.2MG	65	13	$26,911.34	5	$414.02
MORPHINE SUL TAB 200MG ER	48	7	$10,383.52	6.86	$216.32
MORPHINE SUL CAP 30MG ER	33	6	$5,086.02	5.5	$154.12
MORPHINE SUL CAP 60MG ER	26	3	$9,885.62	8.67	$380.22
MORPHINE SUL CAP 50MG ER	21	5	$5,036.53	4.2	$239.83
MORPHINE SUL CAP 20MG ER	19	7	$2,737.27	2.71	$144.07
MORPHABOND TAB 15MG ER	12	3	$3,684.10	4	$307.01
KADIAN CAP 50MG ER	12	1	$11,376.07	12	$948.01
KADIAN CAP 200MG ER	10	1	$46,805.09	10	$4,680.51
MORPHABOND TAB 30MG ER	9	3	$5,724.92	3	$636.10
KADIAN CAP 40MG ER	8	2	$2,744.34	4	$343.04
MORPHINE SUL CAP 10MG ER	8	5	$1,066.86	1.6	$133.36
EMBEDA CAP 50-2MG	6	1	$2,677.89	6	$446.32
MORPHINE SUL CAP 90MG ER	5	1	$2,040.25	5	$408.05
MORPHINE SUL CAP 100MG ER	2	2	$1,508.20	1	$754.10
MORPHINE SUL CAP 40MG ER	1	1	$855.95	1	$855.95
MORPHINE SUL CAP 80MG ER	1	1	$614.87	1	$614.87
SUBTOTAL	**8,384**	**1,254***	**$427,727.74**	**6.69**	**$51.02**
EXTENDED-RELEASE TRAMADOL PRODUCTS					
TRAMADOL HCL TAB 100MG ER	50	19	$2,591.38	2.63	$51.83
TRAMADOL HCL TAB 200MG ER	40	14	$3,117.68	2.86	$77.94
TRAMADOL HCL CAP ER 100MG	4	1	$899.63	4	$224.91
TRAMADOL HCL TAB 100MG ER	4	1	$274.93	4	$68.73

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TRAMADOL HCL TAB 200MG ER	1	1	$103.41	1	$103.41
SUBTOTAL	**99**	**32***	**$6,987.03**	**3.09**	**$70.58**
EXTENDED-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA ER TAB 50MG	26	10	$9,402.72	2.6	$361.64
NUCYNTA ER TAB 100MG	13	6	$8,000.39	2.17	$615.41
NUCYNTA ER TAB 250MG	13	2	$17,371.75	6.5	$1,336.29
NUCYNTA ER TAB 200MG	9	2	$9,699.07	4.5	$1,077.67
NUCYNTA ER TAB 150MG	1	1	$784.39	1	$784.39
SUBTOTAL	**62**	**18***	**$45,258.32**	**3.44**	**$729.97**
EXTENDED-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG ER	13	1	$2,611.69	13	$200.90
OXYMORPHONE TAB 20MG ER	6	1	$2,337.10	6	$389.52
OPANA ER TAB 40MG	6	1	$5,785.50	6	$964.25
OXYMORPHONE TAB 40MG ER	5	1	$2,994.62	5	$598.92
OPANA ER TAB 20MG	3	1	$1,633.56	3	$544.52
OPANA ER TAB 30MG	2	2	$1,206.81	1	$603.41
OXYMORPHONE TAB 30MG ER	1	1	$763.79	1	$763.79
OPANA ER TAB 10MG	1	1	$294.66	1	$294.66
SUBTOTAL	**37**	**7***	**$17,627.73**	**5.29**	**$476.43**
EXTENDED-RELEASE FENTANYL PRODUCTS					
FENTANYL DIS 25MCG/HR	1,149	301	$45,097.16	3.82	$39.25
FENTANYL DIS 50MCG/HR	996	238	$56,835.66	4.18	$57.06
FENTANYL DIS 75MCG/HR	580	115	$46,019.62	5.04	$79.34
FENTANYL DIS 100MCG/H	470	96	$47,606.33	4.9	$101.29
FENTANYL DIS 12MCG/HR	412	133	$42,621.33	3.1	$103.45
FENTANYL DIS 37.5MCG	73	18	$30,885.49	4.06	$423.09
DURAGESIC DIS 50MCG/HR	11	1	$8,036.51	11	$730.59
SUBTOTAL	**3,691**	**624***	**$277,102.10**	**5.92**	**$75.08**
METHADONE PRODUCTS					
METHADONE TAB 10MG	791	107	$16,789.23	7.39	$21.23
METHADONE TAB 5MG	75	15	$1,544.89	5	$20.60
METHADONE SOL 5MG/5ML	68	49	$860.98	1.39	$12.66
METHADONE SOL 10MG/5ML	10	4	$121.48	2.5	$12.15
SUBTOTAL	**944**	**169***	**$19,316.58**	**5.59**	**$20.46**
BUPRENORPHINE PAIN PRODUCTS					
BUPRENORPHIN DIS 10MCG/HR	581	329	$167,468.79	1.77	$288.24
BUPRENORPHIN DIS 15MCG/HR	425	211	$178,988.25	2.01	$421.15
BUPRENORPHIN DIS 20MCG/HR	392	134	$203,788.14	2.93	$519.87
BUTRANS DIS 10MCG/HR	372	218	$146,113.90	1.71	$392.78
BUTRANS DIS 15MCG/HR	277	132	$153,165.46	2.1	$552.94
BUTRANS DIS 20MCG/HR	275	101	$185,996.55	2.72	$676.35
BELBUCA MIS 300MCG	168	70	$75,633.21	2.4	$450.20
BUPRENORPHIN DIS 5MCG/HR	160	89	$30,686.97	1.8	$191.79
BUPRENORPHIN DIS 7.5/HR	130	84	$34,824.99	1.55	$267.88
BELBUCA MIS 150MCG	119	68	$34,861.07	1.75	$292.95
BELBUCA MIS 450MCG	113	49	$70,347.60	2.31	$622.55
BUTRANS DIS 5MCG/HR	78	52	$20,678.32	1.5	$265.11
BUTRANS DIS 7.5/HR	70	43	$25,541.62	1.63	$364.88
BELBUCA MIS 600MCG	65	30	$43,996.52	2.17	$676.87
BELBUCA MIS 75MCG	39	25	$11,645.98	1.56	$298.61

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
BELBUCA MIS 750MCG	9	5	$6,621.27	1.8	$735.70
BELBUCA MIS 900MCG	3	2	$2,207.35	1.5	$735.78
BUPRENORPHIN DIS 10MCG/HR	581	329	$167,468.79	1.77	$288.24
SUBTOTAL	**3,276**	**951***	**$1,392,565.99**	**3.44**	**$425.08**
TOTAL	**26,768**	**4,219***	**$7,124,275.46**	**6.34**	**$266.15**

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

Utilization Details of MAT Medications: Calendar Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
SUBOXONE MIS 8-2MG	9,069	1,268	$4,249,176.19	7.15	$468.54
BUPREN/NALOX SUB 8-2MG	3,548	636	$518,557.70	5.58	$146.15
NALTREXONE TAB 50MG	3,346	744	$130,193.76	4.5	$38.91
BUPRENORPHIN SUB 8MG	2,000	337	$166,254.45	5.93	$83.13
SUBOXONE MIS 2-0.5MG	183	48	$33,073.83	3.81	$180.73
SUBOXONE MIS 4-1MG	156	37	$45,504.45	4.22	$291.70
ZUBSOLV SUB 5.7-1.4MG	135	18	$60,596.82	7.5	$448.87
BUPREN/NALOX SUB 2-0.5MG	129	34	$17,566.28	3.79	$136.17
BUPREN/NALOX MIS 8-2MG	123	72	$39,620.33	1.71	$322.12
VIVITROL INJ 380MG	90	32	$123,269.12	2.81	$1,369.66
SUBOXONE MIS 12-3MG	87	12	$84,901.68	7.25	$975.88
BUPRENORPHIN SUB 2MG	64	19	$3,362.89	3.37	$52.55
ZUBSOLV SUB 8.6-2.1MG	36	3	$28,577.53	12	$793.82
SUBLOCADE INJ 300MG/1.5ML	5	3	$7,949.39	1.67	$1,589.88
ZUBSOLV SUB 1.4-0.36MG	3	1	$873.08	3	$291.03
ZUBSOLV SUB 11.4-2.9MG	2	1	$1,936.70	2	$968.35
BUNAVAIL MIS 6.3-1MG	1	1	$937.75	1	$937.75
ZUBSOLV SUB 2.9-0.71MG	1	1	$232.56	1	$232.56
TOTAL	**18,978**	**2,689***	**$5,512,584.51**	**7.06**	**$290.47**

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

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Appendix Q

Industry News and Updates

Oklahoma Health Care Authority
June 2019

Introduction

The following report is an overview of recent issues, important literature, and select guideline updates impacting pharmacy and health care. Information that is expected to have a particular impact in the SoonerCare population has been included for review.

News and Updates[1,2]

News:

- **Measles:** A recent Centers for Disease Control and Prevention (CDC) report found that from January 1 to April 26, 2019, there were a total of 704 measles cases in the United States, which is the highest number since 1994. Among the 704 measles cases, 71% occurred in unvaccinated individuals. The report emphasizes the importance of the measles, mumps, and rubella (MMR) vaccine and ensuring that children and adults are up-to-date on the vaccine. It is recommended for children to get 2 doses of the MMR vaccine, with the first at 12 to 15 months of age and the second at 4 to 6 years of age.
- **Drug Recyclers:** The FDA has chosen 2 organizations devoted to recycling oral cancer drugs for a drug supply-chain pilot project. Good Shepherd Pharmacy and RemediChain take unused oral chemotherapy medications donated by individuals and cancer clinics and provide them to patients who cannot afford them. In the oncology community, cancer drug recycling is gaining traction. The process has many challenges, and this is where an innovative drug supply-chain management comes into play. Both organizations use "blockchain-enabled" data technology, which allows for the tracking of "medicine transfers" in the drug supply chain. Phil Baker, Pharm.D., cofounder of both organizations, stated that a re-creation of the "chain of custody" via blockchain technology assures a medication's origin and quality. The new pilot project is the result of the federal Drug Supply Chain Security Act, and the FDA wants to evaluate new tools to see if they "enhance the safety and security of the drug supply chain." According to Dr. Baker, there is no tracking process after a drug goes from a pharmacy to another facility or hospital or when a drug is provided to an individual patient. The FDA is interested in seeing if tracking the supply chain further is helpful and therefore created the pilot project.

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Appendix R

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 3rd, 2019

FDA approves new treatment for hospital-acquired and ventilator-associated bacterial pneumonia

The FDA approved a new indication for the previously FDA-approved drug, Zerbaxa® (ceftolozane and tazobactam) for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in patients 18 years and older. The FDA initially approved Zerbaxa® in 2014 to treat complicated intra-abdominal infections and for complicated urinary tract infections.

HABP/VABP occur in patients in hospitals or other health care facilities and can be caused by a variety of bacteria. According to data from the U.S. Centers for Disease Control and Prevention, HABP and VABP are currently the second most common type of hospital-acquired infection in the United States, and are a significant issue in patients in the intensive care unit (ICU).

The safety and efficacy of Zerbaxa® for the treatment of HABP/VABP, administered via injection, was demonstrated in a multinational, double-blind study that compared Zerbaxa® to another antibacterial drug in 726 adult patients hospitalized with HABP/VABP. The study showed that mortality and cure rates were similar between Zerbaxa® and the comparator treatment.

The most common adverse reactions observed in the HABP/VABP trial among patients treated with Zerbaxa® were elevated liver enzyme levels, renal impairment or failure, and diarrhea.

Zerbaxa® should not be used in patients with known serious hypersensitivity to components of Zerbaxa®, as well as hypersensitivity to piperacillin/tazobactam or other members of the beta lactam class of antibacterial drugs.

Zerbaxa® received FDA's Qualified Infectious Disease Product (QIDP) designation for the treatment of HABP/VABP. The QIDP 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. As part of QIDP designation, the Zerbaxa® marketing application for the HABP/VABP indication was granted Priority Review under which the FDA's goal is to take action on an application within an expedited time frame.

The FDA granted the approval of Zerbaxa® for the treatment of HABP/VABP to Merck & Co., Inc.

FDA NEWS RELEASE

For Immediate Release: May 24th, 2019

FDA approves first PI3K inhibitor for breast cancer

The FDA approved Piqray® (alpelisib) tablets, to be used in combination with the FDA-approved endocrine therapy fulvestrant, to treat postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer (as detected by an FDA-approved test) following progression on or after an endocrine-based regimen.

The FDA also approved the companion diagnostic test, therascreen PIK3CA RGQ PCR Kit, to detect the PIK3CA mutation in a tissue and/or a liquid biopsy. Patients who are negative by the therascreen test using the liquid biopsy should undergo tumor biopsy for PIK3CA mutation testing.

Metastatic breast cancer is breast cancer that has spread beyond the breast to other organs in the body (most often the bones, lungs, liver or brain). When breast cancer is hormone-receptor positive, patients may be treated with anti-hormonal treatment (also called endocrine therapy), alone or in combination with other medicines, or chemotherapy.

The efficacy of Piqray® was studied in the SOLAR-1 trial, a randomized trial of 572 postmenopausal women and men with HR-positive, HER2-negative, advanced or metastatic breast cancer whose cancer had progressed while on or after receiving an aromatase inhibitor. Results from the trial showed the addition of

Piqray® to fulvestrant significantly prolonged progression- free survival (median of 11 months vs. 5.7 months) in patients whose tumors had a PIK3CA mutation.
Common side effects of Piqray® are high blood sugar levels, increase in creatinine, diarrhea, rash, decrease in lymphocyte count in the blood, elevated liver enzymes, nausea, fatigue, low red blood cell count, increase in lipase (enzymes released by the pancreas), decreased appetite, stomatitis, vomiting, weight loss, low calcium levels, aPTT prolonged (blood clotting taking longer to occur than it should), and hair loss.
Health care professionals are advised to monitor patients taking Piqray® for severe hypersensitivity reactions (intolerance). Patients are warned of potentially severe skin reactions (rashes that may result in peeling and blistering of skin or mucous membranes like the lips and gums). Health care professionals are advised not to initiate treatment in patients with a history of severe skin reactions such as Stevens-Johnson Syndrome, erythema multiforme, or toxic epidermal necrolysis. Patients on Piqray® have reported severe hyperglycemia, and the safety of Piqray® in patients with Type 1 or uncontrolled Type 2 diabetes has not been established. Before initiating treatment with Piqray®, health care professionals are advised to check fasting glucose and HbA1c, and to optimize glycemic control. Patients should be monitored for pneumonitis/interstitial lung disease (inflammation of lung tissue) and diarrhea during treatment. Piqray® must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks.
Piqray® is the first new drug application (NDA) for a new molecular entity approved under the Real-Time Oncology Review (RTOR) pilot program, which permits the FDA to begin analyzing key efficacy and safety datasets prior to the official submission of an application, allowing the review team to begin their review and communicate with the applicant earlier. Piqray® also used the updated Assessment Aid (AAid), a multidisciplinary review template intended to focus the FDA's written review on critical thinking and consistency and reduce time spent on administrative tasks. With these 2 pilot programs, the approval of Piqray® comes approximately 3 months ahead of the Prescription Drug User Fee Act (PDUFA) VI deadline of August 18, 2019.
The FDA granted this application Priority Review designation. The FDA granted approval of Piqray® to Novartis. The FDA granted approval of the therascreen PIK3CA RGQ PCR Kit to QIAGEN Manchester, Ltd.

FDA NEWS RELEASE

For Immediate Release: May 24th, 2019

FDA approves innovative gene therapy to treat pediatric patients with spinal muscular atrophy, a rare disease and leading genetic cause of infant mortality

The FDA approved Zolgensma® (onasemnogene abeparvovec-xioi), the first gene therapy approved to treat children less than 2 years of age with spinal muscular atrophy (SMA), the most severe form of SMA and a leading genetic cause of infant mortality.
SMA is a rare genetic disease caused by a mutation in the survival motor neuron 1 (SMN1) gene. The gene encodes the survival motor neuron (SMN) protein – a protein found throughout the body, which is critical for the maintenance and function of specialized nerve cells, called motor neurons. Motor neurons in the brain and spinal cord control muscle movement throughout the body. If there is not enough functional SMN protein, then the motor neurons die, leading to debilitating and often fatal muscle weakness. SMA caused by mutations in the SMN1 gene is generally classified into several subtypes, based on the age of onset and severity; infantile-onset SMA is the most severe and most common subtype. Children with this condition have problems holding their head up, swallowing and breathing. These symptoms may be present at birth or may present by the age of 6 months.
Zolgensma® is indicated for the treatment of children less than 2 years of age with SMA. The product is an adeno-associated virus vector-based gene therapy that targets the cause of SMA. The vector delivers a fully functional copy of human SMN gene into the target motor neuron cells. A one-time intravenous administration of Zolgensma® results in expression of the SMN protein in a child's motor neurons, which improves muscle movement and function, and survival of a child with SMA. Dosing is determined based on the weight of the patient.
The safety and effectiveness of Zolgensma® is based on an ongoing clinical trial and a completed clinical trial involving a total of 36 pediatric patients with infantile-onset SMA between the ages of approximately 2 weeks and 8 months at study entry. The primary evidence of effectiveness is based on results from the 21 patients treated with Zolgensma® in the ongoing clinical trial. In this trial, there are 19 remaining patients, who range in age from 9.4 to 18.5 months; 13 of these 19 patients are at least 14 months of age. Compared to the natural history of patients with infantile-onset SMA, patients treated with Zolgensma® also demonstrated significant

improvement in their ability to reach developmental motor milestones (e.g., head control and the ability to sit without support).
The most common side effects of Zolgensma® are elevated liver enzymes and vomiting. Zolgensma® has a boxed warning that acute serious liver injury can occur. Patients with pre existing liver impairment may be at higher risk of experiencing serious liver injury. Clinical examination and laboratory tests to assess liver function should be completed prior to treatment with Zolgensma®, and patients' liver function should be monitored for at least 3 months after Zolgensma® administration.
Certain vaccines are contraindicated for patients on a substantially immunosuppressive steroid dose. Therefore, caregivers should consult with their healthcare professional to determine if adjustments to the patient's vaccination schedule are necessary to accommodate concomitant corticosteroid administration.
The FDA granted this application Fast Track, Breakthrough Therapy, and Priority Review designations. Zolgensma® also received Orphan Drug designation, which provides incentives to encourage the development of drugs for rare diseases.
The FDA also awarded the manufacturer a rare pediatric disease priority review voucher, under a program intended to encourage the development of new drugs and biological products for the prevention and treatment of certain rare pediatric diseases.
The FDA granted the approval of Zolgensma® to AveXis Inc.

FDA NEWS RELEASE

For Immediate Release: May 16th, 2019

FDA approves first anticoagulant (blood thinner) for pediatric patients to treat potentially life-threatening blood clots

The FDA approved Fragmin® (dalteparin sodium) injection, for subcutaneous use, to reduce the recurrence of symptomatic venous thromboembolism (VTE) in pediatric patients 1 month of age and older. VTE can include deep vein thrombosis (blood clot in the deep veins of the leg) and pulmonary embolism (blood clot in the lungs), which can lead to death.
VTE usually develops as a secondary complication of underlying clinical conditions such as a venous catheter, cancer, infection, congenital heart disease, and trauma or surgery. Pediatric VTE is associated with an increased risk of in-hospital mortality, recurrent VTE and post-thrombotic syndrome (damage to vein).
Fragmin® was initially approved by the FDA in 1994 for adults and is a type of heparin, which works as an anticoagulant. The efficacy of Fragmin® in children was based on a single trial with 38 pediatric patients with symptomatic deep vein thrombosis and/or pulmonary embolism. Patients were treated with Fragmin® for up to 3 months, with starting doses by age and weight. At study completion, 21 patients achieved resolution of the qualifying VTE, 7 patients showed regression, 2 patients showed no change, no patients experienced progression of the VTE and 1 patient experienced recurrence of VTE.
Common side effects of patients taking Fragmin® are bleeding, including hemorrhage, thrombocytopenia (low blood platelet count), hematoma (collection of blood) or pain at the injection site and transient elevation of transaminases (elevated level of liver enzymes).
Health care professionals are advised to use caution in conditions with increased risk of hemorrhage and monitor thrombocytopenia of any degree closely. Health care professionals are warned not to use benzyl alcohol preservative multiple-dose formulations in infants as they contain benzyl alcohol and should not be used. Patients are advised to have blood count laboratory tests periodically. Health care professionals are advised to monitor patients closely for bleeding when administering Fragmin® to patients who currently take anticoagulants. Patients at risk for VTE may receive certain treatments or interventions to help reduce the likelihood of the formation of blood clots (known as thromboprophylaxis), including taking anticoagulants.
The label for Fragmin® contains a boxed warning to alert health care professionals and patients that epidural or spinal hematomas (accumulation of blood that can mechanically compress the spinal cord) may occur in patients who are anticoagulated due to taking certain medications called low molecular weight heparins (LMWH) or heparinoids and are receiving neuraxial anesthesia (injection near the spine) or undergoing spinal puncture (removing spinal fluid for testing). These hematomas may result in long-term or permanent paralysis. Health care professionals are advised to consider these risks when scheduling patients for spinal procedures as patients may be at a higher risk of developing VTE. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include: use of indwelling epidural catheters, use of other drugs that affect hemostasis at the same time when using Fragmin®, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors and other anticoagulants; history of traumatic or repeated epidural or spinal

punctures; and a history of spinal deformity or surgery. The optimal timing between the administration of Fragmin® and neuraxial procedures is not known. Health care professionals are advised to monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Health care professionals are advised to consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.
The FDA granted this application Priority Review designation. Pfizer holds the application for Fragmin®.

FDA NEWS RELEASE

For Immediate Release: May 6th, 2019

FDA approves first treatment for children with Lambert-Eaton myasthenic syndrome, a rare autoimmune disorder

The FDA approved Ruzurgi™ (amifampridine) tablets for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age. This is the first FDA approval of a treatment specifically for pediatric patients with LEMS. The only other treatment approved for LEMS is only approved for use in adults.
LEMS is a rare autoimmune disorder that affects the connection between nerves and muscles and causes weakness and other symptoms in affected patients. In people with LEMS, the body's own immune system attacks the neuromuscular junction (the connection between nerves and muscles) and disrupts the ability of nerve cells to send signals to muscle cells. LEMS may be associated with other autoimmune diseases, but more commonly occurs in patients with cancer such as small cell lung cancer, where its onset precedes or coincides with the diagnosis of cancer. LEMS can occur at any age. The prevalence of LEMS specifically in pediatric patients is not known, but the overall prevalence of LEMS is estimated to be 3 per million individuals worldwide.
Use of Ruzurgi™ in patients 6 to less than 17 years of age is supported by evidence from adequate and well-controlled studies of the drug in adults with LEMS, pharmacokinetic data in adult patients, pharmacokinetic modeling and simulation to identify the dosing regimen in pediatric patients and safety data from pediatric patients 6 to less than 17 years of age.
The effectiveness of Ruzurgi™ for the treatment of LEMS was established by a randomized, double-blind, placebo-controlled withdrawal study of 32 adult patients in which patients were taking Ruzurgi™ for at least 3 months prior to entering the study. The study compared patients continuing on Ruzurgi™ to patients switched to placebo. Effectiveness was measured by the degree of change in a test that assessed the time it took the patient to rise from a chair, walk 3 meters, and return to the chair for 3 consecutive laps without pause. The patients that continued on Ruzurgi™ experienced less impairment than those on placebo. Effectiveness was also measured with a self-assessment scale for LEMS-related weakness that evaluated the feeling of weakening or strengthening. The scores indicated greater perceived weakening in the patients switched to placebo.
The most common side effects experienced by pediatric and adult patients taking Ruzurgi™ were burning or prickling sensation (paresthesia), abdominal pain, indigestion, dizziness and nausea. Side effects reported in pediatric patients were similar to those seen in adult patients. Seizures have been observed in patients without a history of seizures. Patients should inform their health care professional immediately if they have signs of hypersensitivity reactions such as rash, hives, itching, fever, swelling or trouble breathing.
The FDA granted this application Priority Review and Fast Track designations. Ruzurgi™ also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.
The FDA granted the approval of Ruzurgi™ to Jacobus Pharmaceutical Company, Inc.

FDA NEWS RELEASE

For Immediate Release: May 6th, 2019

FDA approves new treatments for heart disease caused by a serious rare disease, transthyretin mediated amyloidosis

The FDA approved Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis) capsules for the treatment of the heart disease (cardiomyopathy) caused by transthyretin mediated amyloidosis (ATTR-CM) in adults. These are the first FDA-approved treatments for ATTR-CM. Vyndaqel® and Vyndamax™ have the same active

moiety, tafamidis, but they are not substitutable on a milligram to milligram basis and their recommended doses differ

ATTR is caused by the buildup of abnormal deposits of specific proteins known as amyloid in the body's organs and tissues, interfering with their normal functioning. These protein deposits most frequently occur in the heart and the peripheral nervous system. Heart involvement can result in shortness of breath, fatigue, heart failure, loss of consciousness, abnormal heart rhythms and death. Involvement of the peripheral nervous system can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet. Amyloid deposits can also affect the kidneys, eyes, gastrointestinal tract and central nervous system.

The efficacy of Vyndaqel® and Vyndamax™ in treating ATTR-CM was shown in a clinical trial of 441 patients randomized to receive Vyndaqel® or a placebo. After an average of 30 months, the survival rate was higher in the Vyndaqel® group than in the placebo group. Vyndaqel® was also shown to reduce the number of hospitalizations for cardiovascular problems.

The number of patients in clinical studies was small, but no drug-associated side effects have been identified. Tafamidis may cause fetal harm when administered to a pregnant woman. Women taking Vyndaqel® or Vyndamax™ should discuss pregnancy planning and prevention with their health care professional.

The FDA granted Vyndaqel® Fast Track, Priority Review and Breakthrough Therapy designations. Vyndaqel® and Vyndamax™ each received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

Approval of Vyndaqel® and Vyndamax™ were granted to FoldRx, a subsidiary of Pfizer.

Safety Announcements

Statement on warning for women of childbearing age about possible safety risks of dietary supplements containing vinpocetine

[6/3/19] The FDA is warning consumers about safety concerns regarding an ingredient called vinpocetine that is found in dietary supplements, specifically concerns about the use of this ingredient by women of childbearing age. According to data reviewed by the FDA, including a recent report by the National Institute of Health's (NIH) National Toxicology Program (NTP), consumption of vinpocetine is associated with adverse reproductive effects – in other words, vinpocetine may cause a miscarriage or harm fetal development.

These findings are particularly concerning since products containing vinpocetine are widely available for use by women of childbearing age. That's why today we're advising pregnant women and women who could become pregnant not to take vinpocetine. We are also advising firms marketing dietary supplements containing vinpocetine to evaluate their product labeling to ensure that it provides safety warnings against use by pregnant women and women who could become pregnant.

Vinpocetine is a synthetically produced compound that is used in some products marketed as dietary supplements, either by itself or combined with other ingredients. Vinpocetine may be referred to on product labels as Vinca minor extract, lesser periwinkle extract, or common periwinkle extract. Dietary supplements containing vinpocetine are often marketed for uses that include enhanced memory, focus, or mental acuity; increased energy; and weight loss. Scientists who have studied the effects of vinpocetine on pregnant animals concluded that vinpocetine decreased fetal weight and increased the chances of a miscarriage. The blood levels of vinpocetine measured in the pregnant animals were similar to those reported in people after taking a single dose of vinpocetine, indicating that pregnant women may experience adverse effects from vinpocetine similar to those seen in the pregnant animals.

In some countries outside of the U.S., vinpocetine is regulated as a prescription drug. When products like vinpocetine are sold as dietary supplements in the U.S., they have not been reviewed by the FDA under the safety and effectiveness standards that apply to drug products. This means that the FDA has not reviewed each vinpocetine product, or its labeling, before those products become available to consumers.

In the 1990s, the FDA received several premarket safety submissions (known as new dietary ingredient notifications) for vinpocetine as an ingredient in dietary supplements. In 2016, we requested comment from stakeholders as part of an administrative proceeding to evaluate whether vinpocetine is legal for sale as a dietary supplement. With the results in NTP's report, it was important to issue today's warning because the availability of dietary supplement products containing vinpocetine has grown and the labels of vinpocetine products often have no warnings about the dangers of miscarriage and harm to fetal development. For the same reasons, the FDA will expedite completion of the administrative proceeding that we began in September 2016.

The dietary supplement market is a growing industry, with sales multiplying 10-fold over the past 25 years and more than half of all Americans taking at least 1 dietary supplement on a regular basis. This expansion is 1 reason why earlier this year, the FDA announced new efforts to strengthen the regulation of dietary supplements by modernizing our regulatory framework.

This safety warning is just 1 of many steps the FDA is taking to adapt to the realities of the evolving dietary supplement industry. Protecting the public from unsafe dietary supplements remains a top priority for the FDA. We've also created a public-private partnership, the Botanical Safety Consortium, to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements. In April, we introduced a new tool, the Dietary Supplement Ingredient Advisory List, to more quickly alert the public when we become aware of ingredients that appear to be unlawfully marketed in dietary supplements. And finally, just last month, we held a public meeting with our stakeholders to discuss responsible innovation in the dietary supplements industry.

These efforts, along with this announcement regarding vinpocetine, underscore how the FDA will continue to preserve access to safe, well-manufactured, and accurately labeled dietary supplements, while we protect the American public from potentially unsafe or otherwise unlawful products.

Current Drug Shortages Index (as of June 3rd, 2019):

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

Abciximab (ReoPro) Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Aminophylline Injection, USP	***Currently in Shortage***
Asparaginase Erwinia Chrysanthemi (Erwinaze)	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Bisoprolol Fumarate Tablets	***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***
Buspirone HCl Tablets	***Currently in Shortage***
Calcitriol Injection USP 1MCG /ML	***Currently in Shortage***
Calcium Chloride Injection, USP	***Currently in Shortage***
Capreomycin Injection, USP	***Currently in Shortage***
Carbidopa and Levodopa Extended Release Tablets	***Currently in Shortage***
Carisoprodol Tablets, USP	***Currently in Shortage***
Cefazolin Injection	***Currently in Shortage***
Cefepime Injection	***Currently in Shortage***
Cefotaxime Sodium (Claforan) Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cefoxitin for Injection, USP	***Currently in Shortage***
Deferoxamine Mesylate for Injection, USP	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexrazoxane Injection	***Currently in Shortage***
Dextrose 5% Injection Bags	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Injection, USP	***Currently in Shortage***
Dicyclomine Oral Tablets/Capsules	***Currently in Shortage***
Diltiazem Hydrochloride	***Currently in Shortage***
Diltiazem Hydrochloride ER (Twice-a-Day) Capsules	***Currently in Shortage***
Diphenhydramine Injection	***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***
Eflornithine Hydrochloride (Vaniqa) Cream	***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***
Eprosartan Mesylate Tablets	***Currently in Shortage***
Erythromycin Lactobionate for Injection, USP	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Ethiodized Oil (Lipiodol) Injection	***Currently in Shortage***
Etoposide Injection	***Currently in Shortage***
Etoposide Phosphate (Etopophos) Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fludrocortisone Acetate Tablets	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Fluorescein Strips	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Fluvoxamine ER Capsules	***Currently in Shortage***
Gemifloxacin Mesylate (Factive) Tablets	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Haloperidol Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection, USP	***Currently in Shortage***
Hydroxyprogesterone Caproate Injection	***Currently in Shortage***
Hydroxyzine Pamoate Oral Capsules	***Currently in Shortage***
Imipenem and Cilastatin for Injection, USP	***Currently in Shortage***
Isocarboxazid Tablets	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketoprofen Capsules	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
L-Cysteine Hydrochloride Injection	***Currently in Shortage***
Labetalol Hydrochloride Injection	***Currently in Shortage***
Latanoprost Ophthalmic Solution 0.005%	***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***
Lorazepam Injection, USP	***Currently in Shortage***
Methadone Hydrochloride Injection	***Currently in Shortage***
Methocarbamol Tablets	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride (QUILLICHEW ER) Extended-Release Chew Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride (QUILLIVANT XR) for Extended-Release Oral Susp	***Currently in Shortage***
Metoclopramide Injection, USP	***Currently in Shortage***
Metoprolol Tartrate Injection, USP	***Currently in Shortage***
Metronidazole Injection, USP	***Currently in Shortage***
Morphine Sulfate Injection, USP	***Currently in Shortage***

Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Mupirocin Calcium Nasal Ointment	***Currently in Shortage***
Nelarabine (Arranon) Injection	***Currently in Shortage***
Nystatin Oral Suspension	***Currently in Shortage***
Olmesartan Medoxomil Tablets	***Currently in Shortage***
Ondansetron Hydrochloride Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Penicillamine (Depen) Titratable Tablets	***Currently in Shortage***
Peritoneal Dialysis Solutions	***Currently in Shortage***
Phenytoin Sodium Injection, USP	***Currently in Shortage***
Phosphate Injection Products	***Currently in Shortage***
Physostigmine Salicylate Injection, USP	***Currently in Shortage***
Piperacillin and Tazobactam (Zosyn) Injection	***Currently in Shortage***
Potassium Chloride Injection	***Currently in Shortage***
Prednisolone Acetate 1% Ophthalmic Suspension	***Currently in Shortage***
Procainamide Hydrochloride Injection, USP	***Currently in Shortage***
Progesterone Injection, USP	***Currently in Shortage***
Promethazine (Phenergan) Injection	***Currently in Shortage***
Ranitidine Injection, USP	***Currently in Shortage***
Remifentanil (Ultiva) Lyophilized Powder for Solution Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sclerosol Intrapleural Aerosol	***Currently in Shortage***
Scopolamine Transdermal System	***Currently in Shortage***
Sildenafil Citrate (REVATIO)	***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 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection USP, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphate Injection	***Currently in Shortage***
Sterile Talc Powder	***Currently in Shortage***
Sterile Water	***Currently in Shortage***
Tacrolimus Capsules	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Thioridazine Hydrochloride Tablets	***Currently in Shortage***
Thiothixene Capsules	***Currently in Shortage***
Timolol Maleate Tablets	***Currently in Shortage***
Trifluoperazine Hydrochloride Tablets	***Currently in Shortage***
Valsartan Tablets	***Currently in Shortage***