Oklahoma Health Care Authority

Drug Utilization Review Board

Wednesday,
July 10, 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 – July 10, 2019

DATE: July 3, 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 July meeting.
Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on Medication Coverage Authorization Unit/SoonerPsych Program Update – Appendix B

Action Item – Vote 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 C

Action Item – Vote to Prior Authorize Balversa™ (Erdafitinib) – Appendix D

Action Item – Vote 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 E

Action Item – Vote to Prior Authorize Abilify MyCite® (Aripiprazole Tablet with Sensor), Aristada Initio® [Aripiprazole Lauroxil Extended-Release (ER) Injectable Suspension], and Perseris™ [Risperidone ER Subcutaneous (Sub-Q) Injectable Suspension] – Appendix F

Action Item – Vote to Prior Authorize Cassipa® (Buprenorphine/Naloxone) and Levorphanol – Appendix G

Action Item – Annual Review of Botulinum Toxins – Appendix H

Annual Review of Spinal Muscular Atrophy Medications and 30-Day Notice to Prior Authorize Zolgensma® (Onasemnogene Abeparvovec-xioi) – Appendix I

Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Bryhali™ (Halobetasol Propionate 0.01% Lotion), Duobrii™ (Halobetasol Propionate/Tazarotene 0.01%/0.045% Lotion), and Lexette™ (Halobetasol Propionate 0.05% Foam) – Appendix J

Annual Review of Qbrexza™ (Glycopyrronium) – Appendix K

Industry News and Updates – Appendix L

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 10, 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. June 12, 2019 DUR Minutes – Vote
B. June 12, 2019 DUR Recommendations Memorandum
C. Correspondence

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

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

A. Medication Coverage Activity for June 2019
B. Pharmacy Helpdesk Activity for June 2019
C. SoonerPsych Program Update

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

5. Action Item – Vote 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 C

A. Introduction
B. College of Pharmacy Recommendations

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

6. Action Item – Vote to Prior Authorize Balversa™ (Erdafitinib) – See Appendix D

A. Introduction
B. Recommendations

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

7. Action Item – Vote 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 E

A. Introduction
B. College of Pharmacy Recommendations

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

8. Action Item – Vote to Prior Authorize Abilify MyCite® (Aripiprazole Tablet with Sensor), Aristada Initio® [Aripiprazole Lauroxil Extended-Release (ER) Injectable Suspension], and Perseris™ [Risperidone ER Subcutaneous (Sub-Q) Injectable Suspension] – See Appendix F

A. Introduction
B. College of Pharmacy Recommendations

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

9. Action Item – Vote to Prior Authorize Cassipa® (Buprenorphine/Naloxone) and Levorphanol – See Appendix G

A. Introduction
B. College of Pharmacy Recommendations

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

10. Action Item – Annual Review of Botulinum Toxins – See Appendix H

A. Current Prior Authorization Criteria
B. Utilization of Botulinum Toxins
C. Prior Authorization of Botulinum Toxins
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Botulinum Toxins

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

11. Annual Review of Spinal Muscular Atrophy Medications and 30-Day Notice to Prior Authorize Zolgensma® (Onasemnogene Abeparvovec-xioi) – See Appendix I

A. Current Prior Authorization Criteria
B. Utilization of Spinraza® (Nusinersen)
C. Prior Authorization of Spinraza® (Nusinersen)
D. Market News and Updates
E. Zolgensma® (Onasemnogene Abeparvovec-xioi) Product Summary
F. College of Pharmacy Recommendations

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

12. Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Bryhali™ (Halobetasol Propionate 0.01% Lotion), Duobrii™ (Halobetasol Propionate/Tazarotene 0.01%/0.045% Lotion), and Lexette™ (Halobetasol Propionate 0.05% Foam) – See Appendix J

A. Current Prior Authorization Criteria
B. Utilization of Topical Corticosteroids
C. Prior Authorization of Topical Corticosteroids
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Topical Corticosteroids

Non-Presentation; Questions Only:

13. Annual Review of Qbrexza™ (Glycopyrronium) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Qbrexza™ (Glycopyrronium)
C. Prior Authorization of Qbrexza™ (Glycopyrronium)
D. Market News and Updates
E. College of Pharmacy Recommendations

Non-Presentation; Questions Only:

14. Industry News and Updates – See Appendix L

A. Introduction
B. News and Updates

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

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

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

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

No meeting scheduled for August 2019.

A. Synagis® (Palivizumab)
B. Sickle Cell Medications
C. Breast Cancer Medications
D. Prostate Cancer Medications
E. Antihyperlipidemics
F. Crysvita® (Burosumab-twza)

**Future business subject to change.*

17. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF JUNE 12, 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
Visiting Pharmacy Student(s): Tashrique Rahman	x	

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:		
Suzanne Hensley, Xeris	Dana Koehn, Sanofi-Genzyme	Rhonda Clark, Indivior
Evie Knisely, Novartis	Marc Parker, Sunovion	Cris Valladares, Celgene
Nick Casale, Indivior	Audrey Rattan, Alkermes	Alex Felizarb, Otsuka
Shelley Thompson, Alkermes	Paul Monies, Oklahoma Watch	Chi Kohlhoff, Braeburn
Tara McKinley, Otsuka	Jane Stephen, Amgen	Matt Forney, Merck
Brian Maves, Pfizer	Jim Dunlap, PhRMA	Pauline Whelan, Orexo
Aaron Shaw, BI	Janie Huff	
Denise Roberts, Shatterproof	Jorg Pahl, Orexo	

PRESENT FOR PUBLIC COMMENT:	
Jorg Pahl	Orexo
Denise Roberts	Shatterproof
Tara McKinley	Otsuka
Nick Casale	Indivior
Shelley Thompson	Alkermes

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. 18 JORG PAHL
2B: AGENDA ITEM NO. 18 DENISE ROBERTS
2C: AGENDA ITEM NO. 15 TARA MCKINLEY
2D: AGENDA ITEM NO. 15 NICK CASALE
2E: AGENDA ITEM NO. 15 SHELLEY THOMPSON

ACTION: NONE REQUIRED

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

3A: APRIL 10, 2019 DUR MINUTES – VOTE
3B: APRIL 10, 2019 DUR RECOMMENDATIONS MEMORANDUM
3C: MAY 8, 2019 DUR RECOMMENDATIONS MEMORANDUM

Materials included in agenda packet; presented by Dr. Cothran
Dr. Hardzog-Britt moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 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**

4A: MEDICATION COVERAGE ACTIVITY FOR MAY 2019
4B: PHARMACY HELPDESK ACTIVITY FOR MAY 2019
4C: USE OF ACEI/ARB THERAPY IN PATIENTS WITH DIABETES AND HTN MAILING UPDATE

Materials included in agenda packet; presented by Dr. Abbott, Dr. Connell

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE ALDURAZYME® (LARONIDASE) AND NAGLAZYME® (GALSULFASE)**

5A: INTRODUCTION
5B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Connell
Dr. Broyles moved to approve; seconded by Dr. Huddleston

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE PLENVU® [POLYETHYLENE GLYCOL (PEG)-3350/SODIUM ASCORBATE/SODIUM SULFATE/ASCORBIC ACID/SODIUM CHLORIDE/POTASSIUM CHLORIDE]**

6A: INTRODUCTION

6B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Connell
Dr. Munoz moved to approve; seconded by Dr. Garton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE CONSENSI® (AMLODIPINE/CELECOXIB) AND KAPSPARGO™ SPRINKLE [METOPROLOL SUCCINATE EXTENDED-RELEASE (ER)]**

7A: INTRODUCTION

7B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Abbott
Dr. Huddleston moved to approve; seconded by Dr. Hardzog-Britt

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO UPDATE THE PRIOR AUTHORIZATION CRITERIA FOR H.P. ACTHAR® GEL (REPOSITORY CORTICOTROPIN INJECTION)**

8A: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Abbott
Dr. Garton moved to approve; seconded by Dr. Broyles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE FULPHILA® (PEGFILGRASTIM-JMDB), NIVESTYM™ (FILGRASTIM-AAFI), AND UDENYCA™ (PEGFILGRASTIM-CBQV)**

9A: INTRODUCTION

9B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams
Dr. Broyles moved to approve; seconded by Dr. Garton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE XYOSTED™ [TESTOSTERONE ENANTHATE SUBCUTANEOUS (SUB-Q) AUTO-INJECTOR] AND JATENZO® (TESTOSTERONE UNDECANOATE ORAL CAPSULE)**

10A: INTRODUCTION

10B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Adams
Dr. Hardzog-Britt moved to approve; seconded by Dr. Huddleston

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: **VOTE TO PRIOR AUTHORIZE CABLIVI® (CAPLACIZUMAB-YHDP)**

11A: INTRODUCTION

11B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Chandler
Dr. Garton moved to approve; seconded by Dr. Huddleston

ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: **VOTE TO PRIOR AUTHORIZE DEXTENZA® (DEXAMETHASONE OPHTHALMIC INSERT), INVELTYS™ (LOTEPREDNOL ETABONATE SUSPENSION), LOTEMAX® SM (LOTEPREDNOL ETABONATE GEL), AND OXERVATE™ (CENEGERMIN-BKBJ)**

12A: INTRODUCTION

12B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Chandler
Dr. Broyles moved to approve; seconded by Dr. Munoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: VOTE TO PRIOR AUTHORIZE LORBRENA® (LORLATINIB), MVASI® (BEVACIZUMAB-AWWB), AND VIZIMPRO® (DACOMITINIB)

13A: INTRODUCTION
13B: MARKET NEWS AND UPDATES
13C: RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders
Dr. Huddleston moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: 30-DAY NOTICE TO PRIOR AUTHORIZE BALVERSA™ (ERDAFITINIB)

14A: INTRODUCTION
14B: MARKET NEWS AND UPDATES
14C: BALVERSA™ (ERDAFITINIB) PRODUCT SUMMARY
14D: RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ABILIFY MYCITE® (ARIPIPRAZOLE TABLET WITH SENSOR), ARISTADA INITIO® [ARIPIPRAZOLE LAUROXIL EXTENDED-RELEASE (ER) INJECTABLE SUSPENSION], AND PERSERIS™ [RISPERIDONE ER SUBCUTANEOUS (SUB-Q) INJECTABLE SUSPENSION]

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
15C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
15D: MEDICAID DRUG REBATE PROGRAM
15E: MARKET NEWS AND UPDATES
15F: ABILIFY MYCITE® (ARIPIPRAZOLE TABLET WITH SENSOR) PRODUCT SUMMARY
15G: ARISTADA INITIO® (ARIPIPRAZOLE LAUROXIL ER INJECTABLE SUSPENSION) PRODUCT SUMMARY
15H: PERSERIS™ (RISPERIDONE ER SUB-Q INJECTABLE SUSPENSION) PRODUCT SUMMARY
15I: COLLEGE OF PHARMACY RECOMMENDATIONS
15J: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

AGENDA ITEM NO. 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)

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
16C: PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
16D: MEDICAID DRUG REBATE PROGRAM
16E: MARKET NEWS AND UPDATES
16F: JORNAY PM™ (METHYLPHENIDATE HYDROCHLORIDE ER CAPSULE) PRODUCT SUMMARY
16G: ADHANSIA XR™ (METHYLPHENIDATE HYDROCHLORIDE ER CAPSULE) PRODUCT SUMMARY
16H: SUNOSI™ (SOLRIAMFETOL TABLET) PRODUCT SUMMARY
16I: COLLEGE OF PHARMACY RECOMMENDATIONS
16J: UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS

Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 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)**

17A: INTRODUCTION
17B: CURRENT PRIOR AUTHORIZATION CRITERIA
17C: UTILIZATION OF SPECIAL FORMULATIONS
17D: PRIOR AUTHORIZATION OF SPECIAL FORMULATIONS
17E: ANNOVERA™ (SEGESTERONE ACETATE/ETHINYL ESTRADIOL VAGINAL SYSTEM) PRODUCT SUMMARY
17F: BIJUVA™ (ESTRADIOL/PROGESTERONE CAPSULE) PRODUCT SUMMARY
17G: CEQUA™ (CYCLOSPORINE 0.09% OPHTHALMIC SOLUTION) PRODUCT SUMMARY
17H: CORLANOR® (IVABRADINE ORAL SOLUTION) PRODUCT SUMMARY
17I: CROTAN™ (CROTAMITON 10% LOTION) PRODUCT SUMMARY
17J: GLOPERBA® (COLCHICINE ORAL SOLUTION) PRODUCT SUMMARY
17K: GLYCATE® (GLYCOPYRROLATE TABLET) PRODUCT SUMMARY
17L: KHAPZORY™ (LEVOLEUCOVORIN INJECTION) PRODUCT SUMMARY
17M: QMIIZ™ ODT (MELOXICAM ODT) PRODUCT SUMMARY
17N: SECONAL SODIUM™ (SECOBARBITAL SODIUM CAPSULE) PRODUCT SUMMARY
17O: TAPERDEX™ (DEXAMETHASONE TABLET) PRODUCT SUMMARY
17P: TIGLUTIK™ (RILUZOLE ORAL SUSPENSION) PRODUCT SUMMARY
17Q: TOBRADEX® ST (TOBRAMYCIN/DEXAMETHASONE 0.3%/0.05% OPHTHALMIC SUSPENSION) PRODUCT SUMMARY
17R: TOLSURA™ (ITRACONAZOLE CAPSULE) PRODUCT SUMMARY
17S: YUTIQ™ (FLUOCINOLONE ACETONIDE INTRAVITREAL IMPLANT) PRODUCT SUMMARY
17T: COLLEGE OF PHARMACY RECOMMENDATIONS
17U: UTILIZATION DETAILS OF SPECIAL FORMULATIONS

Materials included in agenda packet; presented by Dr. Chandler

ACTION: NONE REQUIRED

AGENDA ITEM NO. 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**

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF OPIOID ANALGESICS AND MAT MEDICATIONS
18C: PRIOR AUTHORIZATION OF OPIOID ANALGESICS AND MAT MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: CASSIPA® (BUPRENORPHINE/NALOXONE) PRODUCT SUMMARY
18F: LEVORPHANOL PRODUCT SUMMARY
18G: COLLEGE OF PHARMACY RECOMMENDATIONS
18H: UTILIZATION DETAILS OF OPIOID ANALGESICS
18I: UTILIZATION DETAILS OF MAT MEDICATIONS

Materials included in agenda packet; presented by Dr. Abbott

ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: **INDUSTRY NEWS AND UPDATES**

19A: INTRODUCTION

19B: NEWS AND UPDATES
Materials included in agenda packet; Non-presentation; Questions only
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: 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. 21: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
21A: BOTULINUM TOXINS
21B: QBREXZA™ (GLYCOPYRRONIUM)
21C: SPINAL MUSCULAR ATROPHY MEDICATIONS
21D: TOPICAL CORTICOSTEROIDS
**Future business subject to change.*
Materials included in agenda packet; presented by Dr. Abbott
ACTION: NONE REQUIRED

AGENDA ITEM NO. 22: ADJOURNMENT
The meeting was adjourned at 5:45pm.

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

Memorandum

Date: June 13, 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 Meeting of June 12, 2019

Recommendation 1: Use of Angiotensin Converting Enzyme Inhibitor (ACEI)/Angiotensin Receptor Blocker (ARB) Therapy in Patients with Diabetes and Hypertension (HTN) Mailing Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

MOTION CARRIED by unanimous approval.

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.

Recommendation 3: Vote to Prior Authorize Plenvu® [Polyethylene Glycol (PEG)-3350/Sodium Ascorbate/Sodium Sulfate/Ascorbic Acid/Sodium Chloride/Potassium Chloride]

MOTION CARRIED by unanimous approval.

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®.

Recommendation 4: Vote to Prior Authorize Consensi® (Amlodipine/Celecoxib) and Kapspargo™ Sprinkle [Metoprolol Succinate Extended-Release (ER)]

MOTION CARRIED by unanimous approval.

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 Tablet) 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) Capsule] 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 costs:

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®)		

Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
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®)		
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
valsartan/HCTZ (Diovan HCT®)		

HCTZ = hydrochlorothiazide

Recommendation 5: Vote to Update the Prior Authorization Criteria for H.P. Acthar® Gel (Repository Corticotropin Injection)

MOTION CARRIED by unanimous approval.

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.

Recommendation 6: Vote to Prior Authorize Fulphila® (Pegfilgrastim-jmdb), Nivestym™ (Filgrastim-aafi), and Udenyca™ (Pegfilgrastim-cbqv)

MOTION CARRIED by unanimous approval.

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.

Recommendation 7: Vote to Prior Authorize Xyosted™ [Testosterone Enanthate Subcutaneous (Sub-Q) Auto-Injector] and Jatenzo® (Testosterone Undecanoate Oral Capsule)

MOTION CARRIED by unanimous approval.

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.

Recommendation 8: Vote to Prior Authorize Cablivi® (Caplacizumab-yhdp)

MOTION CARRIED by unanimous approval.

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.

Recommendation 9: Vote to Prior Authorize Dextenza® (Dexamethasone Ophthalmic Insert), Inveltys™ (Loteprednol Etabonate Suspension), Lotemax® SM (Loteprednol Etabonate Gel), and Oxervate™ (Cenegermin-bkbj)

MOTION CARRIED by unanimous approval.

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.

Recommendation 10: Vote to Prior Authorize Lorbrena® (Lorlatinib), Mvasi® (Bevacizumab-awwb), and Vizimpro® (Dacomitinib)

MOTION CARRIED by unanimous approval.

- 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
            1. *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

1. *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).

Recommendation 11: 30-Day Notice to Prior Authorize Balversa™ (Erdafitinib)

NO ACTION REQUIRED.

Recommendation 12: Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Abilify MyCite® (Aripiprazole Tablet with Sensor), Aristada Initio® [Aripiprazole Lauroxil Extended-Release (ER) Injectable Suspension], and Perseris™ [Risperidone ER Subcutaneous (Sub-Q) Injectable Suspension]

NO ACTION REQUIRED.

Recommendation 13: 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)

NO ACTION REQUIRED.

Recommendation 14: 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)

NO ACTION REQUIRED.

Recommendation 15: Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Cassipa® (Buprenorphine/Naloxone) and Levorphanol

NO ACTION REQUIRED.

Recommendation 16: Industry News and Updates

NO ACTION REQUIRED.

Recommendation 17: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 18: Future Business

NO ACTION REQUIRED.

Oklahoma Society of Addiction Medicine
A Chapter of American Society of Addiction Medicine

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Wednesday, June 12, 2019

Becky Pasternik-Ikard, RN, JD
Chief Executive Officer, Oklahoma Health Care Authority
John Muchmore, MD, PhD
Chair, Drug Utilization Review Board
Oklahoma Health Care Authority
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

Re: Support for Increased Access to and Coverage of All Opioid Dependence Treatment Medications

Dear Ms. Pasternik-Ikard, Dr. Muchmore, and Members of the Drug Utilization Review Board,

On behalf of the Oklahoma Society of Addiction Medicine (OKSAM), the medical specialty society representing Oklahoma physicians and other clinicians who specialize in the treatment of addiction, we would like to take this opportunity to advocate for the Oklahoma Health Care Authority's Drug Utilization Review Board to increase access to and coverage of all forms of each kind of medication-assisted treatment (MAT) for Medicaid beneficiaries suffering from opioid use disorder (OUD). With the opioid addiction and overdose epidemic significantly impacting Oklahoma, it is imperative that the state provides access to high-quality, evidence-based, and comprehensive addiction treatment for our most vulnerable patients.

OKSAM is dedicated to increasing access to and improving the quality of addiction treatment for patients in Oklahoma. To that end, we are committed to advocating for a state addiction treatment system that provides access to all Food and Drug Administration (FDA)-approved medications, and each of their formulations, to treat OUD. Ensuring addiction treatment services are not subject to arbitrary limits or unfair utilization controls is a critical part of our efforts to improve access to care. We believe the Oklahoma Health Care Authority's Drug Utilization Review Board can move the state towards robust access to MAT for Medicaid beneficiaries by prohibiting utilization controls, such as prior authorization and step therapy, from being placed on these medications and beginning to cover all formulations of each type of MAT: methadone, buprenorphine, and naltrexone.

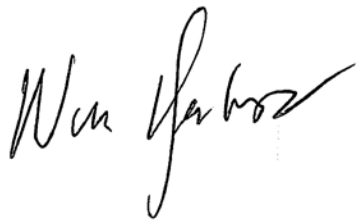
Maintaining open access to MAT for Medicaid beneficiaries would help both providers and patients engaging in addiction treatment services. When a patient presents themselves for treatment, it is vital that the provider stabilize the patient as quickly as possible through the use of MAT combined with psychosocial and recovery support services. MAT has been routinely shown to decrease the likelihood that a patient experiences mortality related to addiction by 75%, but when burdensome prior authorization requirements delay their prescription, physicians cannot offer MAT as quickly as necessary to effectively treat their patients.[i] In fact, a recent survey of physicians found that 92% of them reported care delays due to prior authorization, with 64% reporting a delay of at least one business day.[ii] This lag in treatment can have disastrous consequences. A delay of just one day is enough time for a patient to relapse, overdose, or suffer a myriad of other experiences that can adversely affect

their treatment outcome and even threaten their life. By opening access to MAT, the Drug Utilization Review Board can continue to turn the corner on the opioid epidemic.

Due to the harmful consequences of non-evidenced-based utilization controls and consistent with sound medical care, decisions about the type, modality, and duration of treatment should remain in the purview of doctors and their patients. Additionally, arbitrary limitations on the duration of treatment, medication dosage, or on levels of care that are not supported by medical evidence, are not appropriate and can be specifically detrimental to the wellbeing of the patient and their community. Given how dangerous these non-evidence-based limitations are, they should not be enforced by law, regulation, or health insurance practices. Therefore, OKSAM strongly urges the Drug Utilization Review Board to open access to addiction care for Medicaid beneficiaries.

OKSAM shares the state of Oklahoma's goal of increasing access to high-quality, evidence-based, and comprehensive addiction treatment. We strongly recommend the Oklahoma Health Care Authority's Drug Utilization Review Board open access to all formulations of each type of MAT to ensure patients receive the right care they need when they need it, thus saving lives. Please do not hesitate to contact Dr. William Yarborough, at [redacted], if OKSAM can be of any service to you. We look forward to working with you.

Sincerely,



William H. Yarborough, MD, FACP, FASAM
President, Oklahoma Society of Addiction Medicine

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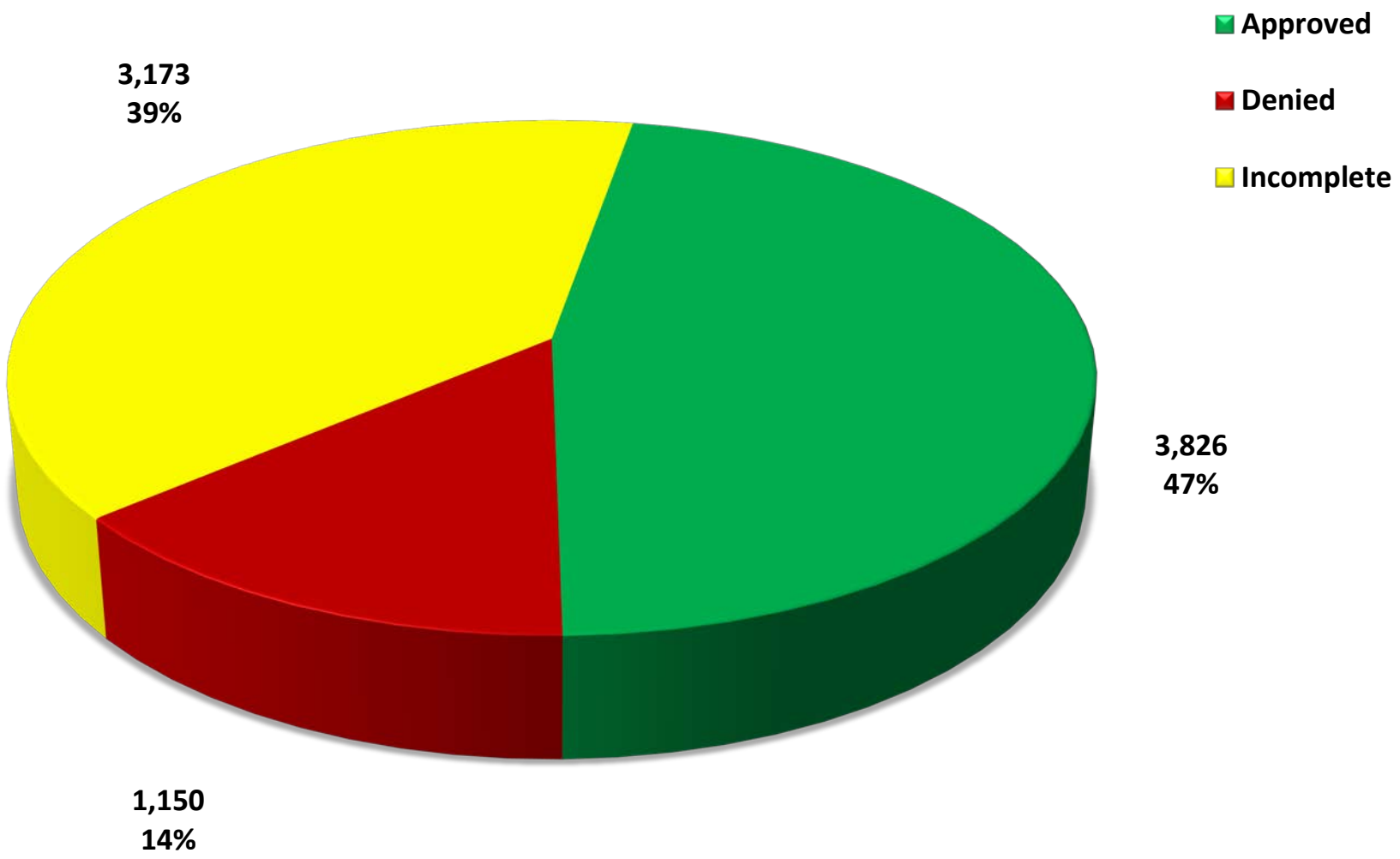
[i] Legal Action Center. (2015). Confronting an Epidemic: The Case for Eliminating Barriers to Medication Assisted Treatment of Heroin and Opioid Addiction. Washington, D.C: Legal Action Center. Available at https://lac.org/resources/substance-use-resources/medication-assisted-treatment-resources/case-for-eliminating-barriers-to-medication-assisted-treatment-of-heroin-and-opioid-addiction/

[ii] The American Medical Association. Survey of 1,000 Physicians to investigate attitudes towards prior authorization. United States, 2017. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf

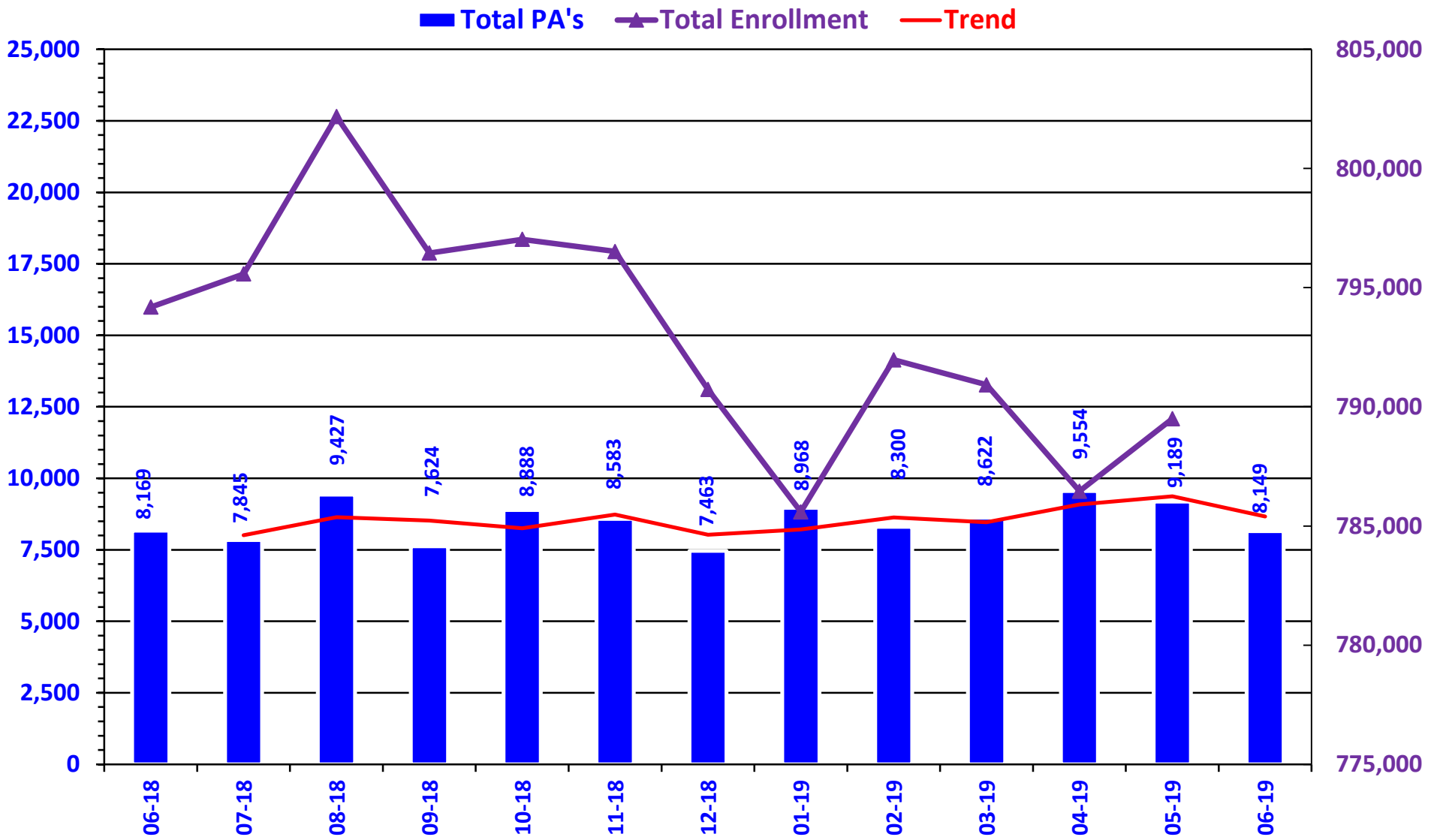
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: JUNE 2019



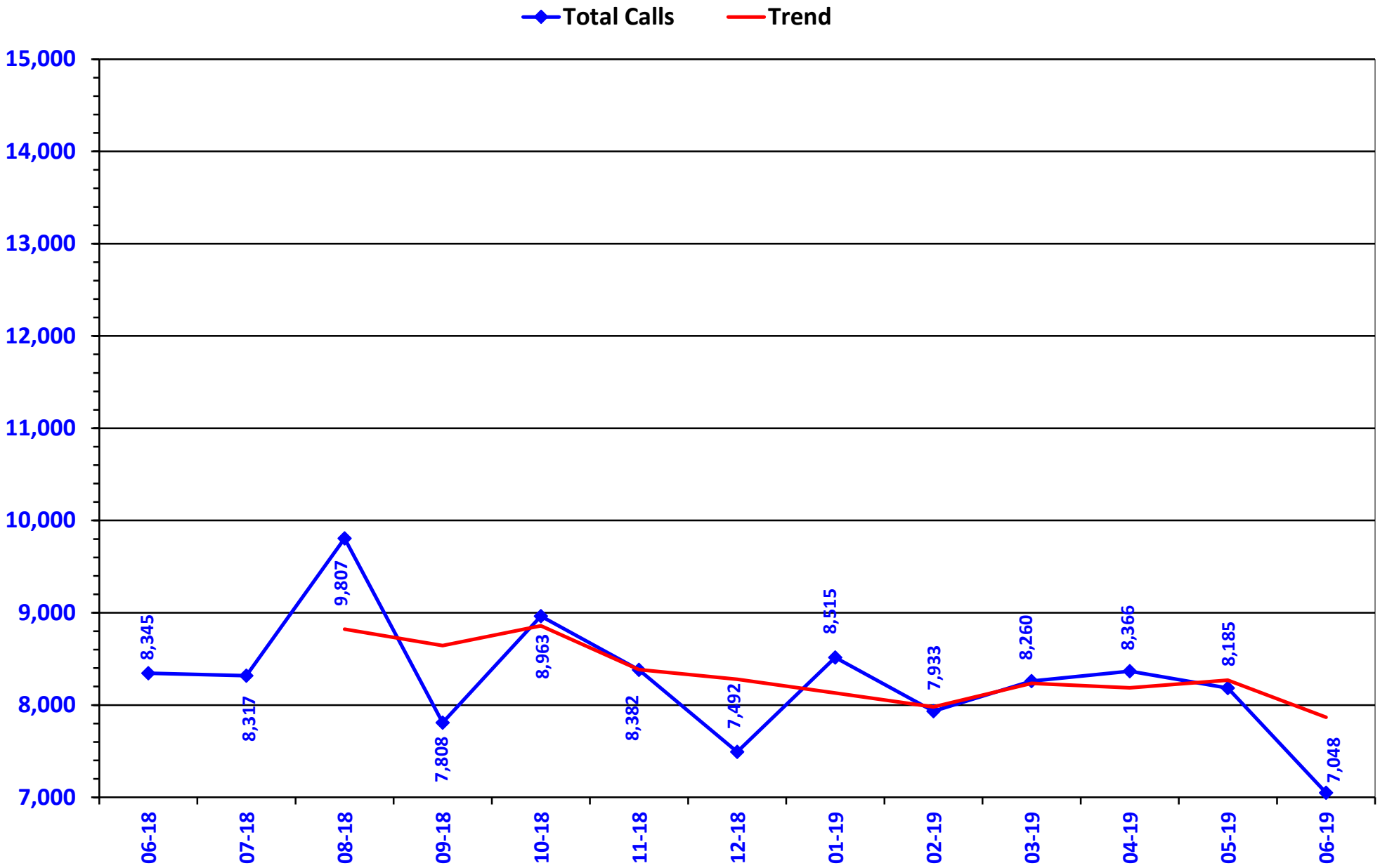
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: JUNE 2018 – JUNE 2019



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JUNE 2018 – JUNE 2019



Prior Authorization Activity

6/1/2019 Through 6/30/2019

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	67	4	13	50	301
Analgesic - NonNarcotic	12	1	1	10	87
Analgesic, Narcotic	376	161	59	156	159
Angiotensin Receptor Antagonist	18	2	5	11	355
Antiasthma	80	28	19	33	299
Antibiotic	28	10	1	17	325
Anticonvulsant	211	84	20	107	287
Antidepressant	185	35	38	112	332
Antidiabetic	275	94	63	118	350
Antihistamine	42	6	22	14	314
Antimigraine	130	23	34	73	172
Antineoplastic	96	57	11	28	166
Antiparasitic	13	1	0	12	8
Antiulcers	149	43	57	49	104
Anxiolytic	17	1	4	12	361
Atypical Antipsychotics	226	107	31	88	354
Biologics	131	76	19	36	283
Bladder Control	44	7	14	23	320
Blood Thinners	284	162	32	90	332
Botox	36	28	4	4	304
Buprenorphine Medications	559	310	22	227	79
Cardiovascular	82	35	11	36	295
Chronic Obstructive Pulmonary Disease	166	33	33	100	324
Constipation/Diarrhea Medications	144	22	50	72	172
Contraceptive	15	11	0	4	329
Corticosteroid	11	3	4	4	207
Dermatological	272	61	80	131	103
Diabetic Supplies	486	277	13	196	207
Endocrine & Metabolic Drugs	142	76	26	40	153
Erythropoietin Stimulating Agents	31	12	7	12	109
Fibromyalgia	16	5	0	11	360
Gastrointestinal Agents	94	21	19	54	215
Glaucoma	10	5	0	5	118
Growth Hormones	80	48	11	21	141
Hematopoietic Agents	10	3	0	7	119
Hepatitis C	152	87	17	48	9
HFA Rescue Inhalers	34	2	2	30	221
Insomnia	31	3	11	17	175
Insulin	125	45	14	66	333
Miscellaneous Antibiotics	20	3	2	15	16
Multiple Sclerosis	42	16	7	19	198
Muscle Relaxant	54	7	11	36	147
Nasal Allergy	61	11	18	32	157
Neurological Agents	98	31	17	50	229
NSAIDs	29	1	5	23	11
Ocular Allergy	54	5	21	28	139
Ophthalmic Anti-infectives	14	2	4	8	99
Osteoporosis	14	8	1	5	338
Other*	304	56	78	170	283

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Otic Antibiotic	29	2	10	17	8
Pediculicide	14	0	3	11	0
Respiratory Agents	21	15	0	6	247
Statins	18	2	11	5	222
Stimulant	567	307	46	214	338
Testosterone	41	10	14	17	321
Topical Antifungal	26	1	9	16	23
Topical Corticosteroids	57	0	31	26	0
Vitamin	84	19	39	26	166
Pharmacotherapy	81	76	0	5	291
Emergency PAs	0	0	0	0	
Total	**6,508**	**2,561**	**1,094**	**2,853**	
Overrides					
Brand	50	25	4	21	238
Compound	11	11	0	0	35
Cumulative Early Refill	2	1	0	1	180
Diabetic Supplies	6	5	0	1	45
Dosage Change	382	356	3	23	13
High Dose	4	2	0	2	220
Ingredient Duplication	5	5	0	0	11
Lost/Broken Rx	114	109	2	3	12
NDC vs Age	256	168	15	73	249
Nursing Home Issue	47	46	0	1	18
Opioid MME Limit	46	19	2	25	79
Opioid Quantity	34	28	2	4	142
Other*	50	37	3	10	19
Quantity vs. Days Supply	581	418	23	140	273
STBS/STBSM	18	10	1	7	92
Stolen	7	6	0	1	10
Temporary Unlock	1	1	0	0	10
Third Brand Request	27	18	1	8	24
Overrides Total	**1,641**	**1,265**	**56**	**320**	
Total Regular PAs + Overrides	**8,149**	**3,826**	**1,150**	**3,173**	

Denial Reasons	
Unable to verify required trials.	2,546
Does not meet established criteria.	1,176
Lack required information to process request.	597
Other PA Activity	
Duplicate Requests	531
Letters	11,172
No Process	7
Changes to existing PAs	563
Helpdesk Initiated Prior Authorizations	530
PAs Missing Information	16

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

SoonerPsych Program Update

Oklahoma Health Care Authority
July 2019

Prescriber Mailing Summary

The SoonerPsych program is an educational quarterly mailing to prescribers treating members utilizing atypical antipsychotic medications. Each mailing includes a gauge showing prescribers how their practice compares to those of other SoonerCare prescribers of atypical antipsychotic medications regarding potential differences from evidence-based prescribing practices. Each mailing also includes an informational page with evidence-based material related to the mailing topics. Mailing topics are comprised of 4 modules: polypharmacy, adherence, metabolic monitoring, and diagnosis.

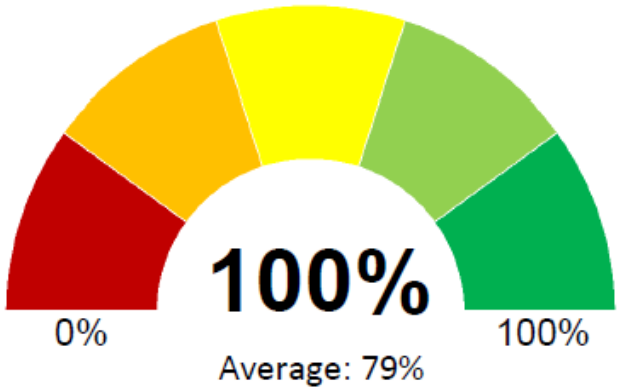
The SoonerPsych program has been using a "report card" format since April 2014. Beginning in April 2016, educational letters were sent to the same group of prescribers with all modules included in each mailing. Included prescribers receive 4 letters per year to better inform them of their SoonerCare patients using atypical antipsychotic medications and to make it more convenient to track patients and prescribing over time including any improvements or changes. Inclusion criteria requires the prescriber to have 5 or more SoonerCare patients taking atypical antipsychotic medications. A total of 225 prescribers were selected for inclusion in the 2016, 2017, and January 2018 mailings, and a total of 247 prescribers were selected for inclusion in the April, July, and October 2018 and January and April 2019 mailings.

Effective January 2017, data collection was expanded from a previous research-based approach to include additional diagnosis fields and monitoring (lipids and glucose) fields in order to provide a more clinically meaningful percentage to send to prescribers. The following list outlines definitions for each module included in the revised SoonerPsych mailing:

- **Polypharmacy:** Polypharmacy is defined as members whose pharmacy claims history indicated concurrent use of 2 or more atypical antipsychotic medications for >90 days.
- **Adherence:** Nonadherence is defined as members whose proportion of days covered (PDC) or adherence calculated from pharmacy claims history for atypical antipsychotic medications was <80%.
- **Metabolic Monitoring:** Missing metabolic monitoring is defined as members whose recent 12-month medical claims history lacked glucose testing and also includes members with a diagnosis of hyperlipidemia whose recent 12-month medical claims history lacked lipid testing.
- **Diagnosis:** Lack of diagnosis is defined as members whose recent 12-month medical claims history lacked a diagnosis with a strong indication for prescribing an atypical antipsychotic medication.

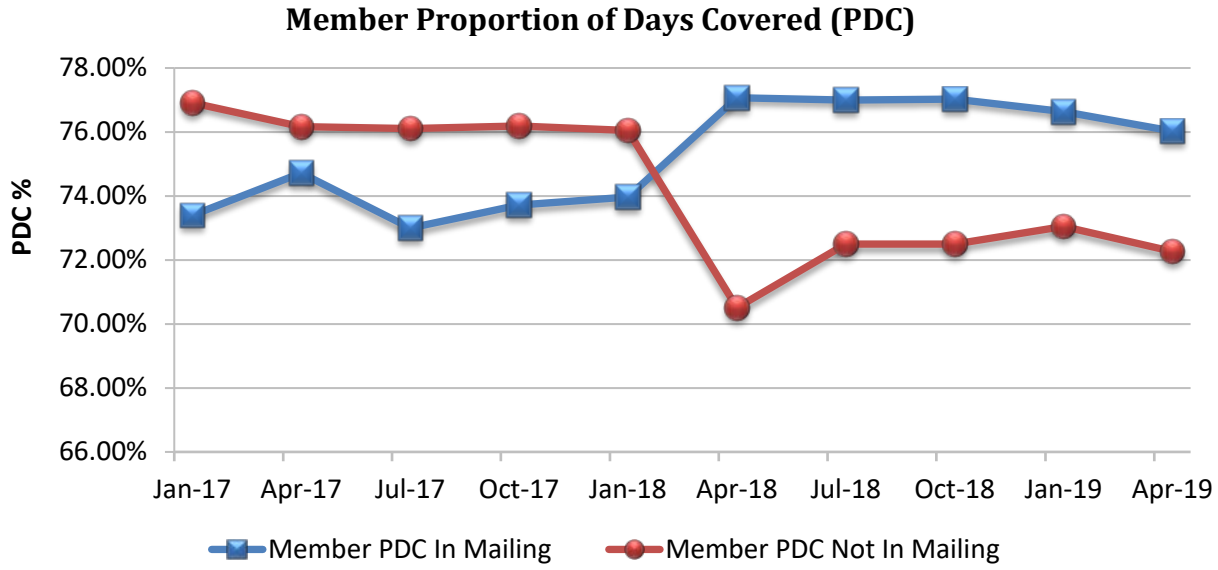
Example Gauge

Each gauge includes the individual prescriber's performance in relation to the specific module as well as the average of other SoonerCare prescribers for comparison. The following is an example gauge included in the mailings.



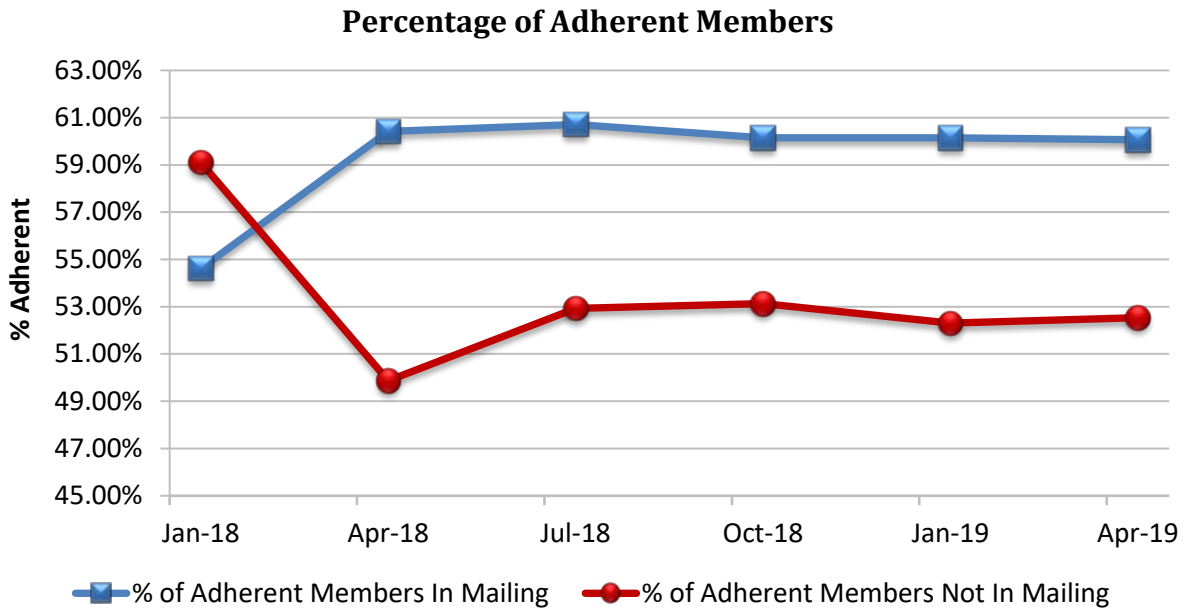
SoonerPsych Trends

The following graph shows the 2017, 2018, and 2019 trends for member PDC. Members whose prescribers are included in the SoonerPsych mailing are designated separately from those members whose prescribers are not included in the mailing. Please note, the vertical axis starts at a PDC of 66% in order to reflect small changes. It is also important to note that the prescriber mailing list was updated in April 2018 to include a larger number of prescribers and prescribers who were not previously receiving a mailing. Although PDC trends are tracked over time, it may be more meaningful to evaluate the mailings starting in April 2018 and going forward as a new data set since the prescriber mailing list was updated in April 2018.

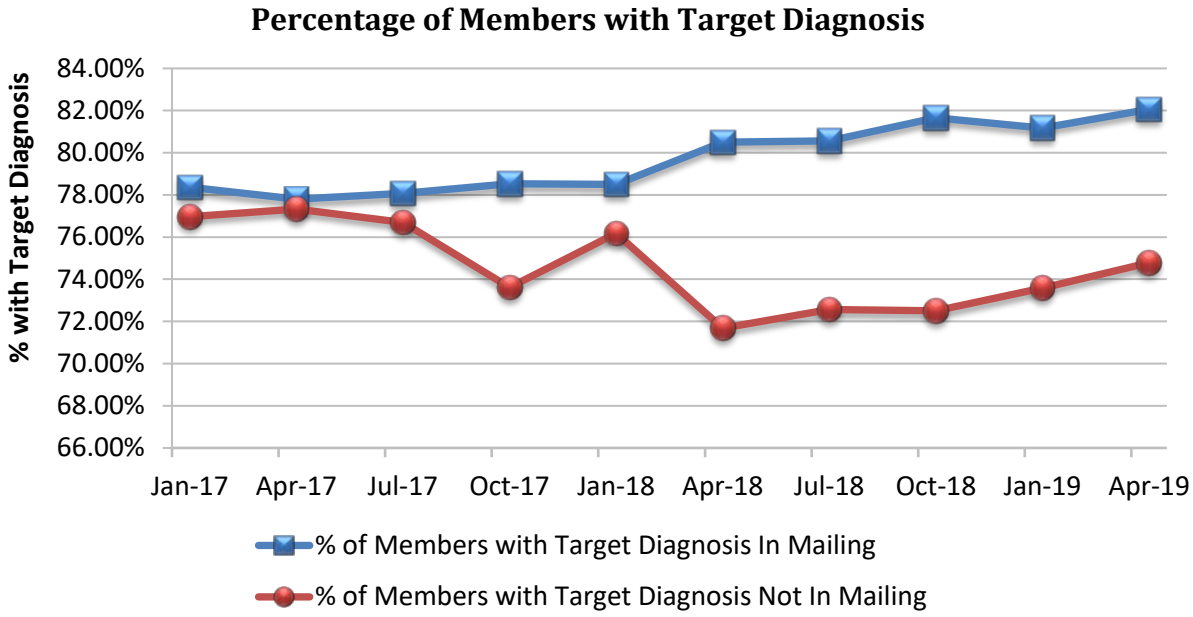


The following graph shows the 2018 and 2019 trends for the percentage of adherent members. Prescribers who received a mailing are designated separately from those who did not. Please note, the vertical axis starts at 45% of members in order to reflect small changes. This data was

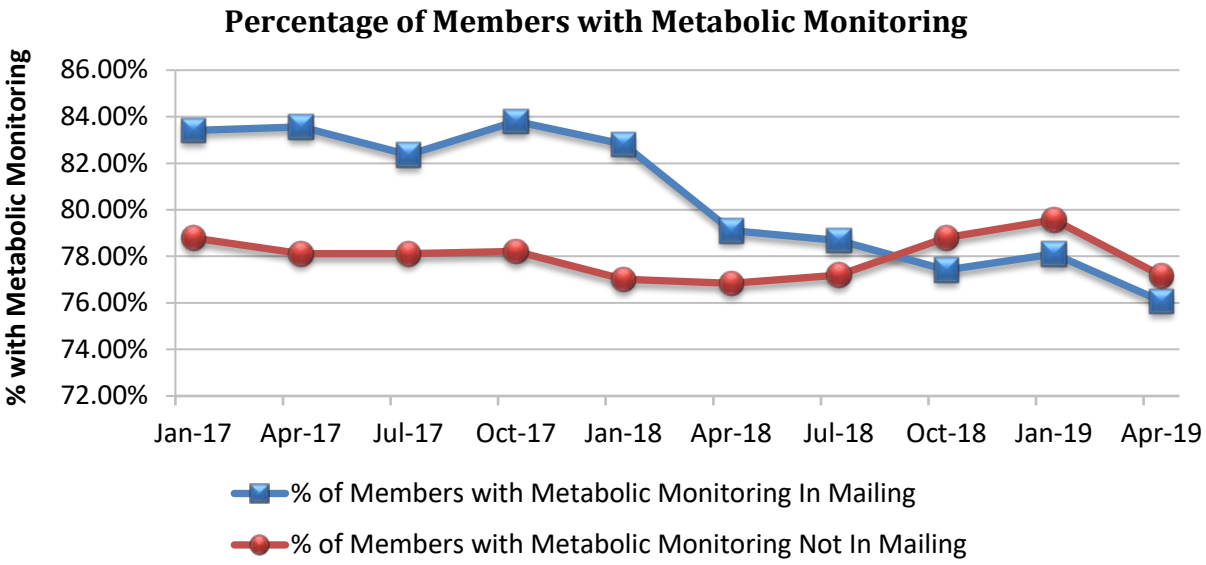
included after input from the Drug Utilization Review (DUR) Board in the December 2017 DUR meeting; the DUR Board indicated it would be an important measure for reporting.



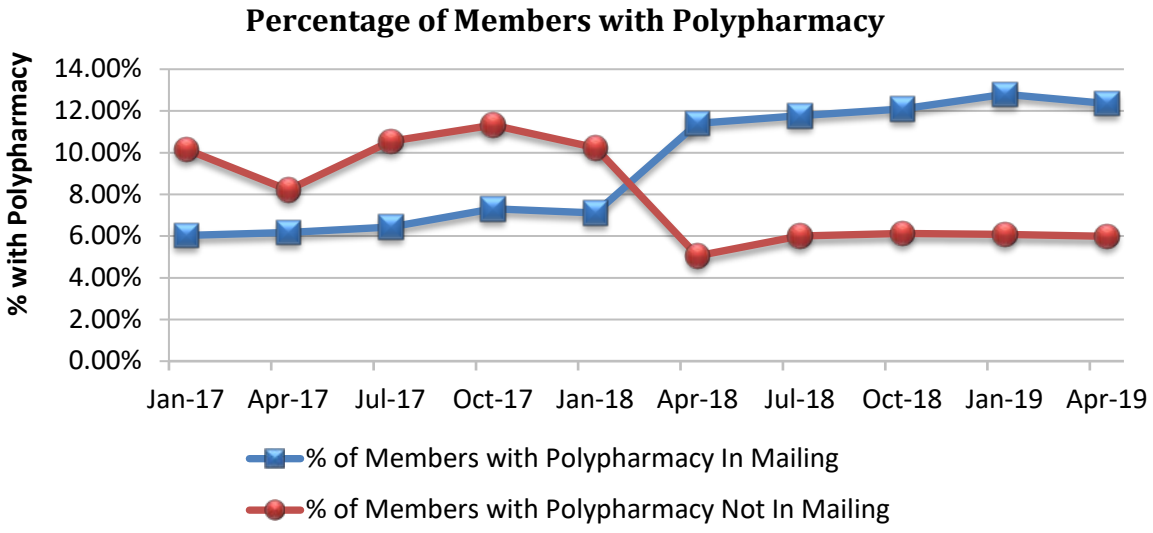
The following graph shows the 2017, 2018, and 2019 trends for the percentage of members whose recent 12-month medical claims history had a diagnosis with a strong indication for prescribing an antipsychotic medication. Prescribers who received a mailing are designated separately from those who did not. Please note, the vertical axis starts at 66% of members in order to reflect small changes. It is also important to note that the prescriber mailing list was updated in April 2018 to include a larger number of prescribers and prescribers who were not previously receiving a mailing.



The following graph shows the 2017, 2018, and 2019 trends for the percentage of members with appropriate metabolic monitoring while on an antipsychotic medication. Prescribers who received a mailing are designated separately from those who did not. Please note, the vertical axis starts at 72% of members in order to reflect small changes. It is also important to note that the prescriber mailing list was updated in April 2018 to include a larger number of prescribers and prescribers who were not previously receiving a mailing.



The following graph shows the 2017, 2018, and 2019 trends for the percentage of members with polypharmacy (concurrent use of 2 or more atypical antipsychotic medications for more than 90 days). Those prescribers who received a mailing are designated separately from those who did not. Please note, unlike the previous graphs, the vertical axis starts at 0% of members and that a lower percentage is a better outcome (indicates less prescribing of concomitant atypical antipsychotic medications). It is also important to note that the prescriber mailing list was updated in April 2018 to include a larger number of prescribers and prescribers who were not previously receiving a mailing.



Conclusions

Recent 2018 and 2019 trends indicate improvements in member PDC, the percentage of adherent members, and the percentage of members with a target diagnosis. The percentage of members with appropriate metabolic monitoring is similar for members whose prescribers received a mailing compared to those not included in the mailing in 2018 and 2019. Polypharmacy did not show positive trends in 2018 and 2019 for those prescribers included in the mailing, but following results of the new prescriber list over time may provide more opportunities for additional prescriber-specific interventions. Overall, results indicate that consistently receiving evidence-based educational mailings reminds providers of evidence-based practices, and averts some potentially inappropriate prescribing. Recent changes to the mailing format (including all modules in each mailing, mailing to consistent prescribers, and updating the prescriber mailing list), as well as expanding the data collection process, are intended to sustain improvements and reduce waning interventions. The College of Pharmacy will continue to work with the Oklahoma Health Care Authority to improve educational mailings with the goal of improving the quality of care for SoonerCare members utilizing atypical antipsychotic medications. Future results of the SoonerPsych educational mailing will be reviewed with the DUR Board as they become available.

Appendix C

Vote 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
July 2019

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

- In August 2018, the U.S. Food and Drug Administration (FDA) approved **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™ ER capsules contain beads that utilize DELEXIS® drug delivery technology, which consists of 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. The recommended starting dose of Jornay PM™ is 20mg daily in the evening. 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. 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. 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. The Wholesale Acquisition Cost (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.
- The FDA approved **Evekeo ODT™ (amphetamine ODT)** in January 2019 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. 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 in 2 strengths: 5mg and 10mg.
- The FDA approved **Adhansia XR™ (methylphenidate ER capsule)** in February 2019 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. 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. The recommended starting dose of Adhansia XR™ is 25mg once daily in the morning. 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. 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 supplied as 25mg, 35mg, 45mg, 55mg, 70mg, and 85mg ER capsules. Cost information for Adhansia XR™ is not yet available.

- In March 2019, the FDA approved **Sunosi™ (solriamfetol tablet)**, a dual-acting dopamine and norepinephrine reuptake inhibitor (DNRI), to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). 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, and modalities to treat the underlying airway obstruction should be continued during treatment with solriamfetol. For adult patients with narcolepsy, the recommended starting dose of solriamfetol is 75mg once daily upon awakening. For adult patients with OSA, the recommended starting dose of solriamfetol is 37.5mg once daily upon awakening. For either diagnosis, based on efficacy and tolerability, the dosage of solriamfetol may be doubled at intervals of at least 3 days, up to a maximum recommended dose of 150mg once daily. Doses above 150mg do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions. Sunosi™ is supplied as 75mg and 150mg oral tablets; Sunosi™ 75mg tablets are functionally scored tablets that can be split in half. Solriamfetol has *Warnings and Precautions* for blood pressure and heart rate increases and for psychiatric adverse reactions. In June 2019, Sunosi™ received Schedule IV designation from the U.S. Drug Enforcement Administration (DEA) and is expected to be commercially available in the United States in July 2019. Cost information for Sunosi™ is not yet available.

Recommendations

The College of Pharmacy recommends the following changes to the ADHD and Narcolepsy Medications Product Based Prior Authorization (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 ADHD Medications Tier Chart and ADHD Medications and Narcolepsy Medications 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)** Methylin® (methylphenidate soln & chew tabs) Mydayis® (amphetamine/ dextroamphetamine ER) ProCentra® (dextroamphetamine) Zenzedi® (dextroamphetamine)
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) QuilliChew ER® (methylphenidate ER chew tabs) Ritalin LA® (methylphenidate ER)	dexmethylphenidate ER (generic Focalin XR®) Quillivant XR® (methylphenidate ER susp)	**Adhansia XR™ (methylphenidate ER)** Concerta® (methylphenidate ER) **Jornay PM™ (methylphenidate ER)** Metadate ER® (methylphenidate ER) Methylin ER® (methylphenidate ER) methylphenidate ER 72mg Ritalin SR® (methylphenidate ER)	

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
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 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®, 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.

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 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.

[1] Ironshore Pharmaceuticals & Development, Inc. Ironshore Pharmaceuticals Announces FDA Approval of Jornay PM™ (Methylphenidate) Extended-Release Capsules CII for the Treatment of ADHD. Available online at: https://www.ironshorepharma.com/pdf/Ironshore-Announces-FDA-Approval-JORNAY-PM.pdf. Issued 08/09/2018. Last accessed 06/10/2019.

[2] Jornay PM™ (Methylphenidate Hydrochloride) Prescribing Information. Ironshore Pharmaceuticals & Development, Inc. Available online at: https://www.ironshorepharma.com/labeling.pdf. Last revised 08/2018. Last accessed 06/10/2019.

[3] OptumRx. Evekeo ODT™ (Amphetamine Sulfate) – New Drug Approval. Available online at: https://professionals.optumrx.com/publications/library/drugapprovals_evekeoodt_2019-0131.html. Issued 01/30/2019. Last accessed 06/10/2019.

[4] Adlon Therapeutics L.P. Adlon Therapeutics L.P. Announces FDA Approval for Adhansia XR™ (Methylphenidate HCl) Extended-Release Capsules CII for the Treatment of ADHD. Available online at: https://adlontherapeutics.com/fda-approval-adhansia/. Issued 03/01/2019. Last accessed 06/10/2019.

[5] Adhansia XR™ (Methylphenidate Hydrochloride) Prescribing Information. Purdue Pharmaceuticals L.P. Available online at: https://app.adlontherapeutics.com/adhansia-xr/fpi.pdf. Last revised 02/2019. Last accessed 06/10/2019.

[6] Jazz Pharmaceuticals. Jazz Pharmaceuticals Announces U.S. FDA Approval of Sunosi™ (Solriamfetol) for Excessive Daytime Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea. Available online at: https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-announces-us-fda-approval-sunositm. Issued 03/20/2019. Last accessed 06/10/2019.

[7] Sunosi™ (Solriamfetol) Prescribing Information. Jazz Pharmaceuticals, Inc. Available online at: http://pp.jazzpharma.com/pi/sunosi.en.USPI.pdf. Last revised 03/2019. Last accessed 06/10/2019.

[8] Jazz Pharmaceuticals. Jazz Pharmaceuticals Receives Schedule IV Designation from DEA for Sunosi™ (Solriamfetol). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-receives-schedule-iv-designation-from-dea-for-sunosi-solriamfetol-300869335.html. Issued 06/17/2019. Last accessed 06/24/2019.

Appendix D

Vote to Prior Authorize Balversa™ (Erdafitinib)

Oklahoma Health Care Authority
July 2019

Introduction[1,2]

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 06/19/2019.
[2] Balversa™ Prescribing Information. Janssen Pharmaceutical. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212018s000lbl.pdf. Last revised 04/2019. Last accessed 06/10/2019.

Appendix E

Vote 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
July 2019

Introduction[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15]

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. It 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).

- Other Formulation(s) Available: NuvaRing® (etonogestrel/EE vaginal ring)

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.

Bijuva™ (estradiol/progesterone capsule) is a combination of an estrogen and progesterone indicated for women with a uterus for the treatment of moderate-to-severe vasomotor symptoms due to menopause. It is supplied as a capsule containing 1mg of estradiol and 100mg of progesterone. The recommended dosage is 1 capsule every evening with food.

- Other Formulation(s) Available: estradiol/norethindrone tablet (Activella®)

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.

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

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.

Corlanor® (ivabradine oral solution) is indicated to reduce the risk of hospitalization for worsening heart failure (HF) in patients with stable, symptomatic chronic HF with reduced left ventricular ejection fraction; and for the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in patients 6 months of age and older. Corlanor® [5mg/5mL (1mg/mL)] oral solution is a colorless liquid supplied in a 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.

- Other Formulation(s) Available: Corlanor® (ivabradine tablets), carvedilol tablets, and carvedilol extended-release (ER) capsules

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.

Crotan™ (crotamiton 10% lotion) is indicated for the eradication of scabies (*Sarcoptes scabiei*) and for symptomatic treatment of pruritic skin. 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. A second application is advisable 24 hours later. For pruritus, the recommended dosing is to gently massage Crotan™ into affected areas until medication is completely absorbed and repeat as needed.

- Other Formulation(s) Available: permethrin 5% cream, Eurax® (crotamiton 10% lotion/cream), and hydrocortisone 2.5% cream

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.

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

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.

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. Glycate® is supplied as 1.5mg glycopyrrolate tablets and 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

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.

Khapzory™ (levoleucovorin injection) is a folate analog indicated for rescue after high-dose methotrexate (MTX) therapy in patients with osteosarcoma, for diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination, and for treatment of patients with metastatic colorectal cancer in combination with fluorouracil. The recommended dosing is based on diagnosis, and is available in the full *Prescribing Information*.

- Other Formulation(s) Available: levoleucovorin calcium injection and leucovorin injection

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.

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. Qmiiz™ ODT is supplied as orange flavored, yellow tablets in 2 strengths: 7.5mg and 15mg. 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 who weigh ≥60kg, the recommended dose is 7.5mg once daily.

- Other Formulation(s) Available: meloxicam 7.5mg and 15mg tablets

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.

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

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 use 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.

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

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.

Tiglutik™ (riluzole suspension) is a benzothiazole indicated for the treatment of amyotrophic lateral sclerosis (ALS). It is supplied as a 50mg/10mL (5mg/mL) riluzole oral suspension in a 300mL amber, glass bottle. 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

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.

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. It is supplied as an ophthalmic suspension containing 3mg/mL tobramycin and 0.5mg/mL dexamethasone. 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.

- Other Formulation(s) Available: neomycin/polymyxin b/dexamethasone ophthalmic suspension and TobraDex® (tobramycin/dexamethasone) ophthalmic suspension

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	$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.

Tolsura™ (itraconazole capsule) is an azole antifungal indicated for the treatment of the blastomycosis, pulmonary and extrapulmonary; histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; and aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy. It is supplied as a hard, gelatin capsule containing 65mg of itraconazole. For blastomycosis, histoplasmosis, and aspergillosis, the recommended dosage is 130 to 260mg daily.

- Other Formulation(s) Available: itraconazole 100mg capsules

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.

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. It 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 implant is placed via needle into the back of the eye under aseptic conditions. Following the injection, patients should be monitored for change in intraocular pressure, endophthalmitis, and cataract formation.

- Other Formulation(s) Available: Retisert® (fluocinolone acetonide intravitreal implant) and Ozurdex® (dexamethasone intravitreal 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.

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 year 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 why 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 18 years of age or older; 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®)

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
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.

Ophthalmic 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.

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Appendix F

Vote to Prior Authorize Abilify MyCite® (Aripiprazole Tablet with Sensor), Aristada Initio® [Aripiprazole Lauroxil Extended-Release (ER) Injectable Suspension], and Perseris™ [Risperidone ER Subcutaneous (Sub-Q) Injectable Suspension]

Oklahoma Health Care Authority
July 2019

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

Abilify MyCite® (aripiprazole tablet with sensor) is a drug-device combination product approved by the U.S. Food and Drug Administration (FDA) in November 2017. Abilify MyCite® is 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). The Abilify MyCite® System includes aripiprazole tablets embedded with an Ingestible Event Marker (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 application (MyCite® APP) to display information to the patient, and a web-based portal for health care providers and caregivers. Aripiprazole tablets with the IEM sensor are 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. Only functions of the MyCite® 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.

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) was approved by the FDA in July 2018 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® is available as a 675mg ER single-dose, pre-filled syringe. 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).

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 injectable suspension) was FDA approved in July 2018 as a 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. 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. Perseris™ is available as 90mg and 120mg ER injectable suspensions. Based on average plasma concentrations of risperidone and total active moiety, Perseris™ 90mg corresponds to 3mg/day oral risperidone and Perseris™ 120mg corresponds to 4mg/day oral risperidone. Patients who are on stable oral risperidone doses lower than 3 mg/day or higher than 4 mg/day may not be candidates for Perseris™. For patients who have never taken risperidone, tolerability should be established with oral risperidone prior to starting Perseris™. Perseris™ should be administered once monthly by sub-Q injection in the abdomen by a health care professional. More than 1 dose (90mg or 120mg) of Perseris™ should not be administered per month. 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®).

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 Product Based Prior Authorization (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 Tablet 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 patient-specific, clinically significant reason why the Tier-1 aripiprazole 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~~ Approvals 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. In addition, a patient-specific, clinically significant reason why the member cannot transition to oral aripiprazole tablets or to any of the oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply.

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

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[4] Aristada® Prescribing Information. Alkermes, Inc. Available online at: https://www.aristadahcp.com/downloadables/ARISTADA-PI.pdf. Last revised 11/2018. Last accessed 06/13/2019.

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Appendix G

Vote to Prior Authorize Cassipa® (Buprenorphine/Naloxone) and Levorphanol

Oklahoma Health Care Authority
July 2019

Introduction[1,2,3]

Cassipa® [buprenorphine/naloxone sublingual (SL) film] was approved by the U.S. Food and Drug Administration (FDA) in September 2018 for the maintenance treatment of opioid dependence. Cassipa® provides a new dosage strength (16mg/4mg) of buprenorphine/naloxone SL film, which is also approved in both brand name and generic versions in various strengths. Cassipa® should be used as part of a complete treatment plan to include counseling and psychological support. It is recommended to administer Cassipa® as a single daily dose, and this medication should only be used after induction and stabilization of the patient, and after 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. 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 information for Cassipa® is not yet available.

Levorphanol tartrate tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. 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 or are not expected to be tolerated; or have not provided or are not expected to provide adequate analgesia. 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. 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. Levorphanol has a *Boxed Warning* for the risk of addiction, abuse, and misuse; a 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 central nervous system (CNS) depressants. The Wholesale Acquisition Cost (WAC) of levorphanol is $44.50 per 2mg tablet.

Recommendations

The College of Pharmacy, in partnership with the Oklahoma Health Care Authority (OHCA), recommends the implementation of a daily morphine milligram equivalent (MME) limit of 90 to coincide with Centers for Medicare and Medicaid Services (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 medication assisted treatment (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~~ treatment options for pain (e.g., non-opioid analgesics, lower-tiered 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; and

2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and
3. For Cassipa®, the member must have been titrated to a dose of 16mg buprenorphine using another buprenorphine product prior to approval; and
4. Buprenorphine products FDA approved for a diagnosis of opioid abuse/dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
5. Member must have an FDA approved diagnosis of opioid abuse/dependence; and
6. Concomitant treatment with 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; and

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.

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[1] U.S. Food and Drug Administration. FDA approves new dosage strength of buprenorphine and naloxone sublingual film as maintenance treatment for opioid dependence. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-dosage-strength-buprenorphine-and-naloxone-sublingual-film-maintenance-treatment. Issued 09/07/2018. Last accessed 06/10/2019.

[2] Cassipa® Prescribing Information. Lohmann Therapy Systems, Corp. and Teva Pharmaceuticals USA, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208042s000lbl.pdf. Last revised 09/2018. Last accessed 06/10/2019.

[3] Levorphanol Drug Label Information. *DailyMed*. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=77f4a54a-6901-46d9-93db-ad4be7eae6c3. Last revised 09/21/2018. Last accessed 06/10/2019.

Appendix H

Calendar Year 2018 Annual Review of Botulinum Toxins

Oklahoma Health Care Authority
July 2019

Current Prior Authorization Criteria

Botulinum Toxins Approval Criteria:

1. Cosmetic indications will not be covered.
2. A diagnosis of chronic migraine headaches, non-neurogenic overactive bladder, and neurogenic overactive bladder will require manual review (see specific criteria below).
3. The following indications have been determined to be appropriate and are covered:

Covered Indications
▪ Spasticity associated with: • Cerebral palsy • Paralysis • Generalized weakness/incomplete paralysis • Larynx • Anal fissure • Esophagus (achalasia and cardiospasms) • Eye and eye movement disorders ▪ Cervical dystonia

Botulinum toxins are billed through the medical claims system and require a manual prior authorization for any covered diagnosis to ensure appropriate reimbursement for the billing provider. Prior authorization requests for botulinum toxins are first reviewed by a clinical pharmacist and if necessary, the prior authorization request is sent to the Oklahoma Health Care Authority (OHCA) for a second review from an OHCA physician. Botulinum toxin claims are denied if submitted through the pharmacy point of sale system. There are 4 covered products in this class: Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), Xeomin® (incobotulinumtoxinA), and Myobloc® (rimabotulinumtoxinB).

Botox® is the only botulinum toxin product that is approved by U.S. Food and Drug Administration (FDA) for the prevention of migraine headaches and for the treatment of non-neurogenic overactive bladder and neurogenic overactive bladder. Approval criteria for Botox® for these diagnoses were developed internally by medical staff at OHCA in collaboration with 2 SoonerCare-contracted specialists. Due to the modest effect, high cost, and potential for severe adverse reactions, it was recommended Botox® should be reserved for patients who have failed all available recommended therapies.

Approval Criteria for Botox® for Prevention of Migraine Headaches *(other botulinum toxins will not be approved for this diagnosis)*:

1. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:

    a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); and
    b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and
2. Migraine headache exacerbation secondary to other medical conditions or medication therapies have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
3. Member has no contraindications to Botox® injections; and
4. FDA indications are met:
    a. Member is 18 years of age or older; and
    b. Member has documented chronic migraine headaches:
        i. Frequency of 15 or more headache days per month with 8 or more migraine days per month and occurring for more than 3 months; and
        ii. Duration of 4 hours of headache per day or longer; and
5. The member has failed medical migraine preventative therapy including at least 2 agents with different mechanisms of action. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blockers); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
6. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
    b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
    c. Opioids (≥10 days/month for >3 months); and
    d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
    e. Ergotamine-containing medications (≥10 days/month for >3 months); and
    f. Triptans (≥10 days/month for >3 months); and
7. Member is not taking any medications that are likely to be the cause of the headaches; and
8. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox® recommended as treatment (not necessarily prescribed or administered by a neurologist); and
9. Members who smoke or use tobacco products will not be approved.

Approval Criteria for Botox® for Non-Neurogenic Overactive Bladder *(other botulinum toxins will not be approved for this diagnosis)*:

1. Member must have severe disease (≥5 urinary incontinence episodes per day on medication) and specific pathology determined via urodynamic studies; and
2. Member must have participated in behavioral therapy for at least 12 weeks that did not yield adequate clinical results; and
3. Member must have had compliant use of at least 3 anti-muscarinic or beta-3 adrenoceptor agonist medications for at least 12 weeks each, alone or in combination with behavioral therapy, that did not yield adequate clinical results. One of those trials must have been an extended-release formulation; and
4. Member must be 18 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
5. Botox® must be administered by a urologist.

Approval Criteria for Botox® for Neurogenic Overactive Bladder (*other botulinum toxins will not be approved for this diagnosis)*:

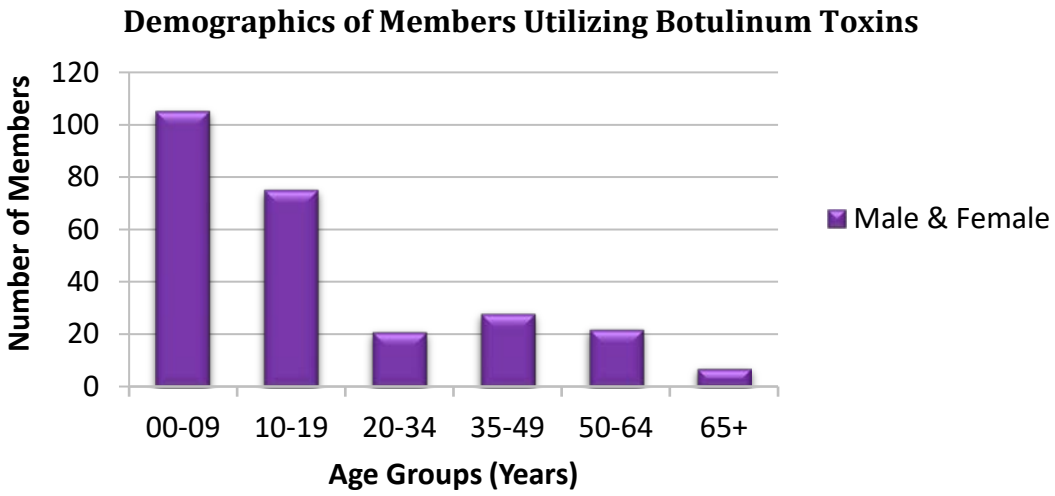
1. Diagnosis of neurogenic bladder including underlying pathological dysfunction subtype confirmed by:
    a. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
    b. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences; and
2. Member must have a clinically significant reason why anticholinergic medications are no longer an option for the member; and
3. Member must be 18 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
4. Botox® must be administered by a urologist.

Utilization of Botulinum Toxins: Calendar Year 2018

Comparison of Calendar Years

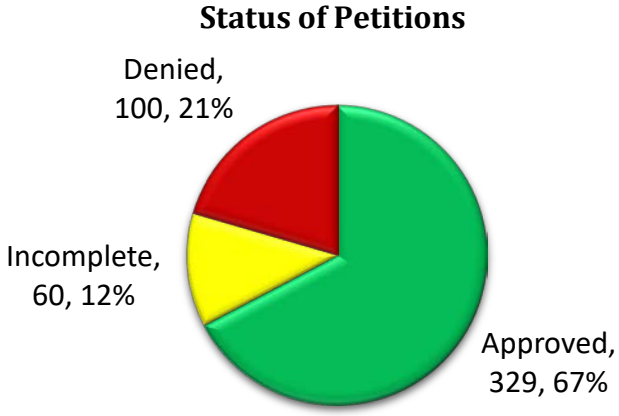
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2017	240	435	$618,054.02	$1,420.81	1.8
2018	250	402	$592,660.57	$1,474.28	1.6
% Change	**4.17%**	**-7.59%**	**-4.11%**	**3.76%**	**-11.11%**
Change	**10**	**-33**	**-$25,393.45**	**$53.47**	**-0.2**

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



Prior Authorization of Botulinum Toxins

There were 489 prior authorization requests submitted for botulinum toxins during calendar year 2018. Botulinum toxins require a manual prior authorization for any covered diagnosis to ensure appropriate reimbursement for the billing provider. The following chart shows the status of the submitted petitions for calendar year 2018.



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

New FDA Approved Indication(s):

- **July 2018:** The FDA approved a supplemental Biologics License Application (sBLA) for Xeomin® (incobotulinumtoxinA) for the treatment of chronic sialorrhea in adult patients. Chronic sialorrhea, or excessive drooling, in adults is a common symptom among patients who suffer from neurological disorders including Parkinson's disease, amyotrophic lateral sclerosis (ALS), and cerebral palsy, or patients who have suffered a traumatic brain injury (TBI) or stroke. Xeomin® was first FDA approved in 2010. The current approval criteria and covered diagnosis codes for botulinum toxins include disturbances of salivary secretion (e.g., chronic sialorrhea).
- **February 2019:** The FDA approved Jeuveau™ (prabotulinumtoxinA-xvfs) for the temporary improvement in the appearance of moderate-to-severe glabellar lines in adult patients. Jeuveau™ is the first aesthetic-only neurotoxin approved in the United

States. This indication is considered cosmetic; therefore, Jeuveau™ is not currently covered by SoonerCare.

- **May 2019:** The FDA approved a sBLA for Xeomin® (incobotulinumtoxinA) for the treatment of blepharospasm in adult patients, based on data from a Phase 3 study in treatment-naïve patients. Xeomin® was previously FDA approved for the treatment of blepharospasm in adult patients previously treated with Botox® (onabotulinumtoxinA); this sBLA approval makes Xeomin® a first-line treatment option for adults with blepharospasm. The current approval criteria and covered diagnosis codes for botulinum toxins include blepharospasm.
- **June 2019:** The FDA approved a sBLA for Botox® (onabotulinumtoxinA) for the treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, making it the first and only FDA-approved botulinum toxin product for the treatment of upper limb spasticity in pediatric patients. Botox® was first FDA approved in 1991 and currently has multiple FDA-approved indications. The current approval criteria and covered diagnosis codes for botulinum toxins include upper limb spasticity. The FDA is reviewing an additional sBLA for Botox® for the treatment of lower limb spasticity in pediatric patients, with a decision expected in the 4th quarter of this year.

News:

- **August 2018:** According to Phase 2 trial results, intramuscular (IM) treatment with Xeomin® decreased tremor severity and improved hand function in patients with essential tremor of the upper limbs. Results of the trial were presented at the 2018 World Congress on Parkinson's Disease and Related Disorders. Essential tremor, often misdiagnosed as Parkinson's disease, is a progressive movement disorder, mainly affecting the hands and arms, but head, voice, and leg tremors may also occur. A total of 30 patients were included in the Phase 2 trial, with 19 patients randomized to receive Xeomin® (at a total dose of up to 195 units) and 11 patients to receive placebo. All patients received an injection in the wrist, with optional injections into the shoulder and/or elbow. Treatment with Xeomin® induced a trend toward decreased wrist-tremor amplitude, compared with placebo, at week 4 and showed a significant improvement at week 8. Persistent anti-tremor effects were seen by motion measurements up to 24 weeks after a single injection of Xeomin®. The data further demonstrated that Xeomin® significantly improved motor performance at both week 4 and week 8.
- **September 2018:** According to results of an observational study published in the journal *Headache*, Botox® injections toward the sphenopalatine ganglion (SPG) may be an effective long-term treatment for chronic cluster headache (CH). CH is considered to be one of the most painful primary headache disorders and has a substantial impact on health-related quality of life. Chronic CH is often refractory to standard drug therapy. The SPG is a large extracranial parasympathetic ganglion located in the pterygopalatine fossa and is thought to play a key role in CH pathogenesis. In a prospective, open-label pilot study, blockade of SPG with 25 to 50 units of Botox® was performed in 10 patients with chronic CH. Investigators conducted a follow-up at 18 and 24 months after the initial Botox® injection against SPG, using headache diaries and questionnaires at month 18 and 24. After completing the pilot study, patients had access to repeated injections

as needed (minimum of 3 months between injections). There were 7 patients from the pilot study that were included in the follow-up study; 3 patients were lost to follow-up after the initial injection. During the first 24 months after the first Botox® injection, 5 of the 7 patients received repeat treatment at different time points (as needed): 1 patient repeated treatment 1 time, 2 patients repeated treatment 2 times, and 2 patients repeated treatment 6 times during the 24 months. The remaining 2 patients did not get repeated injections: 1 patient was headache-free after the initial injection and 1 patient was a non-responder after the initial injection and did not repeat the treatment. The results of this observational study found an overall significant reduction in CH attack frequency per month; additionally, there was a reduction in CH attacks with severe and unbearable intensity and an increase in CH attack-free days. The findings suggest sustained headache relief after repeated Botox® injections toward the SPG in intractable chronic CH; a placebo-controlled trial with long-term follow-up is warranted.

Recommendations

The College of Pharmacy recommends updating the current prior authorization criteria for Botox® (onabotulinumtoxinA) for the prevention of migraine headaches, to be consistent with the current approval criteria for the calcitonin gene-related peptide (CGRP) inhibitors for the prevention of migraine headaches (proposed changes noted in red):

Approval Criteria for Botox® for Prevention of Migraine Headaches *(other botulinum toxins will not be approved for this diagnosis)*:

1. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:
    a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); and
    b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and
2. Migraine headache exacerbation secondary to other medical conditions or medication therapies have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
3. Member has no contraindications to Botox® injections; and
4. FDA indications are met:
    a. Member is 18 years of age or older; and
    b. Member has documented chronic migraine headaches:
        i. Frequency of 15 or more headache days per month with 8 or more migraine days per month and occurring for more than 3 months; and
        ii. Duration of 4 hours of headache per day or longer; and
5. The member has failed medical migraine preventative therapy including at least 2 agents with different mechanisms of action. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blockers); or
    b. Select anticonvulsant therapy; or

c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and

6. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
    b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
    c. Opioids (≥10 days/month for >3 months); and
    d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
    e. Ergotamine-containing medications (≥10 days/month for >3 months); and
    f. Triptans (≥10 days/month for >3 months); and
7. Member is not taking any medications that are likely to be the cause of the headaches; and
8. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox® recommended as treatment (not necessarily prescribed or administered by a neurologist); and
9. ~~Members who smoke or use tobacco products will not be approved.~~ Prescriber must verify that other aggravating factors that are contributing to the development of chronic migraine headaches are being treated when applicable (e.g., smoking); and
10. Member will not use the requested medication concurrently with a calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine headaches.

Utilization Details of Botulinum Toxins: Calendar Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BOTOX® (J0585)	383	236	$578,487.77	$1,510.41	1.6	97.61%
DYSPORT® (J0586)	12	9	$9,440.60	$786.72	1.3	1.59%
XEOMIN® (J0588)	4	2	$1,727.20	$431.80	2	0.29%
MYOBLOC® (J0587)	3	3	$3,005.00	$1,001.67	1	0.51%
TOTAL	**402⁺**	**250***	**$592,660.57**	**$1,474.28**	**1.6**	**100%**

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

[1] Merz North America, Inc. FDA Approves Xeomin® (IncobotulinumtoxinA) for Adult Patients with Sialorrhea. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20180703005550/en/FDA-Approves-XEOMIN%C2%AE-incobotulinumtoxinA-Adult-Patients-Sialorrhea. Issued 07/03/2018. Last accessed 06/11/2019.

[2] Evolus, Inc. Evolus Receives FDA Approval for Jeuveau™ PrabotulinumtoxinA-xvfs for Injection. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2019/02/01/1709411/0/en/Evolus-Receives-FDA-Approval-for-Jeuveau-prabotulinumtoxinA-xvfs-for-Injection.html. Issued 02/01/2019. Last accessed 06/12/2019.

[3] Merz North America, Inc. Xeomin® Approved as First-Line Treatment for Blepharospasm. *MPR*. Available online at: https://www.empr.com/home/news/xeomin-approved-as-first-line-treatment-for-blepharospasm/. Issued 05/13/2019. Last accessed 06/12/2019.

[4] Brooks M. FDA OKs Botox® For Upper Limb Spasticity in Children. *Medscape*. Available online at: https://www.medscape.com/viewarticle/914816?nlid=130345_3901&src=wnl_newsalrt_190624_MSCPEDIT&uac=151193DK&impID=2006002&faf=1. Issued 06/24/2019. Last accessed 06/25/2019.

[5] Lopes JM. Xeomin® Eases Tremor Severity, Improves Hand Function in People with Essential Tremor, Phase 2 Trial Shows. *Parkinson's News Today.* Available online at: https://parkinsonsnewstoday.com/2018/08/28/xeomin-effective-essential-tremor-patients-phase-2-trial/. Issued 08/28/2018. Last accessed 06/12/2019.

[6] Aschehoug I, Bratbak DF, Tronvik EA. Long-Term Outcome of Patients with Intractable Chronic Cluster Headache Treated with Injection of Onabotulinum Toxin A Toward the Sphenopalatine Ganglion – An Observational Study. *Headache* 2018; 58(10):1519-1529. doi: 10.1111/head.13398

Appendix I

Calendar Year 2018 Annual Review of Spinal Muscular Atrophy Medications and 30-Day Notice to Prior Authorize Zolgensma® (Onasemnogene Abeparvovec-xioi)

Oklahoma Health Care Authority
July 2019

Current Prior Authorization Criteria

Spinraza® (Nusinersen) Approval Criteria:

1. A diagnosis of spinal muscular atrophy (SMA):
    a. Type 1; or
    b. Type 2; or
    c. Type 3 with symptoms; and
2. Molecular genetic testing to confirm bi-allelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene; and
3. Member is not currently dependent on permanent ventilation; and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or be an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose and verification that levels are acceptable to the prescriber; and
6. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
    a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
7. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. Hammersmith Infant Neurological Exam (HINE); or
    b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
    c. Upper Limb Module (ULM) Test; or
    d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
8. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically-significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment:
    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or
    d. HFMSE; and

9. Approval quantity will be based on Spinraza® prescribing information and FDA approved dosing regimen(s).
    a. Only one 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

Utilization of Spinraza® (Nusinersen): Calendar Year 2018

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	6	15	$2,623,358.25	$174,890.55	$4,244.92	105	618
2018	10	23	$2,573,311.28	$111,883.10	$1,307.58	120	1,968
% Change	**66.70%**	**53.30%**	**-1.90%**	**-36.00%**	**-69.20%**	**14.30%**	**218.40%**
Change	**4**	**8**	**-$50,046.97**	**-$63,007.45**	**-$2,937.34**	**15**	**1,350**

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

Demographics of Members Utilizing Spinraza® (Nusinersen)

- Due to the small number of members utilizing nusinersen, detailed demographic information could not be provided. All paid claims were for pediatric members.

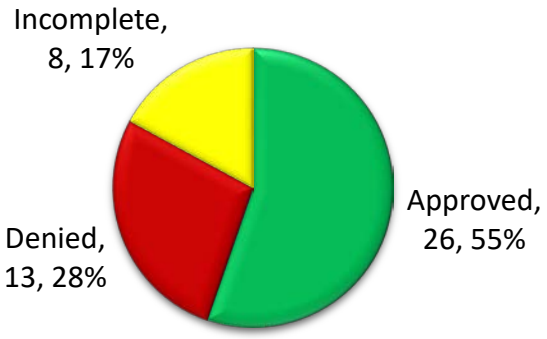
Top Prescriber Specialties of Spinraza® (Nusinersen) by Number of Claims: Pharmacy Claims

- The top prescriber specialties listed on paid nusinersen claims during calendar year 2018 were pediatric pulmonologist and neurologist.

Prior Authorization of Spinraza® (Nusinersen)

There were 47 prior authorization requests submitted for Spinraza® (nusinersen) during calendar year 2018. The following chart shows the status of the submitted petitions for calendar year 2018.

Status of Petitions



Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14]

Anticipated Patent Expiration(s):

- Spinraza® (nusinersen): January 2034

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

- **May 2019:** AveXis, a Novartis company, announced FDA approval of Zolgensma® (onasemnogene abeparvovec-xioi) for the treatment of pediatric patients younger than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the *survival motor neuron 1* (*SMN1*) gene. Zolgensma® is designed to address the genetic cause of SMA by providing a functional copy of the human SMN gene to halt disease progression through sustained SMN protein expression after a single, 1-time intravenous (IV) infusion. Zolgensma® is the first and only gene therapy for the treatment of SMA approved by the FDA.

News:

- **May 2018:** A working group comprised of 15 SMA experts participated in a modified Delphi process to develop a treatment algorithm for SMA-positive infants identified through newborn screening (NBS) based upon *survival motor neuron 2* (*SMN2)* copy number. The treatment algorithm was published prior to the approval of onasemnogene abeparvovec. In the treatment algorithm, the working group emphasized the need for early intervention through NBS to maximize the benefit of treatment. The group recommends the development of reliable and validated screening techniques to enable treatment of pre-symptomatic patients to achieve maximal therapeutic benefit. For patients with 2 or 3 copies of the *SMN2* gene, the group recommends immediate treatment with a disease modifying therapy. For patients with only 1 copy of *SMN2* who are symptomatic at birth, the group states that the attending physician should determine whether the infant and family would benefit from treatment given the patient's current disease state. The working group was divided as to whether infants with 4 copies of *SMN2*, as identified by NBS, should be treated immediately or instead screened carefully for the first signs of mild symptoms to initiate treatment. The committee reached a consensus that patients with more than 4 copies should not be treated immediately but screened carefully for the first presentation of symptoms.
- **July 2018:** Roche announced it stopped the development of olesoxime, a treatment for SMA, following disappointing 18-month results in an ongoing clinical study. Results of the OLEOS Phase 2 trial, an open-label study in Europe on long-term safety, tolerability, and efficacy of olesoxime in SMA type 2 (SMA2) and non-ambulatory SMA type 3 (SMA3) patients, were positive at 12 months of treatment; however, analysis at 18 months showed deterioration of motor function. The company stated that with the emergence of an effective SMA treatment (Spinraza®), requirements for how effective a medication needs to be are now more demanding and impacts the design and conduction of clinical studies. Roche is continuing to advance its SMA program with other treatment candidates which includes RG7916.
- **August 2018:** Results of a study to evaluate the safety and clinical efficacy of Spinraza® (nusinersen) in patients older than 7 months of age with SMA type 1 (SMA1) were

published in the journal *Neurology*. In the study, patients with SMA1 were treated with nusinersen as a part of the Expanded Access Program. Patients were evaluated before treatment initiation and at 2 months and 6 months after treatment initiation. There were 33 children treated ranging in age from 8.3 months to 113.1 months (9 years, 5 months). All patients were alive and were continuing treatment at month 6. Median progress on the modified Hammersmith Infant Neurologic Examination Part 2 (HINE-2) score was 1.5 points after 6 months of treatment (P<0.001). The need for respiratory support significantly increased over time. There were no statistically significant differences between patients presenting with 2 copies and those presenting with 3 copies of the *SMN2* gene. The authors concluded that the results are in line with the Phase 3 study for nusinersen in patients with SMA1 treated before 7 months of age and indicate that patients benefit from nusinersen even at a later stage of the disease.

- **May 2019:** Data from CS2/CS12, an open-label study of the safety and tolerability of nusinersen in individuals with later-onset SMA, were published in the journal *Neurology*. The data shows that individuals with later-onset SMA treated with nusinersen regained motor function that had been previously lost and that treatment stabilized their disease leading to improvements in activities of daily living. The open-label study evaluated 28 patients 5 to 19 years of age at time of study completion with later-onset SMA, including those most likely to develop SMA2 (N=11) and SMA3 (N=17) that were treated with nusinersen for more than 3 years. Participants with SMA2 increased Hammersmith Functional Motor Scale-Expanded (HFMSE) scores by 10.8 points while those with SMA3 improved by 1.8 points. This compares to the natural history of the disease in which individuals with SMA2 and SMA3 who are not being treated typically experience a 1.7 point decline in HFMSE scores after 3 years. All non-ambulant patients with SMA3 achieved a maximum score of 18 points on the Upper Limb Module (ULM) assessment by day 350 and maintained that level through day 1,150. This compares to the natural history of the disease in which non-ambulant children with SMA2 and SMA3 have an average ULM score of 10.23 points with an average 12-month gain of 0.04. Individuals with SMA3 increased their distance walked by 92.0 meters in the 6-minute walk test (6MWT) in comparison to a 1.5 meter decrease in natural history in the same test after 1 year. One of the 11 non-ambulant children with SMA2 gained the ability to walk independently through the course of the studies, an achievement that has never been reported in individuals with SMA2 that are not undergoing treatment. Two of the 4 children with SMA3, who had previously lost the ability to walk, regained the ability to walk independently during the course of the studies, suggesting that reversal of motor function loss may be possible for later-onset individuals treated with nusinersen.
- **May 2019:** Biogen announced new data affirming the safety and durability of nusinersen, as well as highlighting the clinically meaningful benefits for patients with SMA. Interim results from the ENDEAR-SHINE open-label extension study of infants (N=89) followed for up to 4 years demonstrated that treatment with nusinersen resulted in additional or new motor function improvements on the Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND). The infants also exhibited improved event-free survival rates compared to the natural history of the disease. Data from CHERISH-SHINE, which evaluated patients with later-onset SMA

(N=125, most likely to develop SMA2 or SMA3), demonstrated that earlier treatment resulted in greater improvements in motor function and continued improvement or stabilization of motor function scores. Data from the NURTURE study showed that pre-symptomatic treatment of infantile-onset SMA (N=25, most likely to develop SMA1 or SMA2) resulted in motor milestone achievements more consistent with normal motor development.

- **May 2019:** The Institute for Clinical and Economic Review (ICER) published a Final Evidence Report and Report-at-a-Glance on treatments for SMA in April 2019. In May 2019, ICER issued an addendum to its Final Evidence Report following the FDA approval of Zolgensma® (onasemnogene abeparvovec). The update reflected additional data for onasemnogene abeparvovec, as well as the treatment's final FDA label and launch price. According to ICER's report, the cost effectiveness of Spinraza® (nusinersen) is best when used for pre-symptomatic infants, but at its current price it far exceeds commonly accepted thresholds. As part of the addendum, it was stated that when assessing the value of Zolgensma® stakeholders may choose value-based price benchmarks in the range of $1.1 to $1.9 million [prices to reach $100,000 to $150,000 per quality adjusted life year (QALY) gained] and from $1.2 to $2.1 million (prices to reach $100,000 to $150,000 per life year gained). Policy recommendations for payers included negotiating outcomes-based contracts under which a substantial portion of treatment cost is at risk should patients not receive adequate clinical benefit. Sources of uncertainty identified in the report included the lack of long-term safety and efficacy data for both Spinraza® and Zolgensma®; evidence limitations in pre-symptomatic SMA; and generalizability of trial results. For Spinraza®, there is uncertainty in the long-term harms of repeated injections in patients, particularly as they age or progress along the disease course. For Zolgensma®, there is uncertainty in the durability of a gene therapy; however, to date, there has been no waning of treatment effects and longer-term studies will provide further evidence. The New England Comparative Effectiveness Public Advisory Council (CEPAC) unanimously found the evidence sufficient to show a net health benefit in infantile-onset SMA for both Spinraza® and Zolgensma® versus supportive care alone. The Council found the evidence sufficient to show a net health benefit in later-onset and pre-symptomatic patients for Spinraza®. They did not find the evidence sufficient to distinguish between Spinraza® and Zolgensma®, nor did they find the evidence for Zolgensma® to be sufficient to show a net health benefit in pre-symptomatic patients.
- **May 2019:** The National Institute for Health and Care Excellence (NICE) recommended Spinraza® (nusinersen) for funding by the National Health Service (NHS). NICE's favorable decision makes nusinersen the first treatment targeting the underlying cause of SMA to be included in England's public health program for pre-symptomatic and symptomatic SMA1, SMA2, and SMA3. Previously, the agency recommended against nusinersen's inclusion into the subsidized public health system due to concerns over its long-term effectiveness and high cost. The agency reconsidered its opinion following extensive clinical data showing the benefits of nusinersen. In addition, NHS England and Biogen, the manufacturer of Spinraza®, established an agreement to continue to observe the impact of the NHS-funded treatment for a limited time period, allowing further data to be collected on its effectiveness.

Pipeline:

- **Branaplam (LMI070):** Branaplam is an oral therapy candidate that increases the amount of functional SMN protein produced by modulating the expression of the *SMN2* gene, specifically by targeting a process called splicing. Novartis is conducting a Phase 1/2 open-label study of branaplam in infants up to 6 months of age with SMA1. The study aims to evaluate the safety, tolerability, pharmacological properties, and efficacy of branaplam after a 13-week treatment period. In preclinical trials, mice with severe SMA that received oral treatment with branaplam a few days after birth began to produce greater amounts of SMN protein in the brain, which translated into an extended lifespan. The preclinical results supported the progression of branaplam into clinical trials. Novartis announced in May 2019 that enrollment in the ongoing clinical study of branaplam is now closed; 25 infants were enrolled in part 2 of the study and 7 infants continue to receive branaplam in part 1 of the study.
- **Reldesemtiv:** Results of the Phase 2 clinical study of reldesemtiv in patients with SMA were presented at the 2018 Annual Cure SMA Conference. The hypothesis-generating study met its primary objective to determine the potential pharmacodynamic effects of reldesemtiv after multiple oral doses in patients with SMA, and secondary objectives to evaluate the safety, tolerability, and pharmacokinetics of reldesemtiv. Cytokinetics is developing reldesemtiv as a potential treatment for patients with SMA and certain other debilitating diseases and conditions associated with skeletal muscle weakness and/or fatigue. The study showed dose- and concentration-dependent increases in time to muscle fatigue as measured by changes from baseline in 6-minute walk distance (6MWD), a sub-maximal exercise test of aerobic capacity and endurance, and Maximal Expiratory Pressure (MEP), a measure of strength of respiratory muscles, after 8 weeks of treatment with reldesemtiv.
- **Risdiplam (RG7916):** Risdiplam is an investigational splicing modifier targeting the SMN2 RNA, restoring a functional transcript. The medication is taken orally, shows systemic distribution to the organs that are affected by low levels of SMN protein, and crosses the blood brain barrier. Results of a Phase 2/3 clinical trial (FIREFISH) of risdiplam were presented at the World Muscle Society's annual meeting. After 8 months of treatment with risdiplam, 6 out of 14 infants with SMA1 were able to sit and maintain upright head control. In addition, 3 achieved unassisted stable sitting, a milestone typically not reached in infants with SMA1. Initial results from another Phase 2/3 study (SUNFISH) indicated it helped maintain motor function in infants with SMA2 and SMA3. Roche, which licensed the medication from PTC Therapeutics, plans to submit risdiplam for FDA approval in 2019.

Zolgensma® (Onasemnogene Abeparvovec-xioi) Product Summary[15,16]

Indication(s): Zolgensma® (onasemnogene abeparvovec-xioi) is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of pediatric patients younger than 2 years of age with SMA with bi-allelic mutations in *SMN1* gene.

Limitations of Use:

- The safety and effectiveness of repeat administration of onasemnogene abeparvovec-xioi have not been evaluated.
- The use of onasemnogene abeparvovec-xioi in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) has not been evaluated.

Dosing:

- Zolgensma® is supplied as a customized kit to meet dosing requirements for each patient. Each kit contains 2 to 9 vials of onasemnogene abeparvovec-xioi.
- Onasemnogene abeparvovec-xioi is for single-dose IV infusion only. It is recommended to administer onasemnogene abeparvovec-xioi as an IV infusion over 60 minutes.
- Starting 1 day prior to onasemnogene abeparvovec-xioi infusion, systemic corticosteroids equivalent to oral prednisolone at 1mg/kg of body weight per day should be administered for a total of 30 days. *(Refer to Zolgensma® Prescribing Information for detailed recommendations regarding dosing of corticosteroids beyond 30 days.)*
- The recommended dose of onasemnogene abeparvovec-xioi is 1.1×10^{14} vector genomes per kilogram (vg/kg) of body weight.

Boxed Warning: Acute Serious Liver Injury

- Acute serious liver injury and elevated aminotransferases can occur with onasemnogene abeparvovec-xioi. Patients with pre-existing liver impairment may be at higher risk.
- Prior to infusion, it is recommended to assess liver function of all patients by clinical examination and laboratory testing (e.g., hepatic aminotransferases [aspartate aminotransferase (AST) and alanine aminotransferase (ALT)], total bilirubin, prothrombin time). Systemic corticosteroids should be administered to all patients before and after onasemnogene abeparvovec-xioi infusion. Liver function monitoring should continue for at least 3 months after infusion.

Mechanism of Action: Onasemnogene abeparvovec-xioi is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein. SMA is caused by a bi-allelic mutation in the *SMN1* gene, which results in insufficient SMN protein expression. IV administration of onasemnogene abeparvovec-xioi that results in cell transduction and expression of the SMN protein has been observed in 2 human case studies.

Contraindication(s): None

Warnings and Precautions:

- Acute Serious Liver Injury and Elevated Aminotransferases: Acute serious liver injury can occur with onasemnogene abeparvovec-xioi. Administration of onasemnogene abeparvovec-xioi may result in aminotransferase elevations. Two (2/44) patients in clinical trials had increased AST and ALT levels up to 48 times the upper limit of normal (ULN) after onasemnogene abeparvovec-xioi infusion. These patients, who were otherwise asymptomatic with normal total bilirubin, were managed with systemic corticosteroids and the abnormalities resolved without sequelae. Prior to onasemnogene abeparvovec-xioi infusion, liver function should be assessed by clinical

examination and laboratory testing (hepatic aminotransferases, total bilirubin, and prothrombin time).

- Thrombocytopenia: Transient decreases in platelet counts, some of which met the criteria for thrombocytopenia, were observed at different time points after onasemnogene abeparvovec-xioi infusion. Platelet counts should be monitored before onasemnogene abeparvovec-xioi infusion and on a regular basis afterwards (weekly for the first month; every other week for the second and third months until platelet counts return to baseline).
- Elevated Troponin-I: Transient increases in cardiac troponin-I levels (up to 0.176µg/L) were observed following onasemnogene abeparvovec-xioi infusion in clinical trials. The clinical importance of these findings is not known. However, cardiac toxicity was observed in animal studies. Troponin-I should be monitored before onasemnogene abeparvovec-xioi infusion and on a regular basis for at least 3 months afterwards (weekly for the first month, and then monthly for the second and third months until troponin-I level returns to baseline).

Adverse Reactions:

- The most common adverse reactions (incidence ≥5%) following infusion of onasemnogene abeparvovec-xioi in clinical trials were elevated aminotransferases and vomiting.

Use in Specific Populations:

- Pregnancy: There are no available data regarding onasemnogene abeparvovec-xioi use in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with onasemnogene abeparvovec-xioi.
- Lactation: There is no information available on the presence of onasemnogene abeparvovec-xioi in human milk, the effects on the breastfed infant, or the effects on milk production.
- Pediatric Use: Administration of onasemnogene abeparvovec-xioi to premature neonates before reaching full-term gestational age is not recommended because concomitant treatment with corticosteroids may adversely affect neurological development. It is recommended to delay onasemnogene abeparvovec-xioi infusion until the corresponding full-term gestational age is reached. There is no information on whether breastfeeding should be restricted in mothers who may be seropositive for anti-AAV9 antibodies. The safety of onasemnogene abeparvovec-xioi was studied in pediatric patients who received onasemnogene abeparvovec-xioi infusion at age 0.3 to 7.9 months (weight range 3.0 to 8.4kg). The efficacy of onasemnogene abeparvovec-xioi was studied in pediatric patients who received onasemnogene abeparvovec-xioi infusion at age 0.5 to 7.9 months (weight range 3.6 to 8.4kg).
- Hepatic Impairment: One patient who received onasemnogene abeparvovec-xioi developed acute serious liver injury; that patient had elevated aminotransferase levels prior to onasemnogene abeparvovec-xioi infusion. In clinical trials, elevation of aminotransferases was observed in patients following onasemnogene abeparvovec-xioi infusion.

Efficacy: The efficacy of onasemnogene abeparvovec-xioi in pediatric patients younger than 2 years of age with SMA with bi-allelic mutations in the *SMN1* gene was evaluated in an open-label, single-arm clinical trial (ongoing) and an open-label, single-arm, ascending-dose clinical trial (completed). Patients experienced onset of clinical symptoms consistent with SMA before 6 months of age. All patients had genetically confirmed bi-allelic *SMN1* gene deletions, 2 copies of the *SMN2* gene, and absence of the c.859G>C modification in exon 7 of *SMN2* gene (which predicts a milder phenotype). All patients had baseline anti-AAV9 antibody titers of ≤1:50, measured by ELISA. Onasemnogene abeparvovec-xioi was delivered as a single-dose IV infusion in both trials.

Efficacy was established on the basis of survival and achievement of developmental motor milestones, such as sitting without support. Survival was defined as time from birth to either death or permanent ventilation. Permanent ventilation was defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 or more hours per day [including non-invasive ventilator (NIV) support] continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation. Efficacy was also supported by assessments of ventilator use, nutritional support, and scores on the CHOP-INTEND.

The ongoing clinical trial enrolled 21 patients with infantile-onset SMA. None of the 21 patients required NIV support before treatment with onasemnogene abeparvovec-xioi, and all patients could exclusively feed orally (i.e., no need for non-oral nutrition). The mean CHOP-INTEND score at baseline was 31.0 (range 18 to 47). All patients received 1.1×10^{14} vg/kg of onasemnogene abeparvovec-xioi. The mean age of the 21 patients at the time of treatment was 3.9 months (range 0.5 to 5.9 months). As of the March 2019 data cutoff, 19 patients were alive without permanent ventilation (i.e., event-free survival) and were continuing in the trial, while 1 patient died at 7.8 months of age due to disease progression and 1 patient withdrew from the study at 11.9 months of age. The 19 surviving patients who were continuing in the study ranged in age from 9.4 to 18.5 months. By the data cutoff, 13 of the 19 patients remaining in the study reached 14 months of age without permanent ventilation. Assessment of the other co-primary efficacy endpoint found that 10 of the 21 patients (47.6%) achieved the ability to sit without support for ≥30 seconds between 9.2 and 16.9 months of age (mean age was 12.1 months). Based on the natural history of the disease, patients who met the study entry criteria would not be expected to attain the ability to sit without support, and only approximately 25% of these patients would be expected to survive (i.e., being alive without permanent ventilation) beyond 14 months of age. In addition, 16 of the 19 patients had not required daily NIV use. Comparison of the results of the ongoing clinical trial to available natural history data of patients with infantile-onset SMA provides primary evidence of the effectiveness of onasemnogene abeparvovec-xioi.

The completed clinical trial enrolled 15 patients with infantile-onset SMA: 3 patients in a low-dose cohort and 12 patients in a high-dose cohort. At the time of treatment, the mean age of patients in the low-dose cohort was 6.3 months (range 5.9 to 7.2 months) and 3.4 months (range 0.9 to 7.9 months) in the high-dose cohort. The dosage received by patients in the low-dose cohort was approximately one-third of the dosage received by patients in the high-dose cohort. However, the precise dosages of onasemnogene abeparvovec-xioi received by patients

in this completed clinical trial are unclear due to a change in the method of measuring onasemnogene abeparvovec-xioi concentration, and due to decreases in the concentration of stored onasemnogene abeparvovec-xioi over time. The retrospectively-estimated dosage range in the high-dose cohort is approximately 1.1×10^{14} to 1.4×10^{14} vg/kg. By 24 months following onasemnogene abeparvovec-xioi infusion, 1 patient in the low-dose cohort met the endpoint of permanent ventilation; all 12 patients in the high-dose cohort were alive without permanent ventilation. None of the patients in the low-dose cohort were able to sit without support, or able to stand or walk; in the high-dose cohort, 9 of the 12 patients (75.0%) were able to sit without support for ≥30 seconds, and 2 patients (16.7%) were able to stand and walk without assistance. Comparison of the results of the low-dose cohort to the results of the high-dose cohort shows a dose-response relationship that supports the effectiveness of onasemnogene abeparvovec-xioi.

Cost: The Wholesale Acquisition Cost (WAC) of Zolgensma® (onasemnogene abeparvovec-xioi) is $2,125,000 per 1-time infusion.

Recommendations

The College of Pharmacy recommends the prior authorization of Zolgensma® (onasemnogene abeparvovec-xioi) with the following criteria:

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric patients younger than 2 years of age; and
2. Member must have reached full-term gestational age prior to Zolgensma® infusion; and
3. Molecular genetic testing to confirm bi-allelic mutations in the *survival motor neuron 1* (*SMN1*) gene; and
4. Member is not currently dependent on permanent ventilation (defined as at least 16 hours of respiratory assistance per day continuously for more than 21 days in the absence of an acute, reversible illness or a perioperative state); and
5. Zolgensma® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or be an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests, platelet counts, and troponin-I at baseline and as directed by the Zolgensma® prescribing information; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Zolgensma® infusion and continuing as recommended in the prescribing information based on member's liver function; and
9. Zolgensma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the Zolgensma® prescribing information; and
10. Member will not be approved for concomitant treatment with nusinersen following Zolgensma® infusion (current authorizations for nusinersen will be discontinued upon Zolgensma® approval); and

11. Member's recent weight must be provided to ensure accurate dosing in accordance with Zolgensma® prescribing information; and
12. Only 1 Zolgensma® infusion will be approved per member per lifetime.

In addition, the College of Pharmacy recommends the following changes shown in red to the current Spinraza® (nusinersen) approval criteria:

Spinraza® (Nusinersen) Approval Criteria:

1. A diagnosis of spinal muscular atrophy (SMA):
    a. Type 1; or
    b. Type 2; or
    c. Type 3 with symptoms; and
2. Molecular genetic testing to confirm bi-allelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene; and
3. Member is not currently dependent on permanent ventilation (defined as at least 16 hours of respiratory assistance per day continuously for more than 21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or be an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose and verification that levels are acceptable to the prescriber; and
7. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
    a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
8. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. Hammersmith Infant Neurological Exam (HINE); or
    b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
    c. Upper Limb Module (ULM) Test; or
    d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
9. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically-significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment:
    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or
    d. HFMSE; and

10. Approval quantity will be based on Spinraza® prescribing information and FDA approved dosing regimen(s).
    a. Only one 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2019. Last accessed 03/22/2019.

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Appendix J

Calendar Year 2018 Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Bryhali™ (Halobetasol Propionate 0.01% Lotion), Duobrii™ (Halobetasol Propionate/Tazarotene 0.01%/0.045% Lotion), and Lexette™ (Halobetasol Propionate 0.05% Foam)

Oklahoma Health Care Authority
July 2019

Current Prior Authorization Criteria

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

Tier-2 Topical Corticosteroids Approval Criteria:

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

Tier-3 Topical Corticosteroids Approval Criteria:

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

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (**Diprolene AF®**)	**C,G**	amcinonide 0.1%	**C,L**	clobetasol propionate 0.025% (**Impoyz™**)	**C**

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
betamethasone dipropionate 0.05% (**Diprosone®**)	**O**	augmented betamethasone dipropionate 0.05% (**Diprolene®**)	**L,O**	clobetasol propionate 0.05% (**Clobex®**)	**Sh,Spr**
clobetasol propionate 0.05% (**Temovate®**)	**C,L,So**	betamethasone dipropionate 0.05% (**Diprosone®**)	**C**	clobetasol propionate 0.05% (**Olux®, Olux-E®**)	**F**
fluocinonide 0.05%	**C,O,So**	clobetasol propionate 0.05% (**Clobex®**)	**L**	clobetasol propionate 0.05% (**Temovate®**)	**O**
halobetasol propionate 0.05% (**Ultravate®**)	**C**	clobetasol propionate 0.05% (**Temovate®**)	**G**	desoximetasone 0.25% (**Topicort®**)	**C,O,Spr**
		desoximetasone 0.05% (**Topicort®**)	**G**		
		diflorasone diacetate 0.05% (**Apexicon®**)	**C,O**		
		diflorasone diacetate 0.05% (**Apexicon E®**)	**C**		
		fluocinonide 0.05%	**G**		
		fluocinonide 0.1% (**Vanos®**)	**C**		
		flurandrenolide tape 0.05% (**Cordran®**)	**Tape**		
		halcinonide 0.1% (**Halog®**)	**C,O**		
		halobetasol propionate 0.05% (**Ultravate®**)	**L,O**		
		halobetasol propionate/lactic acid 0.05%/10% (**Ultravate X®**)	**C**		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	**L**	betamethasone dipropionate/calcipotriene 0.064%/0.005% (**Taclonex®**)	**O,Spr, Sus**	betamethasone dipropionate 0.05% (**Sernivo®**)	**Spr**
betamethasone valerate 0.1% (**Beta-Val®**)	**C,L,O**	betamethasone valerate 0.12% (**Luxiq®**)	**F**	hydrocortisone valerate 0.2% (**Westcort®**)	**C,O**
fluticasone propionate 0.05% (**Cutivate®**)	**C,O**	calcipotriene/betamethasone dipropionate 0.064%/0.005% (**Enstilar®**)	**F**		
mometasone furoate 0.1% (**Elocon®**)	**C,L,O So**	clocortolone pivalate 0.1% (**Cloderm®**)	**C**		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
triamcinolone acetonide 0.025%	**O**	desoximetasone 0.05% (**Topicort LP®**)	**C,O**		
triamcinolone acetonide 0.1%	**C,L,O**	fluocinolone acetonide 0.025% (**Synalar®**)	**C,O**		
triamcinolone acetonide 0.5%	**C,O**	fluocinonide emollient 0.05% (**Lidex E®**)	**C**		
		flurandrenolide 0.05%	**C,L,O**		
		fluticasone propionate 0.05% (**Cutivate®**)	**L**		
		hydrocortisone butyrate 0.1%	**C,L,O, So**		
		hydrocortisone probutate 0.1% (**Pandel®**)	**C**		
		prednicarbate 0.1% (**Dermatop®**)	**C,O**		
		triamcinolone acetonide 0.147mg/g (**Kenalog®**)	**Spr**		
Low Potency					
desonide 0.05% (**Desonate®**)	**G**	alclometasone dipropionate 0.05% (**Aclovate®**)	**C,O**	fluocinolone acetonide 0.01% (**Derma-Smoothe®; Derma-Smoothe FS®**)	**Oil**
fluocinolone acetonide 0.01% (**Capex®**)	**Sh**	desonide 0.05% (**Verdeso®**)	**F**	desonide 0.05%	**L**
hydrocortisone acetate 1%	**C,O**	fluocinolone acetonide 0.01% (**Synalar®**)	**C,So**	desonide emollient 0.05%	**C,O**
hydrocortisone acetate 2.5%	**C,L,O**	hydrocortisone 2.5% (**Texacort®**)	**So**		
hydrocortisone/urea 1%/10% (**U-Cort®**)	**C**	hydrocortisone/pramoxine 1%/1% (**Pramosone®**)	**C,L**		
triamcinolone acetonide 0.025%	**C,L**				

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

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

Utilization of Topical Corticosteroids: Calendar Year 2018

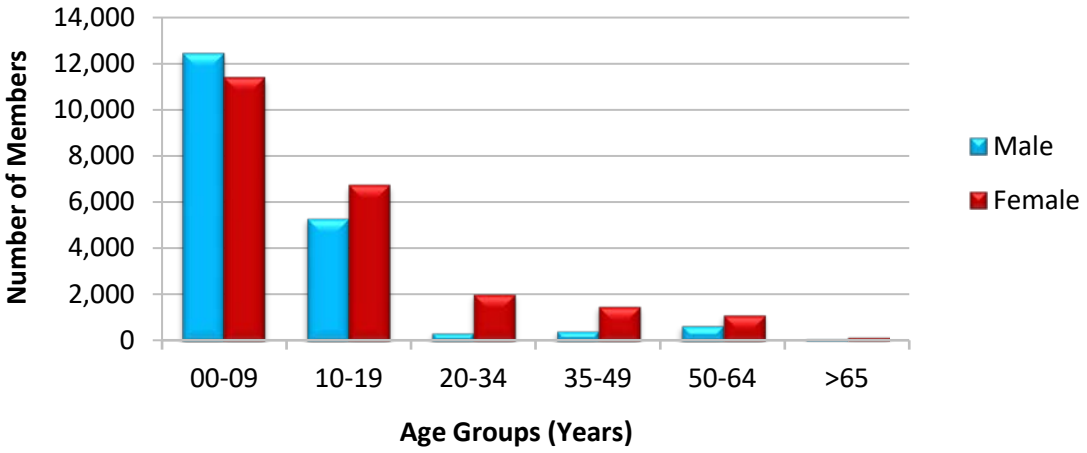
Comparison of Calendar Years

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	44,789	67,625	$1,239,688.36	$18.33	$1.16	4,139,597	1,066,878
2018	42,313	64,521	$1,340,151.31	$20.77	$1.29	4,125,925	1,040,816
% Change	**-5.50%**	**-4.60%**	**8.10%**	**13.30%**	**11.20%**	**-0.30%**	**-2.40%**
Change	**-2,476**	**-3,104**	**$100,462.95**	**$2.44**	**$0.13**	**-13,672**	**-26,062**

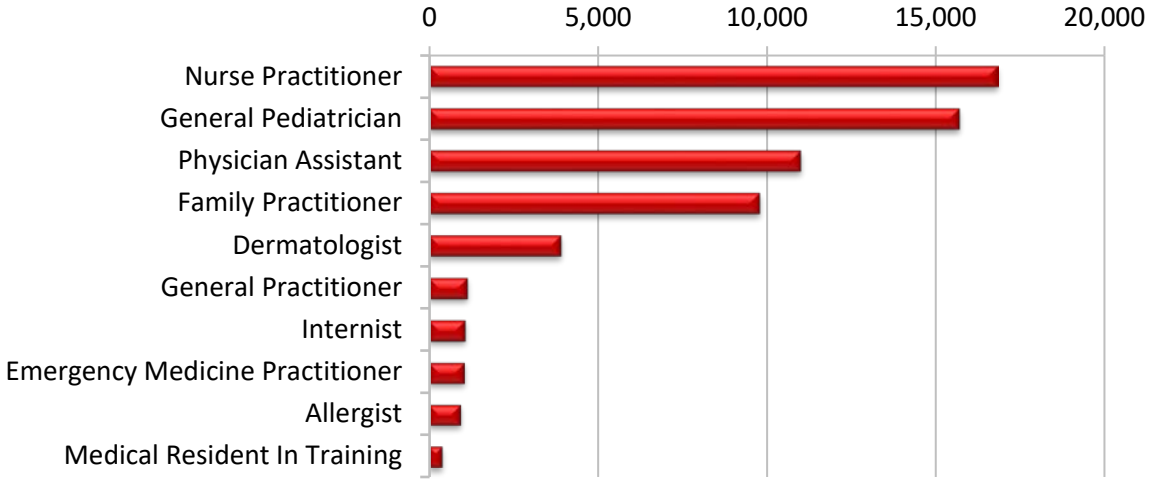
*Total number of unduplicated members.
Costs do not reflect rebated prices or net costs.

- The prior authorization criteria changes for the Topical Corticosteroids Product Based Prior Authorization (PBPA) Tier Chart voted on by the Drug Utilization Review (DUR) Board in November of 2018 went into effect on February 11, 2019. Members who were using the products at the time the prior authorization went into effect were not "grandfathered".
- Please note this category is heavily influenced by rebates and costs do not reflect rebated prices or net costs.
- Eucrisa® (crisaborole ointment) is a steroid-free, phosphodiesterase 4 inhibitor topical ointment indicated for the treatment of mild-to-moderate atopic dermatitis in patients 2 years of age and older. The prior authorization for ages 2 years and older was removed from Eucrisa® on 01/01/2018 due to the manufacturer of Eucrisa® providing a supplemental rebate to provide access to Eucrisa® without prior authorization for members 2 years of age and older and may account for decreased topical corticosteroid utilization. Based on current rebates, the prior authorization of Eucrisa® was reinstated on 01/01/2019; however, members with a paid claim for Eucrisa® in the last 60 days or a topical corticosteroid trial in the last 6 months were grandfathered.[1]

Demographics of Members Utilizing Topical Corticosteroids



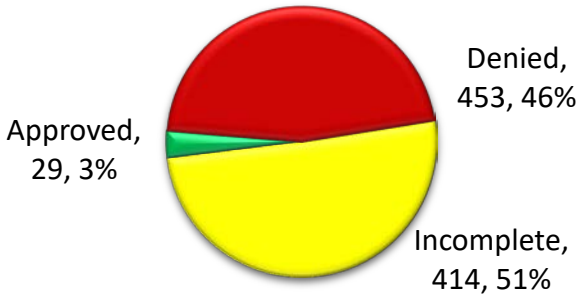
Top Prescriber Specialties of Topical Corticosteroids by Number of Claims



Prior Authorization of Topical Corticosteroids

There were 896 prior authorization requests submitted for topical corticosteroids during calendar year 2018. The following chart shows the status of the submitted petitions for calendar year 2018.

Status of Petitions



Market News and Updates[2,3,4,5,6,7,8,9,10]

Patent Expiration(s):

- Capex® (fluocinolone 0.01% shampoo), Texacort® (hydrocortisone 2.5% topical solution), Halog® (halcinonide 0.1% cream and ointment), Cordran® (flurandrenolide 4mcg/cm^2 tape), Pandel® (hydrocortisone 0.1% cream), MiCort™ HC (hydrocortisone 2.5% cream), and U-Cort® (hydrocortisone/urea 1%/10% cream) are not available generically, but have no unexpired patents or exclusivities.
- Desonate® (desonide 0.05% gel): August 2020
- Topicort® (desoximetasone 0.25% spray): September 2028
- Verdeso® (desonide 0.05% foam): November 2028
- Sernivo® (betamethasone dipropionate 0.05% topical spray): August 2030
- Bryhali™ (halobetasol propionate 0.01% lotion): November 2031

- Ultravate® (halobetasol 0.05% lotion): June 2033
- Impoyz™ (clobetasol propionate 0.025% cream): March 2035
- Duobrii™ (halobetasol propionate/tazarotene 0.01%/0.045% lotion): June 2036

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

- **Bryhali™ (Halobetasol Propionate 0.01% Lotion):** In November 2018, the FDA approved Bryhali™ (halobetasol propionate 0.01% lotion) for the topical treatment of plaque psoriasis in adults. Bryhali™ lotion is a potent to superpotent, once-daily corticosteroid that contains 0.01% halobetasol propionate in a vehicle lotion. It is recommended to apply a thin layer of lotion to the affected areas and rub in gently once daily. Treatment beyond 8 weeks is not recommended and the total dosage should not exceed approximately 50g per week. Treatment with Bryhali™ should be discontinued if control is achieved before 8 weeks. Bryhali™ is available in 2 package sizes, 60g and 100g. The Wholesale Acquisition Cost (WAC) of Bryhali™ is $4 per gram, resulting in a cost of $240 to $400 per tube depending on package size. Halobetasol propionate is also available generically as a 0.05% cream and 0.05% ointment and as the brand name formulations Ultravate® 0.05% lotion and Lexette™ 0.05% foam.
- **Duobrii™ (Halobetasol Propionate/Tazarotene 0.01%/0.045% Lotion):** In April 2019**,** the FDA approved Duobrii™ (halobetasol propionate/tazarotene 0.01%/0.045% lotion) for the topical treatment of plaque psoriasis in adults. Duobrii™ is the first corticosteroid (halobetasol) and retinoid (tazarotene) combination product and is available in a once-daily lotion formulation. It is recommended to apply Duobrii™ as a thin layer once daily to cover the affected areas only. The total dosage should not exceed 50g per week because of the potential for hypothalamic-pituitary-adrenal (HPA) axis suppression. Treatment with Duobrii™ should be discontinued once control is achieved. The long-term safety of Duobrii™ was established in a year-long, open-label study in subjects with plaque psoriasis. Patients used Duobrii™ once daily for 8 weeks and re-evaluated every 4 weeks after for 1 year. Continuous treatment was allowed up to 24 weeks and as needed for up to 52 weeks. Treatment related adverse events >2% were application site reactions such as itching, pain, irritation, and inflamed hair follicles. Duobrii™ is available only in a 100g tube and the current WAC is $8.25 per gram or $825 per tube. Halobetasol propionate is available generically as a 0.05% cream and 0.05% ointment and as the brand name formulations Ultravate® 0.05% lotion, Bryhali™ 0.01% lotion, and Lexette™ 0.05% foam. Tazarotene is available as 0.05% and 0.1% topical cream and gel (Tazorac®). Tazarotene cream and gel currently require prior authorization.
- **Lexette™ (Halobetasol Propionate 0.05% Foam):** In May 2018, the FDA approved Lexette™ (halobetasol propionate 0.05% foam), a potent topical corticosteroid indicated for the treatment of plaque psoriasis in adults. It is recommended to apply Lexette™ as a thin uniform film to the affected skin and rub in gently twice daily for up to 2 weeks. The total dosage should not exceed 50g per week and Lexette™ should be discontinued once control is achieved. Treatment beyond 2 consecutive weeks is not recommended. If no improvement is seen within 2 weeks, the diagnosis should be reassessed. Lexette™ is available in 50g cans and is dispensed as 1 or 2 cans. The WAC for the individual 50g

can is $15.41 per gram, resulting in a cost of $770.50 per can. The WAC is $14.73 per gram for the 100g can (supplied as 2 cans of 50g), resulting in a cost of $1,473.00.

Recommendations

The College of Pharmacy recommends the following changes to the Topical Corticosteroids PBPA category based on net cost:

1. Move Diprosone® (betamethasone dipropionate 0.05% ointment) from Tier-1 to Tier-2 of the Ultra-High to High Potency category of the Topical Corticosteroids PBPA Tier Chart. Current Tier-2 criteria will apply.
2. Move Temovate® (clobetasol propionate 0.05% ointment) from Tier-3 to Tier-1 of the Ultra-High to High Potency category of the Topical Corticosteroids PBPA Tier Chart.
3. Move Apexicon® (diflorasone diacetate 0.05% cream and ointment) and Apexicon E® (diflorasone diacetate/emollient 0.05% cream) from Tier-2 to Tier-3 of the Ultra-High to High Potency category of the Topical Corticosteroids PBPA Tier Chart. Current Tier-3 criteria will apply.
4. Move Trianex® (triamcinolone acetonide 0.05% ointment) from Tier-1 to Tier-2 of the Medium-High to Medium Potency Topical Corticosteroids PBPA Tier Chart. Current Tier-2 criteria will apply.

Additionally, the College of Pharmacy recommends the following:

1. The placement of Bryhali™ (halobetasol propionate 0.01% lotion) and Lexette™ (halobetasol propionate 0.05% foam) into Tier-3 of the Ultra-High to High Potency category of the Topical Corticosteroids PBPA Tier Chart. Current Tier-3 criteria will apply.
2. The prior authorization of Duobrii™ (halobetasol propionate/tazarotene 0.01%/0.045% lotion) with the following criteria:

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

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

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

Tier-2 Topical Corticosteroids Approval Criteria:

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

4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

Tier-3 Topical Corticosteroids Approval Criteria:

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

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (**Diprolene AF®**)	**C,G**	amcinonide 0.1%	**C,L**	clobetasol propionate 0.025% (**Impoyz™**)	**C**
clobetasol propionate 0.05% (**Temovate®**)	**C,L,O, So**	augmented betamethasone dipropionate 0.05% (**Diprolene®**)	**L,O**	clobetasol propionate 0.05% (**Clobex®**)	**Sh,Spr**
fluocinonide 0.05%	**C,O,So**	betamethasone dipropionate 0.05% (**Diprosone®**)	**C,O**	clobetasol propionate 0.05% (**Olux®, Olux-E®**)	**F**
halobetasol propionate 0.05% (**Ultravate®**)	**C**	clobetasol propionate 0.05% (**Clobex®**)	**L**	desoximetasone 0.25% (**Topicort®**)	**C,O,Spr**
		clobetasol propionate 0.05% (**Temovate®**)	**G**	diflorasone diacetate 0.05% **(Apexicon®)**	**C,O**
		desoximetasone 0.05% (**Topicort®**)	**G**	diflorasone diacetate 0.05% **(Apexicon E®)**	**C**
		fluocinonide 0.05%	**G**	halobetasol propionate 0.01% **(Bryhali™)**	**L**
		fluocinonide 0.1% (**Vanos®**)	**C**	halobetasol propionate 0.05% **(Lexette™)**	**F**
		flurandrenolide tape 0.05% (**Cordran®**)	**Tape**		
		halcinonide 0.1% (**Halog®**)	**C,O**		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
		halobetasol propionate 0.05% (**Ultravate®**)	**L,O**		
		halobetasol propionate/lactic acid 0.05%/10% (**Ultravate X®**)	**C**		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	**L**	betamethasone dipropionate/calcipotriene 0.064%/0.005% (**Taclonex®**)	**O,Spr, Sus**	betamethasone dipropionate 0.05% (**Sernivo®**)	**Spr**
betamethasone valerate 0.1% (**Beta-Val®**)	**C,O,L**	betamethasone valerate 0.12% (**Luxiq®**)	**F**	hydrocortisone valerate 0.2% (**Westcort®**)	**C,O**
fluticasone propionate 0.05% (**Cutivate®**)	**C,O**	calcipotriene/betamethasone dipropionate 0.064%/0.005% (**Enstilar®**)	**F**		
mometasone furoate 0.1% (**Elocon®**)	**C,L,O, So**	clocortolone pivalate 0.1% (**Cloderm®**)	**C**		
triamcinolone acetonide 0.025%	**O**	desoximetasone 0.05% (**Topicort LP®**)	**C,O**		
triamcinolone acetonide 0.1%	**C,L,O**	fluocinolone acetonide 0.025% (**Synalar®**)	**C,O**		
triamcinolone acetonide 0.5%	**C,O**	fluocinonide emollient 0.05% (**Lidex E®**)	**C**		
		flurandrenolide 0.05%	**C,L,O**		
		fluticasone propionate 0.05% (**Cutivate®**)	**L**		
		hydrocortisone butyrate 0.1%	**C,L,O, So**		
		hydrocortisone probutate 0.1% (**Pandel®**)	**C**		
		prednicarbate 0.1% (**Dermatop®**)	**C,O**		
		triamcinolone acetonide 0.147mg/g (**Kenalog®**)	**Spr**		
		triamcinolone acetonide 0.05% **(Trianex®)**	**O**		
Low Potency					
desonide 0.05% (**Desonate®**)	**G**	alclometasone dipropionate 0.05% (**Aclovate®**)	**C,O**	fluocinolone acetonide 0.01% (**Derma-Smoothe®; Derma-Smoothe FS®**)	**Oil**

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

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

Utilization Details of Topical Corticosteroids: Calendar Year 2018

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 MEDICATIONS						
LOW POTENCY PRODUCTS						
TRIAMCINOLONE CREAM 0.025%	4,999	3,929	$65,942.37	$0.90	$13.19	4.92%
HYDROCORTISONE CREAM 2.5%	4,343	3,421	$52,105.98	$0.86	$12.00	3.89%
HYDROCORTISONE OINTMENT 2.5%	2,670	1,740	$42,200.36	$1.27	$15.81	3.15%
HYDROCORTISONE CREAM 1%	1,820	1,551	$20,327.91	$1.14	$11.17	1.52%
HYDROCORTISONE LOTION 2.5%	453	362	$11,712.56	$1.45	$25.86	0.87%
HYDROCORTISONE OINTMENT 1%	373	324	$4,703.12	$1.25	$12.61	0.35%
TRIAMCINOLONE LOTION 0.1%	363	297	$13,362.87	$1.90	$36.81	1.00%
DESONATE GEL 0.05%	255	172	$142,118.23	$22.54	$557.33	10.60%
TRIAMCINOLON LOTION 0.025%	164	137	$6,403.07	$2.00	$39.04	0.48%
CAPEX SHAMPOO 0.01%	102	72	$40,107.22	$20.47	$393.21	2.99%
HYDROCORTISONE/ABSORBASE 1% OIN	1	1	$15.09	$0.50	$15.09	0.00%
SUBTOTAL	**15,543**	**12,006**	**$398,998.78**	**$1.85**	**$25.67**	**29.77%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE CREAM 0.1%	23,171	17,868	$313,087.01	$0.83	$13.51	23.36%
TRIAMCINOLONE OINTMENT 0.1%	11,458	8,348	$167,858.42	$0.83	$14.65	12.53%
TRIAMCINOLONE OINTMENT 0.025%	2,633	2,098	$42,664.91	$1.07	$16.20	3.18%
TRIAMCINOLONE CREAM 0.5%	2,563	1,937	$46,840.23	$1.37	$18.28	3.50%
MOMETASONE CREAM 0.1%	1,356	951	$29,786.12	$1.29	$21.97	2.22%
FLUTICASONE CREAM 0.05%	959	691	$21,716.36	$1.47	$22.64	1.62%
TRIAMCINOLONE OINTMENT 0.5%	952	699	$19,678.52	$1.49	$20.67	1.47%
BETAMETHASONE VALERATE CREAM 0.1%	423	293	$16,307.66	$2.23	$38.55	1.22%
FLUTICASONE OINTMENT 0.005%	310	174	$9,034.61	$1.47	$29.14	0.67%
BETAMETHASONE VAL OINTMENT 0.1%	160	131	$5,709.48	$2.01	$35.68	0.43%
BETAMETHASONE DIPROP LOTION 0.05%	117	76	$5,230.59	$1.90	$44.71	0.39%
MOMETASONE SOLUTION 0.1%	94	72	$1,991.94	$0.98	$21.19	0.15%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
BETAMETHASONE VALERATE LOTION 0.1%	40	31	$2,210.66	$2.90	$55.27	0.16%
MOMETASONE OINTMENT 0.1%	19	15	$355.51	$0.88	$18.71	0.03%
TRIDERM CREAM 0.1%	1	1	$21.66	$0.87	$21.66	0.00%
SUBTOTAL	**44,256**	**33,385**	**$682,493.68**	**$0.21**	**$15.42**	**50.93%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
AUG BETAMETHASONE CREAM 0.05%	1,003	675	$19,332.36	$1.04	$19.27	1.44%
BETAMETHASONE DIP OINTMENT 0.05%	838	538	$73,087.55	$4.76	$87.22	5.45%
CLOBETASOL CREAM 0.05%	742	527	$43,424.22	$3.47	$58.52	3.24%
CLOBETASOL SOLUTION 0.05%	663	404	$31,213.56	$1.56	$47.08	2.33%
FLUOCINONIDE SOLUTION 0.05%	497	316	$30,554.22	$2.58	$61.48	2.28%
FLUOCINONIDE OINTMENT 0.05%	333	212	$19,252.09	$2.89	$57.81	1.44%
FLUOCINONIDE CREAM 0.05%	297	192	$15,021.25	$2.43	$50.58	1.12%
HALOBETASOL CREAM 0.05%	112	69	$8,984.39	$3.95	$80.22	0.67%
CLOBETASOL E CREAM 0.05%	43	36	$2,934.31	$4.43	$68.24	0.22%
AUG BETAMETHASONE GEL 0.05%	26	16	$2,088.45	$4.15	$80.33	0.16%
SUBTOTAL	**4,554**	**2,985**	**$245,892.40**	**$2.60**	**$53.99**	**18.35%**
TIER-1 TOTAL	**64,353**	**48,376**	**$1,327,384.86**	**$1.28**	**$20.63**	**99.05%**
TIER-2 MEDICATIONS						
LOW POTENCY PRODUCTS						
FLUOCINOLONE ACETONIDE CREAM 0.01%	70	44	$5,295.52	$5.01	$75.65	0.40%
ALCLOMETASONE DIPROP OINTMENT 0.05%	19	19	$1,497.50	$3.95	$78.82	0.11%
ALCLOMETASONE DIPROP CREAM 0.05%	17	16	$969.67	$3.24	$57.04	0.07%
SUBTOTAL	**106**	**79**	**$7,762.69**	**$4.47**	**$73.23**	**0.58%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIANEX OINTMENT 0.05%	41	34	$1,723.92	$1.55	$42.05	0.13%
HYDROCORTISONE BUTYRATE OINT 0.1%	1	1	$58.30	$8.33	$58.30	0.00%
SUBTOTAL	**42**	**35**	**$1,782.22**	**$1.59**	**$42.43**	**0.13%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
BETAMETHASONE DIPROP CREAM 0.05%	1	1	$33.12	$2.37	$33.12	0.00%
SUBTOTAL	**1**	**1**	**$33.12**	**$2.37**	**$33.12**	**0.00%**
TIER-2 TOTAL	**149**	**115**	**$9,578.03**	**$3.34**	**$64.28**	**0.71%**
TIER-3 MEDICATIONS						
LOW POTENCY PRODUCTS						
DESONIDE CREAM 0.05%	6	1	$638.82	$3.55	$106.47	0.05%
DESONIDE LOTION 0.05%	5	2	$1,115.90	$22.32	$223.18	0.08%
FLUOCINOLONE ACET SCALP OIL 0.01%	1	1	$107.71	$3.59	$107.71	0.01%
FLUOCINOLONE ACET SCALP OIL 0.01%	1	1	$141.04	$9.40	$141.04	0.01%
SUBTOTAL	**13**	**5**	**$2,003.47**	**$7.29**	**$154.11**	**0.15%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL PROP SHAMPOO 0.05%	3	1	$568.38	$6.32	$189.46	0.04%
CLOBETASOL PROP OINTMENT 0.05%	2	2	$104.23	$3.47	$52.12	0.01%
TOPICORT SPRAY 0.25%	1	1	$512.34	$17.08	$512.34	0.04%
SUBTOTAL	**6**	**4**	**$1,184.95**	**$7.90**	**$197.49**	**0.09%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-3 TOTAL	**19**	**9**	**$3,188.42**	**$7.50**	**$351.60**	**0.24%**
TOTAL	**64,521**	**42,313***	**$1,340,151.31**	**$1.29**	**$20.77**	**100%**

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

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[3] Ortho Dermatologics. Ortho Dermatologics Receives Tentative FDA Approval for BRYHALI™ (Halobetasol Propionate) Lotion, 0.01%, For Plaque Psoriasis in Adults. Available online at: http://ortho-dermatologics.com/wp-content/uploads/20181008-Trade-Release-BRYHALI-Approval.pdf. Issued 10/08/2018. Last accessed 06/17/2019.
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[7] DUOBRII™ (Halobetasol Propionate/Tazarotene) Prescribing Information. Ortho Dermatologics. Available online at: https://www.bauschhealth.com/Portals/25/Pdf/PI/Duobrii-PI.pdf. Last revised 04/2019. Last accessed 06/17/2019.
[8] DUOBRII™ (Halobetasol Propionate and Tazarotene) New Drug Approval. OptumRx. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_duobrii_2019-0429.pdf. Issued 2019. Last accessed 06/17/2019.
[9] Mayne Pharma Group. Mayne Pharma Launches Lexette™ (Halobetasol Propionate) Foam 0.05% in the United States. Available online at: https://www.maynepharma.com/media/2236/mayne-pharma-launches-lexette-foam-005-in-the-us.pdf. Issued 02/13/2019. Last accessed 06/17/2019.
[10] Lexette™ (Halobetasol Propionate) Prescribing Information. Mayne Pharma. Available online at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=d5d0d307-37ad-4714-ba3f-5343672bc0e7&type=display. Last revised 04/2019. Last accessed 06/17/2019.

Appendix K

Calendar Year 2018 Annual Review of Qbrexza™ (Glycopyrronium)

Oklahoma Health Care Authority
July 2019

Current Prior Authorization Criteria

Qbrexza™ (Glycopyrronium) Approval Criteria:

1. An FDA approved diagnosis of primary axillary hyperhidrosis in pediatric patients 9 years of age to 20 years of age; and
2. Documentation of assessment by a licensed behavior specialist or the prescribing physician indicating the member's hyperhidrosis is causing social anxiety, depression, or similar mental health-related issues that impact the member's ability to function in day-to-day living must be provided; and
3. Member must have failed a trial of Drysol™ (aluminum chloride 20%) at least 3 weeks in duration; and
4. Prescriber must verify that the member has received counseling on the safe and proper use of Qbrexza™; and
5. A quantity limit of 1 box (30 cloths) per 30 days will apply.

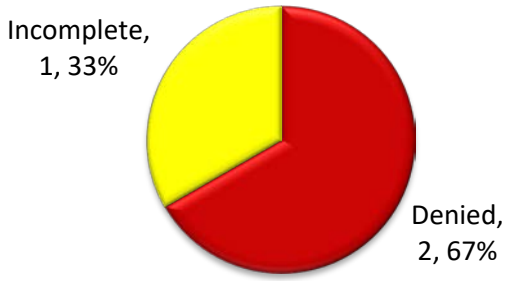
Utilization of Qbrexza™ (Glycopyrronium): Calendar Year 2018

There was no SoonerCare utilization of Qbrexza™ (glycopyrronium) during calendar year 2018.

Prior Authorization of Qbrexza™ (Glycopyrronium)

There were 3 prior authorization requests submitted for Qbrexza™ (glycopyrronium) during calendar year 2018. The following chart shows the status of the submitted petitions for calendar year 2018.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Qbrexza™ (glycopyrronium): February 2033

News:

- **March 2019:** Dermira, Inc. announced the launch of "Life Unfolds," a new direct-to-consumer (DTC) campaign designed to generate awareness of Qbrexza™ (glycopyrronium) as a potential treatment option for people living with primary axillary hyperhidrosis. The multichannel campaign launched with a DTC television advertisement featuring Qbrexza™ patients and highlights uncomfortable situations that people living with the condition routinely experience. Additionally, the campaign launched in national consumer print media outlets, across digital and social media platforms, and in dermatologists' offices across the United States.

Pipeline:

- **THVD-102:** In February 2017, TheraVida announced positive Phase 2 study results with its product THVD-102, an orally administered combination drug product for the treatment of primary focal hyperhidrosis. THVD-102 is a novel, proprietary formulation of oxybutynin 7.5mg plus pilocarpine 7.5mg. The study evaluated the safety and efficacy as well as the effect on dry mouth of THVD-102 versus placebo and oxybutynin alone in patients with primary focal hyperhidrosis. Significantly fewer patients receiving THVD-102 reported "moderate" or "severe" dry mouth while receiving THVD-102 compared to oxybutynin alone. There were no statistically significant differences in efficacy between THVD-102 and oxybutynin alone.
- **Sofpironium Bromide (BBI-4000):** Sofpironium bromide (BBI-4000) is a novel drug in development for the topical treatment of hyperhidrosis. A randomized, open-label, Phase 3 study is ongoing to assess the long-term safety, tolerability, and efficacy of sofpironium bromide gel applied topically to patients with axillary hyperhidrosis. In this trial, patients 12 years of age or older apply sofpironium bromide gel once daily at bedtime, to both axillae.
- **Umeclidinium:** Results of a Phase 2a randomized controlled study to evaluate the pharmacokinetic, safety, tolerability, and clinical effect of topically applied umeclidinium (UMEC) in patients with primary axillary hyperhidrosis were published in *The Journal of The European Academy of Dermatology and Venereology* in October 2017. The proof-of-concept study found that the measurable exposure, acceptable safety, and preliminary clinical activity observed suggests a potential clinical utility of topical UMEC in axillary hyperhidrosis. Developed by GlaxoSmithKline, topical UMEC 1.85% is a long-acting muscarinic antagonist (LAMA) hypothesized to block stimulation of muscarinic receptors by acetylcholine and thereby reduce the overproduction of sweat.

Recommendations

The College of Pharmacy does not recommend any changes to the current Qbrexza™ (glycopyrronium) prior authorization criteria at this time.

[1] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 05/2019. Last accessed 06/14/2019.
[2] Dermira, Inc. Dermira Announces "Life Unfolds" Direct-to-Consumer Campaign to Highlight QBREXZA™ (glycopyrronium) Cloth. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2019/03/25/1759843/0/en/Dermira-Announces-Life-Unfolds-Direct-to-Consumer-Campaign-to-Highlight-QBREXZA-glycopyrronium-Cloth.html. Issued 03/25/2019. Last accessed 06/17/2019.
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Appendix L

Industry News and Updates

Oklahoma Health Care Authority
July 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[1,2,3]

News:

- **Hepatitis Vaccine:** Physicists from Niels Bohr Institute in Denmark and researchers from the University of São Paulo and the Butantan Institute in Brazil are collaborating on the development of a new approach to encapsulate a hepatitis B vaccine to make it more effective after being swallowed. An oral formulation of the vaccine could help increase vaccination rates and decrease the impact of the disease. An oral form of the vaccine would also not require refrigeration and could reduce costs associated with administration. The development might also have important global implications, especially in developing countries with low vaccination rates. According to an article published in *Scientific Reports*, the researchers are using 3-D imaging techniques to "open new paths to overcome the challenges in the development of the oral vaccine, by allowing direct visualization of the components within the encapsulation."
- **Direct-to-Consumer (DTC) Advertising:** Starting in July 2019, manufacturers' DTC television ads for prescription drugs and biologic products covered by Medicare and Medicaid will have to include their wholesale acquisition cost (WAC) if it exceeds $35 per month. The requirement comes as a result of a U.S. Health and Human Services (HHS) Department final rule published in the *Federal Register* in May 2019. The inclusion of WAC is intended to foster competition among drug manufacturers. Drug companies have criticized that the WAC price does not provide an accurate picture of what a drug costs, since payers and pharmacy benefit managers (PBMs) negotiate prices using drug rebates. HHS has mandated the inclusion of a disclaimer stating that "…If you have health insurance that covers drugs, your cost may be different."
- **U.S. Prescription Use:** According to a recent report, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*, prepared by the IQVIA Institute for Human Data Science, Americans filled a record 5.8 billion prescriptions in 2018 (rate of 17.6 prescriptions per person). This is an increase of 2.7% from 2017; however, opioid prescriptions declined. Due to changes in regulations, clinical guidelines, and increased public awareness, morphine milligram equivalents (MMEs) dispensed declined by 17% in 2018, the largest single-year drop ever recorded (43% decrease since the peak in 2011). More than two-thirds of prescriptions filled in 2018 were for common chronic

conditions, such as hypertension and diabetes. These prescriptions were increasingly filled with a 90-supply through mail order.

[1] Sederstrom J. Scientists Are One Step Closer to Needleless Hepatitis B Vaccine. *Drug Topics*. Available online at: https://www.drugtopics.com/vaccination-and-immunization/scientists-are-one-step-closer-needleless-hepatitis-b-vaccine. Issued 05/17/2019. Last accessed 06/10/2019.

[2] Balick R. Direct-to-consumer drug ad prices rule hints at future avenues for pharmacist reimbursement. *American Pharmacists Association*. Available online at: https://pharmacist.com/article/direct-consumer-drug-ad-prices-rule-hints-future-avenues-pharmacist-reimbursement?is_sso_called=1. Issued 05/14/2019. Last accessed 06/10/2019.

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Appendix M

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

FDA NEWS RELEASE

For Immediate Release: June 27th, 2019

FDA approves first treatment for neuromyelitis optica spectrum disorder, a rare autoimmune disease of the central nervous system

The FDA approved Soliris® (eculizumab) injection for intravenous use for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. NMOSD is an autoimmune disease of the central nervous system that mainly affects the optic nerves and spinal cord.

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

NMOSD can be associated with antibodies that bind to a protein called aquaporin-4 (AQP4). Binding of the anti-AQP4 antibody appears to activate other components of the immune system, causing inflammation and damage to the central nervous system.

The effectiveness of Soliris® for the treatment of NMOSD was demonstrated in a clinical study of 143 patients with NMOSD who had antibodies against AQP4 (anti-AQP4 positive) who were randomized to receive either Soliris® treatment or placebo. Compared to treatment with placebo, the study showed that treatment with Soliris® reduced the number of NMOSD relapses by 94 percent over the 48-week course of the trial. Soliris® also reduced the need for hospitalizations and the need for treatment of acute attacks with corticosteroids and plasma exchange.

Soliris® has a boxed warning to alert health care professionals and patients that life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris®, and that such infections may become rapidly life-threatening or fatal if not recognized and treated early. Patients should be monitored for early signs of meningococcal infections and evaluated immediately if infection is suspected. Use should be discontinued in patients who are being treated for serious meningococcal infections. Health care professionals should use caution when administering Soliris® to patients with any other infection. In the NMOSD clinical trial, no cases of meningococcal infection were observed.

Soliris® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Prescribers must enroll in the REMS program. Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials and ensure patients are vaccinated with meningococcal vaccine(s). The drug must be dispensed with the FDA-approved patient Medication Guide that provides important information about the drug’s uses and risks.

The most frequently reported adverse reactions reported by patients in the NMOSD clinical trial were: upper respiratory infection, common cold (nasopharyngitis), diarrhea, back pain, dizziness, influenza, joint pain (arthralgia), sore throat (pharyngitis) and contusion.

The FDA granted the approval of Soliris® to Alexion Pharmaceuticals.

Soliris® was first approved by the FDA in 2007. The drug is approved to reduce destruction of red blood cells in adults with a rare blood disease called paroxysmal nocturnal hemoglobinuria, for the treatment of adults and children with a rare disease that causes abnormal blood clots to form in small blood vessels in the kidneys (atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy), and for the treatment of adults with Myasthenia Gravis who are anti-acetylcholine receptor antibody positive.

The FDA granted this application Priority Review. The use for NMOSD received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

FDA NEWS RELEASE

For Immediate Release: June 26th, 2019

FDA approves first treatment for chronic rhinosinusitis with nasal polyps

The FDA approved Dupixent® (dupilumab) to treat adults with nasal polyps (growths on the inner lining of the sinuses) accompanied by chronic rhinosinusitis (prolonged inflammation of the sinuses and nasal cavity). This is the first treatment approved for inadequately controlled chronic rhinosinusis with nasal polyps.

Dupixent® is given by injection. The efficacy and safety of Dupixent® were established in two studies with 724 patients, 18 years and older with chronic rhinosinusitis with nasal polyps who were symptomatic despite taking intranasal corticosteroids. Patients who received Dupixent® had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group. Patients taking Dupixent® also reported an increased ability to smell and required less nasal polyp surgery and oral steroids.

Dupixent® may cause serious allergic reactions and eye problems, such as inflammation of the eye (conjunctivitis) and inflammation of the cornea (keratitis). If patients experience new or worsening eye symptoms, such as redness, itching, pain or visual changes, they should consult their health care professional. The most common side effects reported include injection site reactions as well as eye and eyelid inflammation, which included redness, swelling and itching. Patients receiving Dupixent® should avoid receiving live vaccines.

Dupixent® was originally approved in 2017 for patients 12 and older with eczema that is not controlled adequately by topical therapies or when those therapies are not advisable. In 2018, Dupixent® was approved as an add-on maintenance treatment for patients 12 years and older with moderate-to-severe eosinophilic asthma or with oral corticosteroid-dependent asthma.

The FDA granted this application Priority Review. The approval of Dupixent® was granted to Regeneron Pharmaceuticals.

FDA NEWS RELEASE

For Immediate Release: June 21st, 2019

FDA approves new treatment for hypoactive sexual desire disorder in premenopausal women

The FDA approved Vyleesi™ (bremelanotide) to treat acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women.

HSDD is characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to a co-existing medical or psychiatric condition, problems within the relationship or the effects of a medication or other drug substance. Acquired HSDD develops in a patient who previously experienced no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of sexual activity, situation or partner.

Vyleesi™ activates melanocortin receptors, but the mechanism by which it improves sexual desire and related distress is unknown. Patients inject Vyleesi™ under the skin of the abdomen or thigh at least 45 minutes before anticipated sexual activity and may decide the optimal time to use Vyleesi™ based on how they experience the duration of benefit and any side effects, such as nausea. Patients should not use more than one dose within 24 hours or more than eight doses per month. Patients should discontinue treatment after eight weeks if they do not report an improvement in sexual desire and associated distress.

The effectiveness and safety of Vyleesi™ were studied in two 24-week, randomized, double-blind, placebo-controlled trials in 1,247 premenopausal women with acquired, generalized HSDD. Most patients used Vyleesi™ two or three times per month and no more than once a week. In these trials, about 25% of patients treated with Vyleesi™ had an increase of 1.2 or more in their sexual desire score (scored on a range of 1.2 to 6.0, with higher scores indicating greater sexual desire) compared to about 17% of those who took placebo. Additionally, about 35% of the patients treated with Vyleesi™ had a decrease of one or more in their distress score (scored on a range of zero to four, with higher scores indicating greater distress from low sexual desire) compared to about 31% of those who took placebo. There was no difference between treatment groups in the change from the start of the study to end of the study in the number of satisfying sexual events. Vyleesi™ does not enhance sexual performance.

The most common side effects of Vyleesi™ are nausea and vomiting, flushing, injection site reactions and headache. About 40% of patients in the clinical trials experienced nausea, most commonly with the first

Vyleesi™ injection, and 13% needed medications for the treatment of nausea. About 1% of patients treated with Vyleesi™ in the clinical trials reported darkening of the gums and parts of the skin, including the face and breasts, which did not go away in about half the patients after stopping treatment. Patients with dark skin were more likely to develop this side effect.
In the clinical trials, Vyleesi™ increased blood pressure after dosing, which usually resolved within 12 hours. Because of this effect, Vyleesi™ should not be used in patients with high blood pressure that is uncontrolled or in those with known cardiovascular disease. Vyleesi™ is also not recommended in patients at high risk for cardiovascular disease.
When naltrexone is taken by mouth, Vyleesi™ may significantly decrease the levels of naltrexone in the blood. Patients who take a naltrexone-containing medication by mouth to treat alcohol or opioid dependence should not use Vyleesi™ because it could lead to naltrexone treatment failure.
In 2012, the FDA identified female sexual dysfunction as one of 20 disease areas of high priority and focused attention. The FDA held a two-day meeting in October 2014 to advance the agency's understanding of female sexual dysfunction. During the first day of the meeting, the FDA solicited perspectives directly from patients about their condition and its impact on daily life. In 2016, the FDA published a draft guidance titled "Low Sexual Interest Desire and/or Arousal in Women: Developing Drugs for Treatment," to assist companies developing drugs for the treatment of these conditions. The FDA is committed to continuing to work with companies to develop safe and effective treatments for female sexual dysfunction.
The FDA granted approval of Vyleesi™ to AMAG Pharmaceuticals.

FDA NEWS RELEASE

For Immediate Release: June 21st, 2019
FDA expands approval of treatment for cystic fibrosis to include patients ages 6 and older

The FDA expanded the indication for Symdeko® (a combination of tezacaftor/ivacaftor) tablets for treatment of pediatric patients ages 6 years and older with cystic fibrosis who have certain genetic mutations. Last year, the FDA approved Symdeko® to treat patients ages 12 and older who had the same specific genetic mutations. Cystic fibrosis is a serious genetic disorder that results in the formation of thick mucus that builds up in the lungs, digestive tract and other parts of the body. It leads to severe respiratory and digestive problems as well as other complications such as infections and diabetes. Cystic fibrosis is caused by a defective protein that results from mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. There are approximately 2,000 known mutations of the CFTR gene. Symdeko® is used to treat patients who have two copies of the most common type of mutation – F508del mutation – or who have at least one of the mutations in the CFTR gene that is responsive to the active ingredients in Symdeko® based on in vitro data and/or clinical evidence. Patients with cystic fibrosis and their caregivers should speak with a health care professional and have tests performed to understand which gene mutations patients have and whether Symdeko® is likely to work for them.
The efficacy of Symdeko® in patients with cystic fibrosis age 12 years and older was evaluated in three Phase 3, double blind, placebo-controlled trials, which demonstrated improvements in lung function and other key measures of the disease, including a reduction in exacerbations. The efficacy in patients ages 6 to 12 was extrapolated from patients age 12 years and older, with additional support from data in patients age 6 to 12 years.
The safety of Symdeko® to treat cystic fibrosis patients age 6 to less than 12 years was supported by data from a study that included a 24-week, open-label treatment period with 70 cystic fibrosis patients ages 6 to less than 12, and had similar observations of safety to clinical trials in ages 12 and older. Symdeko® should always be taken with food that contains fat and never in combination with certain antibiotics, seizure medicines, St. John's wort, or food containing grapefruit or Seville oranges, as indicated on the label. The prescribing information for Symdeko® includes warnings related to elevated enzymes in the liver (transaminases) in people taking Symdeko®, for those who use inducers for another liver enzyme called Cytochrome P450 3A4 (CYP3A), and for the risk of cataracts in pediatric patients. Patients and their caregivers should speak with a health care professional about these risks and any medicines they take before starting Symdeko®. The most common side effects include headache, nausea, sinus congestion and dizziness.
The safety and efficacy of Symdeko® in patients with cystic fibrosis younger than 6 years of age have not been studied.
The FDA granted this application Priority Review. The approval of Symdeko® was granted to Vertex Pharmaceuticals Incorporated.

FDA NEWS RELEASE

For Immediate Release: June 17th, 2019

FDA approves new treatment for pediatric patients with type 2 diabetes

The FDA approved Victoza® (liraglutide) injection for treatment of pediatric patients 10 years or older with type 2 diabetes. Victoza® is the first non-insulin drug approved to treat type 2 diabetes in pediatric patients since metformin was approved for pediatric use in 2000. Victoza® has been approved to treat adult patients with type 2 diabetes since 2010.

Type 2 diabetes is the most common form of diabetes, occurring when the pancreas cannot make enough insulin to keep blood sugar at normal levels. Although type 2 diabetes primarily occurs in patients over the age of 45, the prevalence rate among younger patients has been rising dramatically over the past couple of decades. The Diabetes Report Card published by the U.S. Centers for Disease Control and Prevention estimates that more than 5,000 new cases of type 2 diabetes are diagnosed each year among U.S. youth younger than age 20.

Victoza® improves blood sugar levels by creating the same effects in the body as the glucagon-like peptide (GLP-1) receptor protein in the pancreas. GLP-1 is often found in insufficient levels in type 2 diabetes patients. Like GLP-1, Victoza® slows digestion, prevents the liver from making too much glucose, and helps the pancreas produce more insulin when needed. As noted on the label, Victoza® is not a substitute for insulin and is not indicated for patients with type 1 diabetes or those with diabetic ketoacidosis, a condition associated with diabetes where the body breaks down fat too quickly because there is inadequate insulin or none at all. Victoza® is also indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease; however, its effect on major adverse cardiovascular events in pediatrics was not studied and it is not indicated for this use in children.

The efficacy and safety of Victoza® for reducing blood sugar in patients with type 2 diabetes was studied in several placebo-controlled trials in adults and one placebo-controlled trial with 134 pediatric patients 10 years and older for more than 26 weeks. Approximately 64% of patients in the pediatric study had a reduction in their hemoglobin A1c (HbA1c) below 7% while on Victoza®, compared to only 37% who achieved these results with the placebo. HbA1c is a blood test that is routinely performed to evaluate how well a patient's diabetes is controlled, and a lower number indicates better control of the disease. These results occurred regardless of whether the patient also took insulin at the same time. Adult patients who took Victoza® with insulin or other drugs that increase the amount of insulin the body makes (e.g., sulfonylurea) may have an increased risk of hypoglycemia (low blood sugar). Meanwhile, pediatric patients 10 years and older taking Victoza® had a higher risk of hypoglycemia regardless of whether they took other therapies for diabetes.

The prescribing information for Victoza® includes a Boxed Warning to advise health care professionals and patients about the increased risk of thyroid C-cell tumors. For this reason, patients who have had, or have family members who have ever had medullary thyroid carcinoma (MTC) should not use Victoza®, nor should patients who have an endocrine system condition called multiple endocrine neoplasia syndrome type 2 (MEN 2). In addition, people who have a prior serious hypersensitivity reaction to Victoza® or any of the product components should not use Victoza®. Victoza® also carries warnings about pancreatitis, Victoza® pen sharing, hypoglycemia when used in conjunction with certain other drugs known to cause hypoglycemia including insulin and sulfonylurea, renal impairment or kidney failure, hypersensitivity and acute gallbladder disease. The most common side effects are nausea, diarrhea, vomiting, decreased appetite, indigestion and constipation.

The FDA granted this application Priority Review. The approval of Victoza® was granted to Novo Nordisk.

FDA NEWS RELEASE

For Immediate Release: June 10th, 2019

FDA approves first chemoimmunotherapy regimen for patients with relapsed or refractory diffuse large B-cell lymphoma

The FDA granted accelerated approval to Polivy™ (polatuzumab vedotin-piiq), in combination with the chemotherapy bendamustine and a rituximab product (a combination known as "BR"), to treat adult patients with diffuse large B-cell lymphoma (DLBCL) that has progressed or returned after at least two prior therapies. Polivy™ is a novel antibody-drug conjugate, and DLBCL is the most common type of non-Hodgkin lymphoma.

More than 18,000 people are diagnosed with DLBCL each year in the U.S. Although it can be cured, about 30 to 40% of patients suffer relapse. This type of cancer grows quickly in the lymph nodes and may affect the bone marrow, spleen, liver or other organs. Signs and symptoms of DLBCL may include swollen lymph nodes, fever, recurring night sweats and weight loss.

Polivy™ is an antibody that is attached to a chemotherapy drug. Polivy™ binds to a specific protein (called CD79b) found only on B cells (a type of white blood cell), then releases the chemotherapy drug into those cells. Efficacy was evaluated in a study of 80 patients with relapsed or refractory DLBCL who were randomized to receive Polivy™ with BR or BR alone. Efficacy was based on complete response rate and duration of response (DOR), defined as the time the disease stays in remission. At the end of treatment, the complete response rate was 40% with Polivy™ plus BR compared to 18% with BR alone. Of the 25 patients who achieved a partial or complete response to Polivy™ plus BR, 16 (64%) had a DOR of at least six months and 12 (48%) had a DOR of at least 12 months.

The most common side effects of Polivy™ plus BR include low levels of white blood cells (neutropenia), platelets (thrombocytopenia) and red blood cells (anemia); nerve damage (peripheral neuropathy); fatigue; diarrhea; fever; decreased appetite; and pneumonia.

Health care professionals are advised to monitor patients closely for infusion-related reactions, low blood counts and fatal and/or serious infections. Health care professionals should also monitor patients for tumor lysis syndrome (a complication from many tumor cells being killed off at the same time), liver damage (hepatotoxicity) and progressive multifocal leukoencephalopathy (PML), a fatal or life-threatening infection of the brain. FDA advises health care professionals to tell females of reproductive age to use effective contraception during treatment with Polivy™ and for three months after the last dose. Women who are pregnant or breastfeeding should not take Polivy™ because it may cause harm to a developing fetus or newborn baby.

Polivy™ in combination with BR was granted accelerated approval, which enables the FDA to approve drugs for serious conditions to fill an unmet medical need based on an endpoint that is reasonably likely to predict a clinical benefit to patients. Further clinical trials are required to verify and describe Polivy™ clinical benefit.

The FDA granted this application Breakthrough Therapy and Priority Review designations. Polivy™ 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 Polivy™ to Genentech.

FDA NEWS RELEASE

For Immediate Release: June 4th, 2019

FDA approves first treatment for episodic cluster headache that reduces the frequency of attacks

The FDA approved Emgality® (galcanezumab-gnlm) solution for injection for the treatment of episodic cluster headache in adults.

Cluster headache is a form of headache that produces extreme pain and tends to occur in clusters, often at the same time(s) of the day, for several weeks to months. The headaches are accompanied by symptoms that may include: bloodshot eyes, excessive tearing of the eyes, drooping of the eyelids, runny nose and/or nasal congestion and facial sweating. Some people experience restlessness and agitation. Cluster headache attacks may strike several times a day, generally lasting between 15 minutes and three hours.

The effectiveness of Emgality® for the treatment of episodic cluster headache was demonstrated in a clinical trial that compared the drug to placebo in 106 patients. The trial measured the average number of cluster headaches per week for three weeks and compared the average changes from baseline in the Emgality® and placebo groups. During the three-week period, patients taking Emgality® experienced 8.7 fewer weekly cluster headache attacks than they did at baseline, compared to 5.2 fewer attacks for patients on placebo.

There is a risk of hypersensitivity reactions with Emgality® use. If a serious hypersensitivity reaction occurs, treatment should be discontinued. Hypersensitivity reactions could occur days after administration and may be prolonged. The most common side effect reported by participants in the clinical trials was injection site reactions.

Emgality® is given by patient self-injection. It was first approved by the FDA in September 2018 for the preventive treatment of migraine in adults. The FDA granted the approval of Emgality® to Eli Lilly.

The FDA granted this application Priority Review and Breakthrough Therapy designation.

Safety Announcements

FDA alerts patients and health care professionals to Infusion Options' voluntary recall due to quality issues

[6/21/19] The FDA is alerting health care professionals and patients of a voluntary recall of all unexpired compounded drugs intended to be sterile produced by Infusion Options, Inc. of Brooklyn, N.Y., due to lack of sterility assurance and other significant quality issues. These drugs may pose a safety risk to patients. Administration of a non-sterile drug intended to be sterile may result in serious and potentially life-threatening infections or death.

Health care professionals should immediately check their medical supplies, quarantine any drugs prepared by Infusion Options, and not administer or provide them to patients. FDA urges health care professionals, who obtained products from Infusion Options, to make alternative arrangements to obtain medications from sources that adhere to proper quality standards. Patients who have received any drug produced by Infusion Options and have concerns should contact their health care professional.

FDA investigators most recently inspected Infusion Options' Brooklyn facilities in May and June of 2019 and observed conditions that could cause Infusion Options' drugs to become contaminated or otherwise pose risks to patients.

On June 14, Infusion Options agreed to voluntarily recall all unexpired drug products intended to be sterile, cease sterile operations until the company takes adequate corrective actions and voluntarily destroy all drugs and drug components with FDA officials present, following FDA's recommendations.

To date, FDA is not aware of any reports of illness associated with the use of Infusion Options' drugs. The agency asks health care professionals and patients to report unexpected side effects or quality problems associated with Infusion Options' drugs to FDA's MedWatch Adverse Event Reporting program.

Current Drug Shortages Index (as of July 1st, 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***
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***
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***
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 Chewable Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride (QUILLIVANT XR) for Extended-Release Oral Suspension	***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 Acetate Injection, USP	***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 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***