Oklahoma Health Care Authority

Drug Utilization Review Board

Wednesday, January 10, 2018

No live January meeting. January is a packet only meeting.

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: Bethany Holderread, Pharm.D.

SUBJECT: Packet Contents for Board Packet – January 10th, 2018

DATE: December 15th, 2017

Enclosed are the following items related to the January packet.
Material is arranged in order of the agenda.

DUR Board Meeting Minutes – Appendix A

Update on Medication Coverage Authorization Unit/Long-Acting Beta$_2$ Agonist Utilization: Pediatric Members – Appendix B

Annual Review of Potassium Binders – Appendix C

Annual Review of Kanuma® (Sebelipase Alfa) – Appendix D

Annual Review of Defitelio® (Defibrotide) – Appendix E

Annual Review of Injectable and Vaginal Progesterone Products – Appendix F

Annual Review of Zinplava™ (Bezlotoxumab) – Appendix G

Annual Review of Lumizyme® (Alglucosidase Alfa) – Appendix H

Industry News and Updates – Appendix I

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
January 10, 2018

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. DUR Board Meeting Minutes – See Appendix A
A. December 13, 2017 DUR Meeting Minutes
B. December 13, 2017 DUR Recommendations Memorandum

Items to be presented by Dr. Muchmore, Chairman:

2. Update on Medication Coverage Authorization Unit/Long-Acting Beta$_2$ Agonist Utilization: Pediatric Members – See Appendix B
A. Medication Coverage Activity for December 2017
B. Pharmacy Help Desk Activity for December 2017
C. Long-Acting Beta$_2$ Agonist Utilization: Pediatric Members

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

3. Annual Review of Potassium Binders – See Appendix C
A. Current Prior Authorization Criteria
B. Utilization of Potassium Binders
C. Prior Authorization of Potassium Binders
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Potassium Binders

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

4. Annual Review of Kanuma® (Sebelipase Alfa) – See Appendix D
A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Kanuma® (Sebelipase Alfa)
D. Prior Authorization of Kanuma® (Sebelipase Alfa)
E. Market and News Updates
F. College of Pharmacy Recommendations

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

5. Annual Review of Defitelio® (Defibrotide) – See Appendix E
A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Defitelio® (Defibrotide)
D. Prior Authorization of Defitelio® (Defibrotide)
E. Market and News Updates
F. College of Pharmacy Recommendations

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

6. Annual Review of Injectable and Vaginal Progesterone Products – See Appendix F
A. Current Prior Authorization Criteria
B. Utilization of Injectable and Vaginal Progesterone Products
C. Prior Authorization of Injectable and Vaginal Progesterone Products
D. Market News and Updates
E. College of Pharmacy Recommendations

F. Utilization Details of Injectable and Vaginal Progesterone Products

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

7. Annual Review of Zinplava™ (Bezlotoxumab) – See Appendix G

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

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

8. Annual Review of Lumizyme® (Alglucosidase Alfa) – See Appendix H

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Lumizyme® (Alglucosidase Alfa)
D. Prior Authorization of Lumizyme® (Alglucosidase Alfa)
E. Market News and Updates
F. College of Pharmacy Recommendations

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

9. Industry News and Updates – See Appendix I

A. Introduction
B. News and Updates

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

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

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

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

A. Osteoporosis Medications
B. Anti-Migraine Medications
C. Anticonvulsant Medications
D. Glaucoma Medications
E. Parkinson's Disease Medications
F. Antiviral Medications

**Future business subject to change.*

12. Adjournment

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES OF MEETING OF DECEMBER 13, 2017

BOARD MEMBERS:	PRESENT	ABSENT
Stephen Anderson, Pharm.D.	x	
Theresa Garton, M.D.	x	
Carla Hardzog-Britt, M.D.	x	
Anetta Harrell, Pharm.D.	x	
Ashley Huddleston, Pharm.D., BCOP		x
John Muchmore, M.D., Ph.D.; Chairman	x	
Lee Munoz, Pharm.D.		x
James Osborne, Pharm.D.	x	
Paul Louis Preslar, D.O., MBA; Vice Chairman	x	
Bruna Varalli-Claypool, MHS, PA-C	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	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	x	
Erin Ford, Pharm.D.; Clinical Pharmacist		x
Bethany Holderread, Pharm.D.; Clinical Coordinator	x	
Shellie Keast, Ph.D.; Assistant Professor	x	
Carol Moore, Pharm.D.; Clinical Pharmacist		x
Brandy Nawaz, Pharm.D.; Clinical Pharmacist	x	
Stephanie Nichols, Pharm.D., BCGP; Clinical Pharmacist	x	
Timothy Pham, Ph.D.; Postdoctoral Research Fellow	x	
Leslie Robinson, D.Ph.; PA Coordinator		x
Ashley Teel, Pharm.D.; Clinical Pharmacist	x	
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	x	
Graduate Students: Christina Bulkley, Pharm.D.		x
Corby Thompson, Pharm.D.		x
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Melody Anthony, Deputy State Medicaid Director		x
Marlene Asmussen, R.N.; Population Care Management Director	x	
Burl Beasley, D.Ph.; M.P.H.; M.S. Pharm.; Assistant Pharmacy Director	x	
Kelli Brodersen, Marketing Coordinator	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	
Garth Splinter, M.D.; M.B.A.; Deputy Chief Executive Officer		x
Joseph Young, J.D.; Deputy General Counsel IV	x	
Kerri Wade, Pharmacy Operations Manager	x	

OTHERS PRESENT:		
Partrick Mumme, Alexion	Jeremy Franklin, Alexion	Avatar Jones, Artia Solutions
Michele Puyear, Gilead	Jim Chapman, AbbVie	Candy Vandewater, Sarepta
Frank Alvarado, Actelion	Marc Parker, Sunovion	Mark DeClerk, Lilly
Jim Dunlap, PhRMA	Jason Schwier, Amgen	Nicole Wilkerson, Novartis
Charlie Collins, Sanofi/Genzyme	Travis Tate, Health Choice	Jimmy Davis, Boehringer Ingelheim
Amber Schrantz, Lilly	Eric Gardner, Vertex	

PRESENT FOR PUBLIC COMMENT:	
Jeremy Franklin	Alexion
Michele Puyear	Gilead

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. 5 SPEAKER: MICHELE PUYEAR

2B: AGENDA ITEM NO. 9 SPEAKER: JEREMY FRANKLIN

ACTION: NONE REQUIRED

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

3A: NOVEMBER 8, 2017 DUR MINUTES – VOTE

3B: NOVEMBER 8, 2017 DUR RECOMMENDATIONS MEMORANDUM

Materials included in agenda packet; presented by Dr. Cothran

Correction(s) to November minutes were discussed prior to voting. Correction(s) included the attendance noted of Kelli Brodersen from the last DUR meeting. Dr. Cothran made announcement and the DUR board voted on the minutes with correction(s).

Dr. Preslar moved to approve; seconded by Dr. Harrell

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/SOONERPSYCH PROGRAM UPDATE

4A: MEDICATION COVERAGE ACTIVITY FOR NOVEMBER 2017

4B: PHARMACY HELP DESK ACTIVITY FOR NOVEMBER 2017

4C: SOONERPSYCH PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Holderread

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE MAVYRET™ (GLECAPREVIR/ PIBRENTASVIR) AND VOSEVI® (SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR)

5A: INTRODUCTION

5B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Holderread

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE BAXDELA™ (DELAFLOXACIN INJECTION AND TABLETS), OFLOXACIN 300MG TABLETS, MINOLIRA™ (MINOCYCLINE EXTENDED-RELEASE TABLETS), SOLOSEC™ (SECNIDAZOLE ORAL GRANULES), AND VABOMERE™ (MEROPENEM/ VABORBACTAM INJECTION)

6A: INTRODUCTION

6B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Nichols
Dr. Harrell moved to approve; seconded by Ms. Varalli-Claypool
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE DUZALLO® (LESINURAD/ALLOPURINOL)
7A: INTRODUCTION
7B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
Ms. Varalli-Claypool moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF PHOSPHATE BINDERS
8A: CURRENT PRIOR AUTHORIZATION CRITERIA
8B: UTILIZATION OF PHOSPHATE BINDERS
8C: PRIOR AUTHORIZATION OF PHOSPHATE BINDERS
8D: MARKET NEWS AND UPDATES
8E: COLLEGE OF PHARMACY RECOMMENDATIONS
8F: UTILIZATION DETAILS OF PHOSPHATE BINDERS
Materials included in agenda packet; presented by Dr. Abbott
Dr. Harrell moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF SOLIRIS® (ECULIZUMAB)
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF SOLIRIS® (ECULIZUMAB)
9C: PRIOR AUTHORIZATION OF SOLIRIS® (ECULIZUMAB)
9D: MARKET NEWS AND UPDATES
9E: SOLIRIS® (ECULIZUMAB) FOR MYASTHENIA GRAVIS (MG) SUMMARY
9F: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Holderread
Dr. Garton moved to approve; seconded by Ms. Varalli-Claypool
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF DUCHENNE MUSCULAR DYSTROPHY (DMD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EMFLAZA® (DEFLAZACORT)
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF DMD MEDICATIONS [EXONDYS 51™ (ETEPLIRSEN)]
10C: PRIOR AUTHORIZATION OF DMD MEDICATIONS [EXONDYS 51™ (ETEPLIRSEN)]
10D: MARKET NEWS AND UPDATES
10E: EMFLAZA® (DEFLAZACORT) PRODUCT SUMMARY
10F: GUIDELINE RECOMMENDATIONS
10G: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF MAINTENANCE ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ARMONAIR™ RESPICLICK® (FLUTICASONE PROPIONATE), TRELEGY™ ELLIPTA® (FLUTICASONE FUROATE/UMECLIDINIUM/VILANTEROL), QVAR® REDIHALER™ (BECLOMETHASONE DIPROPIONATE), AIRDUO™ RESPICLICK® (FLUTICASONE PROPIONATE/SALMETEROL), AND FASENRA™ (BENRALIZUMAB)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF MAINTENANCE ASTHMA AND COPD MEDICATIONS
11C: PRIOR AUTHORIZATION OF MAINTENANCE ASTHMA AND COPD MEDICATIONS
11D: MARKET NEWS AND UPDATES

11E: ARMONAIR™ RESPICLICK® (FLUTICASONE PROPIONATE INHALATION POWDER) PRODUCT SUMMARY
11F: TRELEGY™ ELLIPTA® (FLUTICASONE FUROATE/UMECLIDINIUM/VILANTEROL INHALATION POWDER) PRODUCT SUMMARY
11G: QVAR® REDIHALER™ (BECLOMETHASONE DIPROPIONATE HFA) PRODUCT SUMMARY
11H: AIRDUO™ RESPICLICK® (FLUTICASONE PROPIONATE/SALMETEROL INHALATION POWDER) PRODUCT SUMMARY
11I: FASENRA™ (BENRALIZUMAB INJECTION) PRODUCT SUMMARY
11J: COLLEGE OF PHARMACY RECOMMENDATIONS
11K: UTILIZATION DETAILS OF MAINTENANCE ASTHMA AND COPD MEDICATIONS
11L: UTILIZATION DETAILS OF ASTHMA MONOCLONAL ANTIBODIES (PHARMACY CLAIMS)
11M: UTILIZATION DETAILS OF ASTHMA MONOCLONAL ANTIBODIES (MEDICAL CLAIMS)
11N: UTILIZATION DETAILS OF INHALED CORTICOSTEROIDS
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF ANTI-EMETIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE VARUBI® IV (ROLAPITANT) AND CINVANTI™ (APREPITANT)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ANTI-EMETIC MEDICATIONS
12C: PRIOR AUTHORIZATION OF ANTI-EMETIC MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF ANTI-EMETIC MEDICATIONS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: 30-DAY NOTICE TO PRIOR AUTHORIZE ZILRETTA™ (TRIAMCINOLONE ACETONIDE EXTENDED-RELEASE INJECTABLE SUSPENSION)
13A: INTRODUCTION
13B: ZILRETTA™ (TRIAMCINOLONE ACETONIDE EXTENDED-RELEASE INJECTABLE SUSPENSION) PRODUCT SUMMARY
13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Nichols
Dr. Muchmore recommended that methylprednisolone be added as a trial.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF OPHTHALMIC ALLERGY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZERVIATE™ (CETIRIZINE OPHTHALMIC SOLUTION)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF OPHTHALMIC ALLERGY MEDICATIONS
14C: PRIOR AUTHORIZATION OF OPHTHALMIC ALLERGY MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: ZERVIATE™ (CETIRIZINE OPHTHALMIC SOLUTION) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF OPHTHALMIC ALLERGY MEDICATIONS
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: INDUSTRY NEWS AND UPDATES
15A: INTRODUCTION
15B: NEWS AND UPDATES
Materials included in agenda packet; Non-presentation; Questions only
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: **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. 17: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

No live meeting scheduled for January. January will be a packet only meeting.

17A: INJECTABLE AND VAGINAL PROGESTERONE PRODUCTS

17B: POTASSIUM BINDING MEDICATIONS

17C: DEFITELIO® (DEFIBROTIDE)

17D: KANUMA® (SEBELIPASE ALFA)

17E: ZINPLAVA™ (BEZLOTOXUMAB)

17F: LUMIZYME® (ALGLUCOSIDASE ALFA)

FUTURE BUSINESS SUBJECT TO CHANGE

Materials included in agenda packet; presented by Dr. Holderread

ACTION: **NONE REQUIRED**

AGENDA ITEM NO. 18: **ADJOURNMENT**

The meeting was adjourned at 5:02 pm.

Materials included in agenda packet; presented by Dr. Nichols
Dr. Harrell moved to approve; seconded by Ms. Varalli-Claypool
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE DUZALLO® (LESINURAD/ALLOPURINOL)
7A: INTRODUCTION
7B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
Ms. Varalli-Claypool moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

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Dr. Harrell moved to approve; seconded by Dr. Garton
ACTION: MOTION CARRIED

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9F: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Holderread
Dr. Garton moved to approve; seconded by Ms. Varalli-Claypool
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF DUCHENNE MUSCULAR DYSTROPHY (DMD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EMFLAZA® (DEFLAZACORT)
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10B: UTILIZATION OF DMD MEDICATIONS [EXONDYS 51™ (ETEPLIRSEN)]
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10G: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Chandler
ACTION: NONE REQUIRED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF MAINTENANCE ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ARMONAIR™ RESPICLICK® (FLUTICASONE PROPIONATE), TRELEGY™ ELLIPTA® (FLUTICASONE FUROATE/UMECLIDINIUM/VILANTEROL), QVAR® REDIHALER™ (BECLOMETHASONE DIPROPIONATE), AIRDUO™ RESPICLICK® (FLUTICASONE PROPIONATE/SALMETEROL), AND FASENRA™ (BENRALIZUMAB)
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11N: UTILIZATION DETAILS OF INHALED CORTICOSTEROIDS
Materials included in agenda packet; presented by Dr. Nawaz
ACTION: NONE REQUIRED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF ANTI-EMETIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE VARUBI® IV (ROLAPITANT) AND CINVANTI™ (APREPITANT)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ANTI-EMETIC MEDICATIONS
12C: PRIOR AUTHORIZATION OF ANTI-EMETIC MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF ANTI-EMETIC MEDICATIONS
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: 30-DAY NOTICE TO PRIOR AUTHORIZE ZILRETTA™ (TRIAMCINOLONE ACETONIDE EXTENDED-RELEASE INJECTABLE SUSPENSION)
13A: INTRODUCTION
13B: ZILRETTA™ (TRIAMCINOLONE ACETONIDE EXTENDED-RELEASE INJECTABLE SUSPENSION) PRODUCT SUMMARY
13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Nichols
Dr. Muchmore recommended that methylprednisolone be added as a trial.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF OPHTHALMIC ALLERGY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZERVIATE™ (CETIRIZINE OPHTHALMIC SOLUTION)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF OPHTHALMIC ALLERGY MEDICATIONS
14C: PRIOR AUTHORIZATION OF OPHTHALMIC ALLERGY MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: ZERVIATE™ (CETIRIZINE OPHTHALMIC SOLUTION) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF OPHTHALMIC ALLERGY MEDICATIONS
Materials included in agenda packet; presented by Dr. Holderread
ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: INDUSTRY NEWS AND UPDATES
15A: INTRODUCTION
15B: NEWS AND UPDATES
Materials included in agenda packet; Non-presentation; Questions only
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: **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. 17: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

No live meeting scheduled for January. January will be a packet only meeting.

17A: INJECTABLE AND VAGINAL PROGESTERONE PRODUCTS

17B: POTASSIUM BINDING MEDICATIONS

17C: DEFITELIO® (DEFIBROTIDE)

17D: KANUMA® (SEBELIPASE ALFA)

17E: ZINPLAVA™ (BEZLOTOXUMAB)

17F: LUMIZYME® (ALGLUCOSIDASE ALFA)

FUTURE BUSINESS SUBJECT TO CHANGE

Materials included in agenda packet; presented by Dr. Holderread

ACTION: **NONE REQUIRED**

AGENDA ITEM NO. 18: **ADJOURNMENT**

The meeting was adjourned at 5:02 pm.

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

Memorandum

Date: December 14, 2017

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

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

Subject: DUR Board recommendations from meeting of December 13, 2017

Recommendation 1: SoonerPsych Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Mavyret™ (Glecaprevir/ Pibrentasvir) and Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following:

1. The prior authorization of Mavyret™ (glecaprevir/pibrentasvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) with criteria similar to the other prior authorized hepatitis C medications.
2. Adding the following criteria to all prior authorized hepatitis C medications regarding short life expectancy in accordance with the hepatitis C treatment guidelines: Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy.

The following table highlights the preferred regimens for each genotype in treatment-naïve members (listed in alphabetical order). Additional regimens for treatment-experienced

members are covered, just not included in the following table. Additional regimens other than those listed may be considered based on patient-specific clinical situations. Preferred regimens are based on treatment guidelines and supplemental rebate participation and are subject to change if the manufacturer chooses not to participate in supplemental rebates.

Genotype	Patient Factors	Preferred Regimen(s)
Genotype 1		
1	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Harvoni® for 8 or 12 weeks Mavyret™ for 8 weeks 1a: Zepatier® for 12 weeks (w/o baseline RAVs) 1a: Zepatier® + RBV for 16 weeks (w/ baseline RAVs) 1b: Zepatier® for 12 weeks
1	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (w/ RBV if decompensated) Harvoni® for 12 weeks (w/ RBV if decompensated) Mavyret™ for 12 weeks 1a: Zepatier® for 12 weeks (w/o baseline RAVs) 1a: Zepatier® + RBV for 16 weeks (w/ baseline RAVs) 1b: Zepatier® for 12 weeks
Genotype 2		
2	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Mavyret™ for 8 weeks
2	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (w/ RBV if decompensated) Mavyret™ for 12 weeks
Genotype 3		
3	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Mavyret™ for 8 weeks
3	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (w/ RBV if decompensated) Mavyret™ for 12 weeks
Genotype 4		
4	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Harvoni® for 12 weeks Mavyret™ for 8 weeks Technivie™ + RBV for 12 weeks Zepatier® for 12 weeks
4	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (w/ RBV if decompensated) Harvoni® for 12 weeks (w/ RBV if decompensated) Mavyret™ for 12 weeks Technivie™ + RBV for 12 weeks Zepatier® for 12 weeks
Genotype 5 or 6		
5 or 6	Treatment-naïve, non-cirrhotic	Epclusa® for 12 weeks Mavyret™ for 8 weeks Harvoni® for 12 weeks (w/ RBV if decompensated)
5 or 6	Treatment-naïve, cirrhotic	Epclusa® for 12 weeks (w/ RBV if decompensated) Mavyret™ for 12 weeks Harvoni® for 12 weeks (w/ RBV if decompensated)

If not specified, regimen applies to all genotypic subtypes.
w/o = without; w/ = with; RBV = ribavirin; RAV= resistance-associated variants
Preferred regimens based on clinical efficacy data, guideline recommendations, supplemental rebate participation, and/or National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.

Harvoni® (sofosbuvir/ledipasvir), Zepatier® (elbasvir/grazoprevir), Epclusa® (sofosbuvir/ velpatasvir), Mavyret™ (glecaprevir/pibrentasvir), and Vosevi® (sofosbuvir/velpatasvir/ voxilaprevir) are the preferred direct-acting antivirals (DAAs) for the treatment of chronic hepatitis C virus (HCV) genotype 1. Use of an alternative regimen including Viekira Pak™ (ombitasvir/paritaprevir/ ritonavir/dasabuvir), Viekira XR™ (ombitasvir/paritaprevir/ ritonavir/dasabuvir ER), Sovaldi® (sofosbuvir) alone, Sovaldi® (sofosbuvir) and Olysio® (simeprevir) in combination, Olysio® (simeprevir) alone, or Sovaldi® (sofosbuvir) and Daklinza™ (daclatasvir) in combination for the treatment of HCV genotype 1 requires patient-specific, clinically significant reasoning why the preferred DAAs are not appropriate for the member. Detailed criteria for medications with no changes to the coverage criteria other than the addition of criteria regarding short life expectancy are not included in the criteria on the following pages. The criteria for each medication may include U.S. Food and Drug Administration (FDA) approved regimens or American Association for the Study of Liver Diseases (AASLD) guideline recommended regimens that are not included in the SoonerCare preferred regimens table. Preferred regimens for each genotype can be found in the preferred regimens table. Additional regimens other than those listed in the preferred regimens table may be considered based on patient-specific clinical situations.

Mavyret™ (Glecaprevir/Pibrentasvir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6; and
3. METAVIR fibrosis score or equivalent scoring with an alternative test must be indicated on prior authorization request; and
4. Mavyret™ must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on the prior authorization request; and
6. Pre-treatment viral load (HCV-RNA) must be confirmed and indicated on the petition. Viral load should have been taken within the last three months; and
7. The following regimens and requirements based on cirrhosis status, viral genotype, and treatment history will apply (new regimens will apply as approved by the FDA):

Genotype	Prior Treatment Experience	No Cirrhosis	Compensated Cirrhosis
1, 2, 3, 4, 5, or 6	Treatment Naïve	8 weeks	12 weeks
1	NS5A w/o NS3/4A PI	16 weeks	16 weeks
1	NS3/4A PI w/o NS5A	12 weeks	12 weeks
1, 2, 4, 5, or 6	PRS	8 weeks	12 weeks
3	PRS	16 weeks	16 weeks

w/o = without; PI = protease inhibitor; PRS = pegylated interferon, ribavirin, and/or sofosbuvir
Examples of NS5A inhibitors include: daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, velpatasvir
Examples of NS3/4A PIs include: boceprevir, glecaprevir, grazoprevir, paritaprevir, simeprevir, telaprevir, voxilaprevir

8. Member must sign and submit the Hepatitis C Intent to Treat contract; and

9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
11. Prescriber must agree to counsel members on the potential harms of illicit IV drug use or alcohol use and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C); and
14. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
15. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy; and
16. Member must not be taking the following medications: carbamazepine, rifampin, ethinyl estradiol-containing medications, St. John's wort, atazanavir, darunavir, lopinavir, ritonavir, efavirenz, atorvastatin, lovastatin, simvastatin, rosuvastatin doses greater than 10mg per day, cyclosporine doses greater than 100mg per day; and
17. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight-management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
18. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
19. Approval of the 8-week carton (in place of the 4-week carton) requires a patient-specific, clinically significant reason why the member requires the 8-week carton in place of the 4-week carton; and
20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and
21. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 16 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6; and
3. METAVIR fibrosis score or equivalent scoring with an alternative test must be indicated on prior authorization request; and

4. Vosevi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on the prior authorization request; and
6. Pre-treatment viral load (HCV-RNA) must be confirmed and indicated on the petition. Viral load should have been taken within the last three months; and
7. The following regimens and requirements based on treatment history will apply:
    a. **Adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A):**
        i. **Genotype 1, 2, 3, 4, 5, or 6 patients who were previously treated with an HCV regimen containing an NS5A inhibitor** (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir): Vosevi® for 12 weeks; or
        ii. **Genotype 1a or 3 patients who were previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor:** Vosevi® for 12 weeks; or
    b. New regimens will apply as approved by the FDA; and
8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
11. Prescriber must agree to counsel members on the potential harms of illicit IV drug use or alcohol use and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C); and
14. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
15. Member must not have severe renal impairment [estimated Glomerular Filtration Rate (eGFR) <30mL/min/1.73m^2]; and
16. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy; and
17. Member must not be taking the following medications: H_2-receptor antagonists at doses greater than 40mg famotidine twice daily equivalent, omeprazole doses greater than 20mg daily or other proton pump inhibitors, amiodarone, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, St. John's wort, pravastatin doses greater than 40mg daily, rosuvastatin, pitavastatin, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan; and

18. If member is using antacids they must agree to separate antacid and Vosevi® administration by four hours; and
19. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight-management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
20. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
21. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and
22. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Recommendation 3: Vote to Prior Authorize Baxdela™ (Delafloxacin Injection and Tablets), Ofloxacin 300mg Tablets, Minolira™ (Minocycline Extended-Release Tablets), Solosec™ (Secnidazole Oral Granules), and Vabomere™ (Meropenem/Vaborbactam Injection)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Baxdela™ (delafloxacin injection and tablets), Solosec™ (secnidazole oral granules), and Vabomere™ (meropenem/vaborbactam injection) with the following criteria:

Baxdela™ (Delafloxacin Injection and Tablets) Approval Criteria:

1. An FDA approved diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria; and
2. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost effective therapeutic equivalent alternative(s).
3. Approval quantity will be based on Baxdela™ prescribing information and FDA approved dosing regimen(s).
    a. For Baxdela™ vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

Solosec™ (Secnidazole Oral Granules) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient-specific, clinically significant reason why the member cannot use metronidazole, tinidazole, or other cost effective therapeutic equivalent alternative(s).
3. A quantity limit of 1 packet per 30 days will apply.

Vabomere™ (Meropenem/Vaborbactam Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI) or pyelonephritis; and
2. A patient-specific, clinically significant reason why the member cannot use piperacillin/tazobactam or other cost effective therapeutic equivalent alternative(s).
3. Approval quantity will be based on Vabomere™ prescribing information and FDA approved dosing regimen(s).

The College of Pharmacy also recommends the following changes to the Various Systemic Antibiotic Medications Prior Authorization category:

1. Add cephalexin 250mg tablets to the Antibiotic Special Formulation category based on net cost. Current special formulation criteria will apply.
2. Add Minolira™ (minocycline hydrochloride ER tablets) to the Antibiotic Special Formulation category. Current special formulation criteria will apply.
3. Add oflaxacin 300mg tablets with criteria similar to ofloxacin 400mg tablets and moxifloxacin prior authorization criteria based on net cost. Current criteria will apply.
4. Add Sivextro® (tedizolid) vial formulation with criteria similar to Sivextro® tablet formulation based on net cost. Current criteria will apply.

The proposed changes can be seen in red in the following criteria:

Antibiotic Special Formulation Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.
2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:
    - Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)
    - Amoxicillin ER 775mg tablets (Moxatag®)
    - Cephalexin **250mg and** 500mg tablets
    - Cephalexin 750mg capsules
    - Ciprofloxacin 100mg tablets
    - Ciprofloxacin 500mg and 1,000mg ER tablets
    - Doxycycline hyclate 75mg capsules (Acticlate®)
    - Doxycycline hyclate delayed-release (DR) tablets (Doryx®)
    - Doxycycline monohydrate 75mg and 150mg capsules and tablets
    - Doxycycline monohydrate DR 40mg capsules (Oracea®)
    - **Minocycline ER tablets (Minolira™)**
    - Minocycline ER tablets (Solodyn®)
    - Minocycline immediate-release (IR) tablets
    - Tetracycline 250mg and 500mg capsules

Ofloxacin 300mg and 400mg Tablets and Moxifloxacin 400mg Tablets Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use ciprofloxacin tablets, levofloxacin tablets, and/or other cost effective therapeutic equivalent medication(s).

Sivextro® (Tedizolid) Tablet and Vial Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent and resistant to the cephalosporin-class of antibiotics and other antibiotics commonly used for diagnosis or infection; and
2. A patient-specific, clinically significant reason why the member cannot use Zyvox® (linezolid) or other cost effective therapeutic equivalent medication(s).
3. A quantity limit of six tablets **or vials** per six days will apply.

Suprax® (Cefixime), Cedax® (Ceftibuten), ~~and Spectracef® (Cefditoren)~~ Approval Criteria:

1. Indicated diagnosis or infection known to be susceptible to requested agent; and
2. A patient-specific, clinically significant reason why the member cannot use cephalexin, cefdinir, or other cost effective therapeutic equivalent medication(s).

Recommendation 4: Vote to Prior Authorize Duzallo® (Lesinurad/Allopurinol)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Duzallo® (lesinurad/ allopurinol) with criteria similar to Zurampic® (lesinurad):

Duzallo® (Lesinurad/Allopurinol) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved indication for the treatment of symptomatic hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a medically appropriate daily dose of allopurinol alone; and
3. Failure of allopurinol or febuxostat alone defined by serum urate levels greater than 6.0mg/dL; and
4. Prior to starting treatment with Duzallo®, member must be on at least 300mg of allopurinol daily, unless creatinine clearance (CrCl) is less than 60mL/min then 200mg daily is required. Duzallo® 200mg/200mg will only be approved for members with a CrCl less than 60mL/min; and
5. Prescriber must verify that member has a CrCl greater than 45mL/min prior to initiating treatment. For continued approval, prescriber must verify CrCl is greater than 45mL/min and serum creatinine is not greater than two times baseline when Duzallo® was initiated; and
6. Prescriber must document member has no contraindications for use of Duzallo® including any of the following**:** Tumor lysis syndrome or Lesch-Nyhan syndrome, severe renal impairment (CrCl less than 30mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis.
7. A quantity limit of one tablet daily will apply.

Recommendation 5: Annual Review of Phosphate Binders

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Auryxia® (ferric citrate) prior authorization criteria based on new FDA approved indications with the following changes noted in red:

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis; and
    a. Documented trials of inadequate response to at least two of the phosphate binders available without a prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without a prior authorization; or
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in patients with CKD not on dialysis; and
    a. Documented lab results verifying IDA; and
    b. A documented intolerance or inadequate response to prior treatment with oral iron.
3. A quantity limit of 12 tablets per day will apply based on maximum recommended dose.

Recommendation 6: Annual Review of Soliris® (Eculizumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following criteria for Soliris® (eculizumab) for a diagnosis of generalized myasthenia gravis:

Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Positive serologic test for anti-acetylcholine receptor (AchR) antibodies; and
3. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV; and
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet one of the following:
    a. Failed treatment over one year or more with two or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least one IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and
6. Initial approvals will be for the duration of six months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of one year.

Recommendation 7: Annual Review of Duchenne Muscular Dystrophy (DMD) Medications and 30-Day Notice to Prior Authorize Emflaza® (Deflazacort)

NO ACTION REQUIRED.

Recommendation 8: Annual Review of Maintenance Asthma and Chronic Obstructive Pulmonary Disease (COPD) Medications and 30-Day Notice to Prior Authorize ArmonAir™ RespiClick® (Fluticasone Propionate), Trelegy™ Ellipta® (Fluticasone Furoate/Umeclidinium/Vilanterol), Qvar® RediHaler™

(Beclomethasone Dipropionate), AirDuo™ RespiClick® (Fluticasone Propionate/ Salmeterol), and Fasenra™ (Benralizumab)

NO ACTION REQUIRED.

Recommendation 9: Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Varubi® IV (Rolapitant) and Cinvanti™ (Aprepitant)

NO ACTION REQUIRED.

Recommendation 10: 30-Day Notice to Prior Authorize Zilretta™ (Triamcinolone Acetonide Extended-Release Injectable Suspension)

NO ACTION REQUIRED.

Recommendation 11: Annual Review of Ophthalmic Allergy Medications and 30-Day Notice to Prior Authorize Zerviate™ (Cetirizine Ophthalmic Solution)

NO ACTION REQUIRED.

Recommendation 12: Industry News and Updates

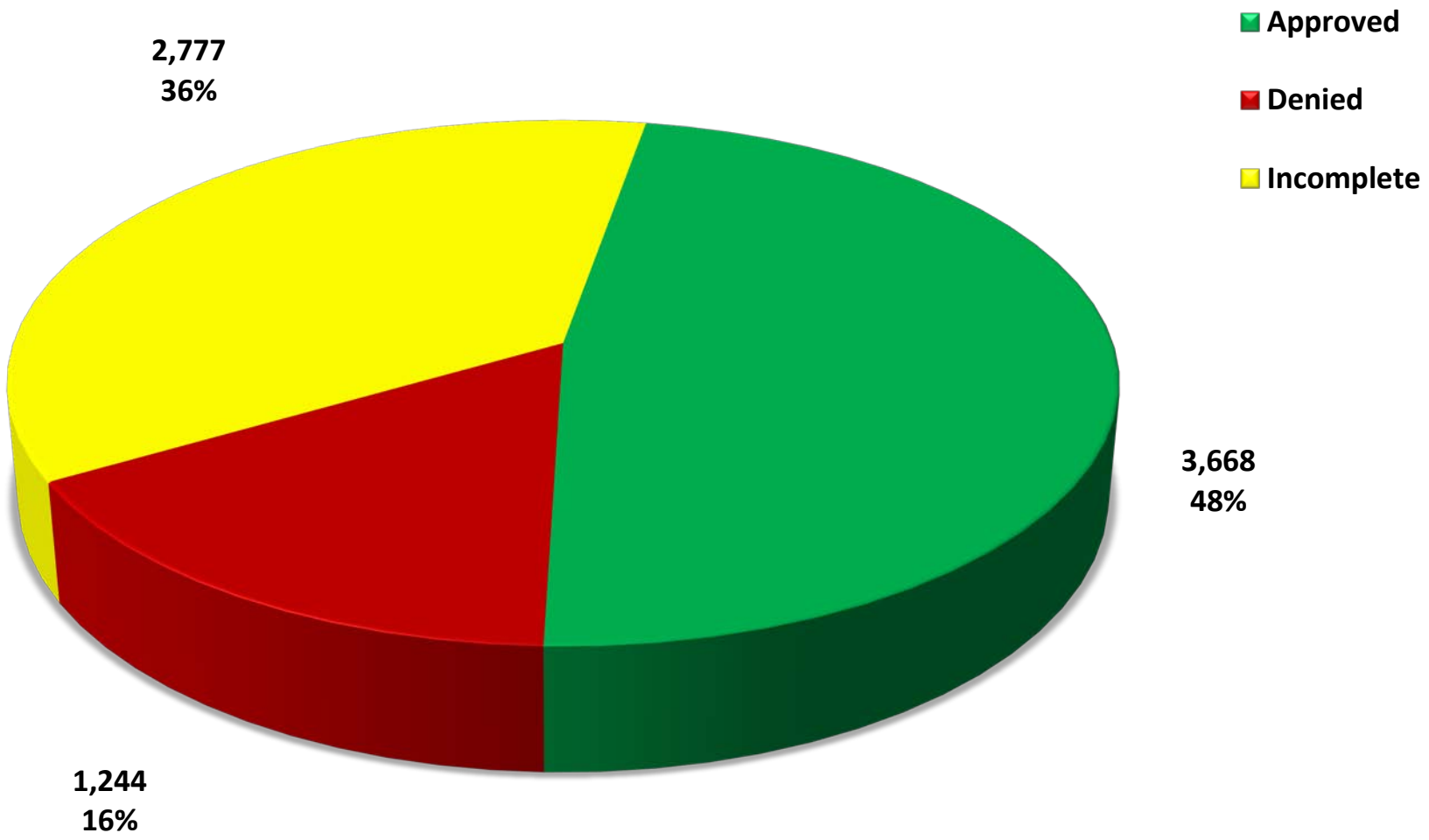
NO ACTION REQUIRED.

Recommendation 13: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

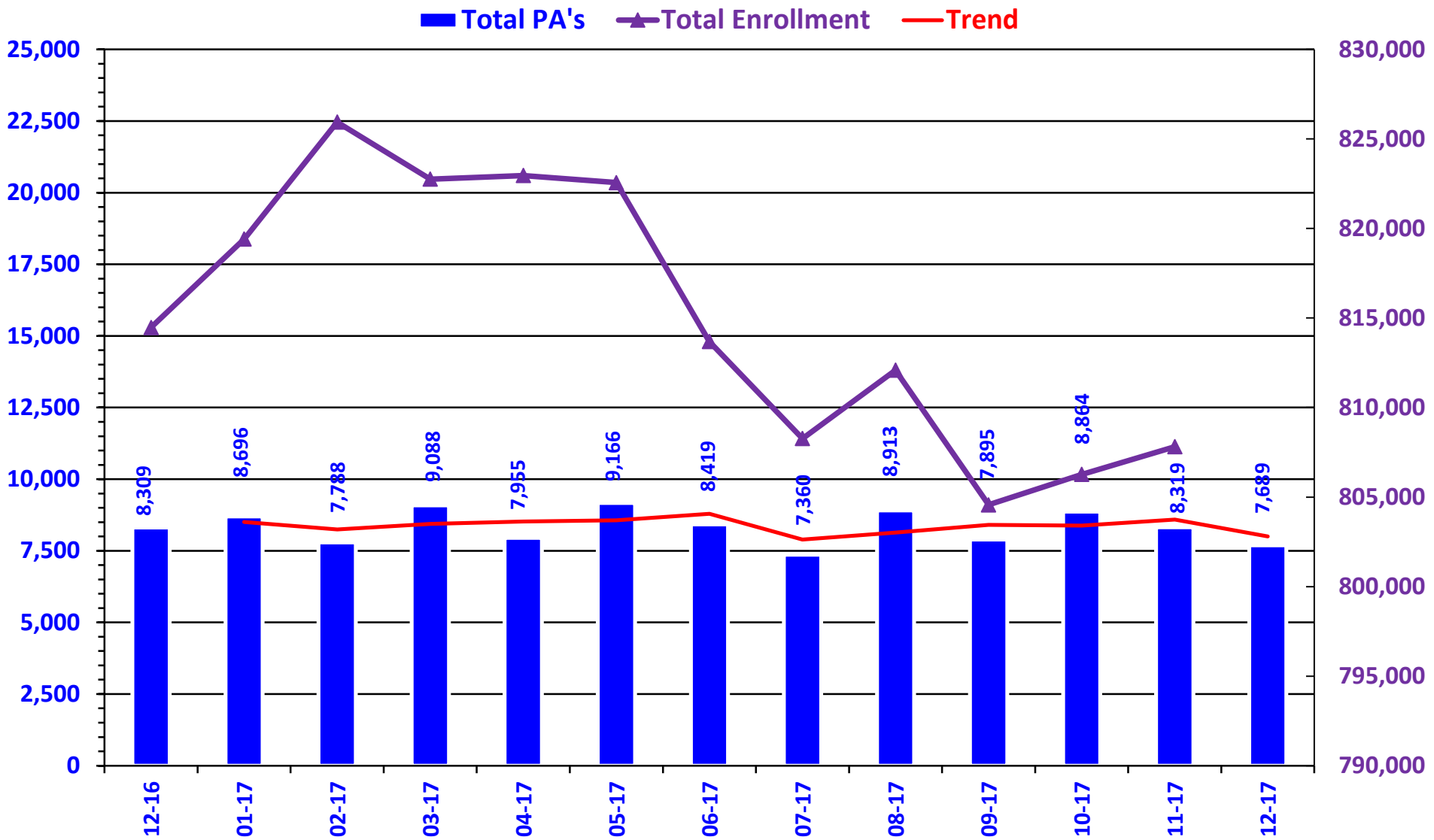
Appendix B

PRIOR AUTHORIZATION ACTIVITY REPORT: DECEMBER 2017



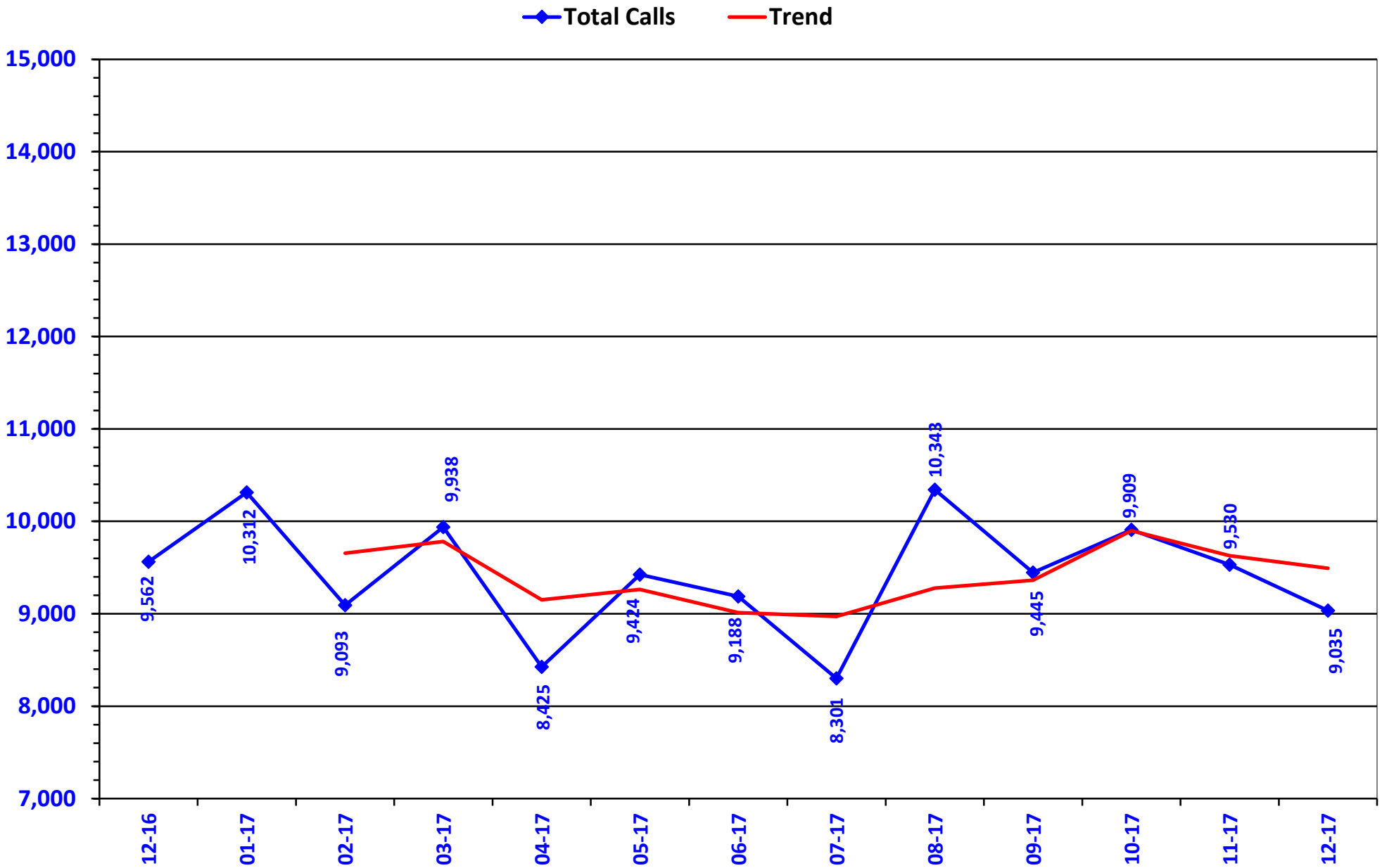
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION REPORT: DECEMBER 2016 – DECEMBER 2017



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
DECEMBER 2016 – DECEMBER 2017



Prior Authorization Activity

12/1/2017 Through 12/31/2017

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	97	13	23	61	332
Analgesic - NonNarcotic	26	0	7	19	0
Analgesic - Narcotic	432	230	55	147	154
Angiotensin Receptor Antagonist	10	2	4	4	357
Antiasthma	43	7	7	29	313
Antibiotic	50	18	4	28	201
Anticonvulsant	95	41	13	41	315
Antidepressant	166	52	28	86	332
Antidiabetic	210	79	35	96	347
Antihistamine	23	2	16	5	222
Antimigraine	32	9	9	14	129
Antineoplastic	52	30	8	14	152
Antiulcers	138	37	42	59	120
Anxiolytic	53	29	2	22	291
Atypical Antipsychotics	162	94	10	58	306
Biologics	120	58	25	37	316
Bladder Control	47	10	14	23	357
Blood Thinners	209	129	21	59	335
Botox	27	22	1	4	328
Buprenorphine Medications	334	231	17	86	79
Cardiovascular	93	40	16	37	334
Chronic Obstructive Pulmonary Disease	157	18	49	90	341
Constipation/Diarrhea Medications	124	23	43	58	219
Contraceptive	20	11	4	5	328
Dermatological	389	141	96	152	161
Diabetic Supplies	444	240	20	184	196
Endocrine & Metabolic Drugs	110	62	20	28	140
Erythropoietin Stimulating Agents	17	11	4	2	110
Fibromyalgia	205	35	102	68	339
Fish Oils	12	2	5	5	355
Gastrointestinal Agents	98	25	25	48	136
Growth Hormones	70	51	4	15	151
Hepatitis C	183	131	16	36	9
HFA Rescue Inhalers	39	0	8	31	0
Insomnia	23	2	7	14	206
Insulin	80	31	14	35	311
Miscellaneous Antibiotics	17	2	4	11	10
Multiple Sclerosis	32	14	4	14	161
Muscle Relaxant	52	11	16	25	116
Nasal Allergy	61	9	17	35	78
Neurological Agents	70	21	24	25	263
NSAIDs	154	33	33	88	187
Ocular Allergy	28	5	7	16	84
Ophthalmic Anti-infectives	19	4	7	8	23
Osteoporosis	21	10	1	10	358
Other*	332	64	93	175	218
Otic Antibiotic	14	0	3	11	0
Statins	16	4	3	9	357
Stimulant	748	392	81	275	326
Synagis	145	65	36	44	107

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Topical Antifungal	29	1	6	22	28
Topical Corticosteroids	87	12	29	46	115
Vitamin	50	13	24	13	204
Pharmacotherapy	96	87	0	9	292
Emergency PAs	0	0	0	0	
Total	**6,398**	**2,676**	**1,171**	**2,551**	
Overrides					
Brand	29	14	5	10	251
Compound	15	13	1	1	67
Diabetic Supplies	7	5	1	1	118
Dosage Change	293	278	2	13	12
High Dose	3	2	0	1	87
Ingredient Duplication	18	14	0	4	8
Lost/Broken Rx	107	101	2	4	16
NDC vs Age	245	173	21	51	238
Nursing Home Issue	29	28	0	1	21
Opioid Quantity	17	13	3	1	147
Other*	45	34	5	6	11
Quantity vs. Days Supply	464	309	35	120	238
STBS/STBSM	22	12	3	7	103
Stolen	15	14	0	1	15
Third Brand Request	21	13	0	8	13
Overrides Total	**1,291**	**992**	**73**	**226**	
Total Regular PAs + Overrides	**7,689**	**3,668**	**1,244**	**2,777**	

Denial Reasons	
Unable to verify required trials.	2,103
Does not meet established criteria.	1,275
Lack required information to process request.	627
Other PA Activity	
Duplicate Requests	485
Letters	8,286
No Process	17
Changes to existing PAs	550
Helpdesk Initiated Prior Authorizations	532
PAs Missing Information	34

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

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

Oklahoma Health Care Authority
January 2018

Introduction[1]

The Drug Utilization Review (DUR) Board requested a review of claims for pediatric SoonerCare members utilizing single component long-acting beta$_2$ agonists (LABA) in late 2014. The claims analysis was conducted and presented to the DUR Board in February 2015 and again in October 2016. The following report is an update to ensure appropriate utilization is still in effect.

Current clinical guidelines do not recommend use of LABA medications alone in pediatric patients with asthma. Guidelines suggest using a concomitant inhaled corticosteroid (ICS) with a LABA medication or using an ICS alone. The purpose of this claims analysis was to evaluate potential inappropriate use of single-component LABA medications in the pediatric SoonerCare population.

Claims Analysis

The claims analysis included members 18 years of age and younger with a paid claim for a single-component LABA medication. The review period was for one year (November 1, 2016 to October 31, 2017) and members with a single-component LABA medication claim were further evaluated for a single-component ICS medication during the same month.

Results

11 Members had a paid claim for a single-component LABA medication. This is a decline of 63% from 2016.

4 Members (of the 11) did not have a paid claim for an ICS medication during the same month as the LABA medication. Half of the 4 members had only one paid claim for a LABA medication. This is a decline of 67% from 2016.

2 Members (of the 4) had more than one paid claim for a LABA medication; the maximum number of claims was two. This is a decline of 67% from 2016.

1 Member (of the 4) had a paid claim for a LABA medication within the last 90 days (this member has had only one paid claim for a LABA medication). This is equivalent to the 2016 analysis.

Recommendations

The SoonerCare claims analysis of pediatric utilization of single-component LABA medications did not reveal a pressing need for intervention. Results of this analysis revealed reduced single-component LABA utilization in the pediatric population when compared to the previous analysis completed in February 2015 and October 2016. Most pediatric members utilizing single-component LABA medications required a unique dosage formulation, had only one paid claim for a single-component LABA medication, or were being followed by a pulmonary specialist. Based on these findings, the College of Pharmacy does not recommend any changes to the current LABA criteria at this time.

[1] U.S. Department of Health and Human Services and National Heart Lung and Blood Institute. Guidelines from the National Asthma Education and Prevention Program: Diagnosing and Managing Asthma. Available online at: https://www.nhlbi.nih.gov/files/docs/guidelines/asthma_qrg.pdf. Last revised 09/2012. Last accessed 12/06/2017.

Appendix C

Fiscal Year 2017 Annual Review of Potassium Binders

Oklahoma Health Care Authority
January 2018

Current Prior Authorization Criteria

Veltassa® (Patiromer) Approval Criteria:

1. An FDA approved diagnosis of hyperkalemia; and
2. A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member; and
3. Documentation of a low potassium diet; and
4. A patient-specific, clinically significant reason why member cannot use sodium polystyrene sulfonate powder which is available without a prior authorization; and
5. A quantity limit of 30 packets per month will apply.

Utilization of Potassium Binders: Fiscal Year 2017

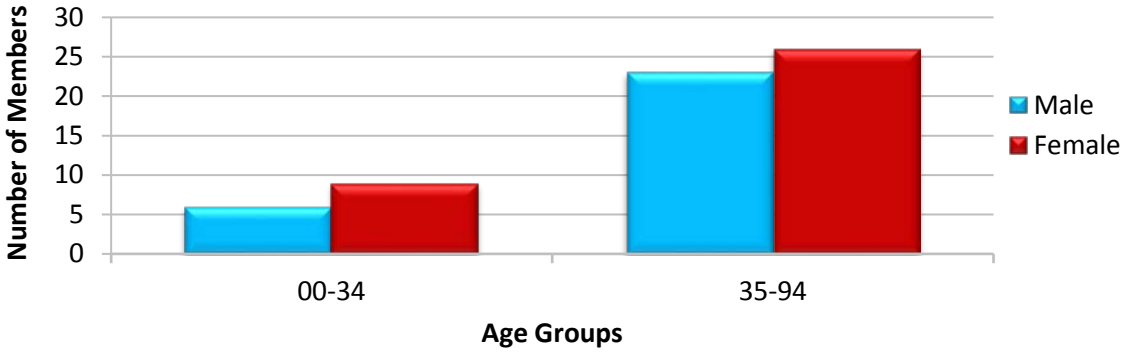
Comparison of Fiscal Years

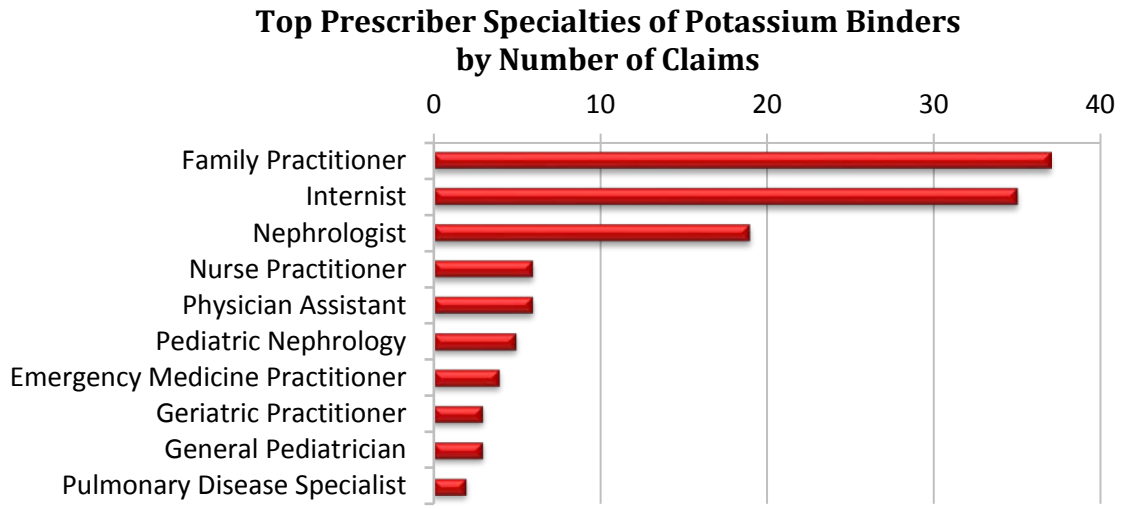
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	70	127	$6,793.94	$53.50	$3.65	44,204	1,863
2017	64	128	$16,142.37	$126.11	$8.82	43,911	1,831
% Change	**-8.60%**	**0.80%**	**137.60%**	**135.70%**	**141.60%**	**-0.70%**	**-1.70%**
Change	**-6**	**1**	**$9,348.43**	**$72.61**	**$5.17**	**-293**	**-32**

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

- In October 2015, a new potassium binder, Veltassa® (patiromer), was approved by the U.S. Food and Drug Administration (FDA) for the treatment of hyperkalemia. The prior authorization for Veltassa® (patiromer) went into effect May 22, 2017.

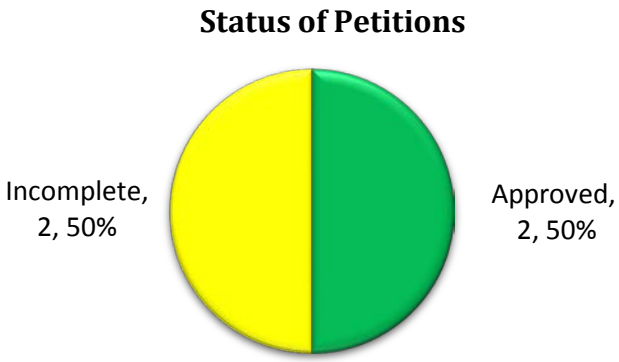
Demographics of Members Utilizing Potassium Binders





Prior Authorization of Potassium Binders

There were 4 prior authorization requests submitted for Veltassa® during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.



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

Anticipated Patent Expiration(s):

- Veltassa® (patiromer): October 2033

Pipeline:

- **March 2017:** The FDA issued the second Complete Response Letter (CRL) rejection for sodium zirconium cyclosilicate oral suspension (ZS-9) for the treatment of hyperkalemia after having rejected the New Drug Application (NDA) in May of 2016. Both rejections were due to manufacturing concerns. An 11-page citation (FDA Form 483) was issued to AstraZeneca's ZS Pharma unit following a January inspection of its plant in Coppell, TX and included five observations over concerns ranging from incomplete validation records to particulates in some samples. AstraZeneca and ZS Pharma plan to work with the FDA to resolve the cited issues as soon as possible. In February 2017, ZS-9 received a positive opinion by the Committee for Medicinal Products for Human Use in the European Union.

Safety Update(s):

- **September 2017:** The FDA issued a drug safety communication and is recommending that patients avoid taking the potassium-lowering drug sodium polystyrene sulfonate (Kayexalate®) at the same time as any other medicines taken by mouth. A study found that sodium polystyrene sulfonate binds to many commonly prescribed oral medicines, decreasing the absorption and therefore effectiveness of those oral medicines. To reduce this likelihood, the FDA recommends separating the dosing of sodium polystyrene sulfonate from other orally administered medicines by at least three hours. The sodium polystyrene sulfonate drug labels will be updated to include information about this dosing separation.

Recommendations

The College of Pharmacy does not recommend any changes to the potassium binders prior authorization criteria at this time.

Utilization Details of Potassium Binders: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SODIUM POLYSTYRENE SULFONATE PRODUCTS						
SOD POLY SUL POW	43	20	$1,849.76	$2.37	$43.02	11.46%
KIONEX SUS 15GM/60ML	40	26	$2,426.47	$5.90	$60.66	15.03%
SPS SUS 15GM/60ML	26	18	$764.63	$5.79	$29.41	4.74%
SOD POLY SUL SUS 15GM/60ML	2	1	$127.29	$9.09	$63.65	0.79%
SUBTOTAL	**111**	**65**	**$5,168.15**	**$3.87**	**$46.56**	**32.02%**
PATIROMER PRODUCTS						
VELTASSA POW 8.4GM	13	5	$8,227.44	$22.00	$632.88	50.97%
VELTASSA POW 16.8GM	4	1	$2,746.78	$22.89	$686.70	17.02%
SUBTOTAL	**17**	**6**	**$10,974.22**	**$22.22**	**$645.54**	**67.99%**
TOTAL	**128**	**64***	**$16,142.37**	**$8.82**	**$126.11**	**100%**

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

[1] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?resetfields=1. Last revised 09/2017. Last accessed 11/17/2017.

[2] AstraZeneca. AstraZeneca receives Complete Response Letter from US FDA for ZS-9 (sodium zirconium cyclosilicate) for hyperkalemia. Available online at: https://www.astrazeneca.com/media-centre/press-releases/2017/astrazeneca-receives-complete-response-letter-from-us-fda-for-zs-sodium-zirconium-cyclosilicate-for-hyperkalaemia-17032017.html. Issued 03/2017. Last accessed 11/17/2017.

[3] Palmer, E. FDA document lays out issues undermining approval of AstraZeneca's ZS Pharma drug. *Fierce Pharma*. Available online at: https://www.fiercepharma.com/regulatory/fda-document-lays-out-issues-undermining-approval-astrazeneca-s-zs-pharma-drug. Issued 04/2017. Last accessed 11/17/2017.

[4] U.S. Food and Drug Administration (FDA) Drug Safety and Availability. FDA Drug Safety Communication: FDA recommends separating dosing of potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) from all other oral drugs. Available online at: https://www.fda.gov/Drugs/DrugSafety/ucm572484.htm. Issued 09/2017. Last accessed 11/17/2017.

Appendix D

Fiscal Year 2017 Annual Review of Kanuma® (Sebelipase Alfa)

Oklahoma Health Care Authority
January 2018

Introduction[1,2,3]

Lysosomal acid lipase deficiency (LAL-D) is a rare autosomal recessive lysosomal storage disease characterized by problems with the breakdown and use of lipids accumulated in cells and tissues throughout the body. LAL-D is caused by mutations in the *LIPA* gene which leads to a deficiency of functional lysosomal acid lipase and is estimated to occur in approximately 1 in 40,000 to 300,000 individuals. In the infantile-onset form of LAL-D, lipids accumulate throughout the body, particularly in the liver within the first week of life. This accumulation of lipids results in severe health conditions including poor weight gain, jaundice, hepatosplenomegaly, steatorrhea, malabsorption, anemia, and cirrhosis. Infants with LAL-D develop multi-organ failure and severe malnutrition and generally do not survive past 1 year. Late-onset LAL-D signs and symptoms usually begin in mid-childhood, but can appear anytime up to late adulthood. The signs and symptoms can vary in late-onset LAL-D; however, almost all affected individuals develop hepatomegaly. Some individuals with late-onset LAL-D can develop atherosclerosis, usually at an earlier age than the general population, which can lead to an increased risk of cardiovascular disease, including heart attack and stroke. The late-onset form of LAL-D is more common than the infantile-onset form.

In December 2015, the U.S. Food and Drug Administration (FDA) approved Kanuma® (sebelipase alfa) for the treatment of patients with LAL-D. It is currently the only FDA-approved treatment for LAL-D. Prior to the approval of Kanuma®, the management of LAL-D focused on supportive therapies, such as lipid-lowering therapies, to reduce the burden of disease complications. Kanuma® is available as a 20mg/10mL solution in single-use vials. The recommended starting dose for patients with rapidly progressive LAL-D presenting within the first six months of life is 1mg/kg as an intravenous (IV) infusion once weekly. The dose may be increased to 2mg/kg once weekly for patients who do not achieve an optimal clinical response. For pediatric and adult patients with LAL-D, the recommended dosage is 1mg/kg as an IV infusion once every other week. The wholesale acquisition cost (WAC) of Kanuma® is $10,000 per 20mg/10mL vial. The average cost of treatment will vary depending on patient specific circumstances.

Current Prior Authorization Criteria

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Lysosomal Acid Lipase (LAL) deficiency; and
2. Kanuma® (sebelipase alfa) must be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis; and
3. 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.

Utilization of Kanuma® (Sebelipase Alfa): Fiscal Year 2017

There was no utilization of Kanuma® (sebelipase alfa) during fiscal year 2017.

Prior Authorization of Kanuma® (Sebelipase Alfa)

There were no prior authorization requests submitted for Kanuma® (sebelipase alfa) during fiscal year 2017.

Market News and Updates[4]

News:

- **November 2017:** Alexion Pharmaceuticals, Inc. announced new interim data from an ongoing, open-label study of sebelipase alfa in infants who presented with signs or symptoms of rapidly progressive LAL-D. The study included 10 patients who had initiated treatment with sebelipase alfa prior to 8 months of age and received 1mg/kg once weekly. One patient died at 5 months of age and another at 13.8 months of age, with both causes of death considered by investigators to be unrelated to treatment with sebelipase alfa. Of the 9 patients that survived to 12 months of age, a dose increase to at least 3mg/kg once weekly was done following protocol-defined criteria. Additional trial results included the following:
    - The median weight-for-age percentile increased from 0.15 at baseline to 37.8 at week 48, which resulted in a median percentile increase of 27.2 from baseline.
    - The median low-density lipoprotein cholesterol (LDL-C) level was 118.8mg/dL at baseline and changed by a median of -47.5% at week 48 (2 patients), and median high-density lipoprotein cholesterol (HDL-C) was 9.4mg/dL at baseline and changed by a median of 33.3% at week 49 (3 patients).
    - The median alanine aminotransferase (ALT) level was 37U/L at baseline and did not change by week 48 [median percentage change, 0% (7 patients)], and median aspartate aminotransferase (AST) was 99.5U/L at baseline and changed by a median of -35.3% (6 patients) at week 48. The median albumin level was 20g/L at baseline and increased by a median of 30% at week 48 (7 patients), the median hemoglobin was 90g/L and increased by a median of 21.7% (5 patients), and the median platelet count was 146/µL and increased by a median of 54.3% at week 48 (5 patients).
    - All patients experienced one or more treatment emergent adverse events. A total of 6 patients experienced serious adverse events that were considered related to sebelipase alfa; however, all resolved and there were no discontinuations due to adverse events.

Recommendations

The College of Pharmacy does not recommend any changes to the Kanuma® (sebelipase alfa) prior authorization criteria at this time.

[1] Kanuma® Prescribing Information. Alexion Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125561s000lbl.pdf. Last revised 12/2015. Last accessed 12/07/2017.

[2] Alexion Pharmaceuticals, Inc. FDA Approves Kanuma® (Sebelipase Alfa) For The Treatment of Patients With Lysosomal Acid Lipase Deficiency (LAL-D). Available online at: http://news.alexionpharma.com/press-release/product-news/fda-approves-kanuma-sebelipase-alfa-treatment-patients-lysosomal-acid-lip. Issued 12/08/2015. Last accessed 12/07/2017.

[3] U.S. National Library of Medicine – Genetics Home Reference. Lysosomal Acid Lipase Deficiency. Available online at: https://ghr.nlm.nih.gov/condition/lysosomal-acid-lipase-deficiency#. Last revised 12/06/2017. Last accessed 12/07/2017.

[4] Alexion Pharmaceuticals, Inc. New Interim Data Presented at NASPGHAN 2017 Meeting Show Survival Beyond 1 Year of Age in Infants With LAL-D Treated With Kanuma® (Sebelipase Alfa). Available online at: http://news.alexionpharma.com/press-release/product-news/new-interim-data-presented-naspghan-2017-meeting-show-survival-beyond-1-y. Issued 11/03/2017. Last accessed 12/07/2017.

Appendix E

Fiscal Year 2017 Annual Review of Defitelio® (Defibrotide)

Oklahoma Health Care Authority
January 2018

Introduction[1]

Defitelio® (defibrotide) is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with pulmonary or renal dysfunction following hematopoietic stem-cell transplantation (HSCT). The recommended dose for adult and pediatric patients is 6.25mg/kg every six hours given as a 2-hour intravenous (IV) infusion. The dose should be based on the patient's baseline body weight, defined as the weight prior to the preparative regimen for HSCT. Defibrotide sodium is administered for a minimum of 21 days. If after 21 days the signs and symptoms of hepatic VOD have not resolved, defibrotide sodium is continued until resolution of VOD or up to a maximum of 60 days. Concomitant administration of defibrotide with systemic anticoagulants or fibrinolytic therapy is contraindicated.

Cost:

Medication	Cost Per Vial	Cost for 21 Days of Therapy*	Cost for 60 Days of Therapy*
Defitelio® (defibrotide) 200mg/2.5mL vial	**$849.75**	**$142,758.00**	**$407,880.00**

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Dosing based on 64kg patient.

Current Prior Authorization Criteria

Defitelio® (Defibrotide) Approval Criteria:

1. An FDA approved diagnosis of hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT).
2. Initial approvals will be for one month of therapy. An additional month of therapy (maximum of 60 days) may be granted if the physician documents the continued need for therapy.
3. 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.

Utilization of Defitelio® (Defibrotide): Fiscal Year 2017

Defitelio® (defibrotide) was approved by the U.S. Food and Drug Administration (FDA) in March 2016. There was no utilization of Defitelio® (defibrotide) during fiscal year 2017.

Prior Authorization of Defitelio® (Defibrotide)

There were no prior authorization requests submitted for Defitelio® (defibrotide) during fiscal year 2017.

Market News and Updates[2]

Anticipated Exclusivity Expiration(s):

- Defitelio® (defibrotide): March 2023

Recommendations

The College of Pharmacy does not recommend any changes to the Defitelio® (defibrotide) prior authorization criteria at this time.

[1] Defitelio® Prescribing Information. Jazz Pharmaceuticals. Available online at: http://pp.jazzpharma.com/pi/defitelio.en.USPI.pdf. Last revised 03/2016. Last accessed 12/05/2017.

[2] U.S. Food and Drug Administration (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 10/2017. Last accessed 12/05/2017.

Appendix F

Fiscal Year 2017 Annual Review of Injectable and Vaginal Progesterone Products

Oklahoma Health Care Authority
January 2018

Current Prior Authorization Criteria

Makena® (Hydroxyprogesterone Caproate Injection) Approval Criteria:

1. Documented history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation; and
2. Current singleton pregnancy; and
3. Gestational age between 16 weeks, 0 days and 26 weeks, 6 days of gestation.
4. Authorizations will be for once a week administration by a healthcare professional through 36 weeks, 6 days of gestation.

When it is determined to be appropriate to use the compounded hydroxyprogesterone caproate product, this product is covered through SoonerCare as a medical-only benefit without a prior authorization requirement.

Hydroxyprogesterone Caproate 250mg/mL Injection (Generic Delalutin®) Approval Criteria:

1. An FDA approved indication of one of the following in non-pregnant women:
    a. For the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); or
    b. For the management of amenorrhea (primary and secondary) or abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer; or
    c. As a test for endogenous estrogen production or for the production of secretory endometrium and desquamation; and
2. The quantity approved will be patient-specific depending on patient diagnosis, maximum recommended dosage, and manufacturer packaging.
3. Requests for the prevention of preterm birth in pregnant women with a history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation will not be approved for generic Delalutin® and should be resubmitted for authorization of Makena® (hydroxyprogesterone caproate).

Crinone® (Progesterone Vaginal Gel) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. A patient-specific, clinically significant reason why the member cannot use Endometrin® (progesterone vaginal insert).

6. Authorizations will be given for treatment through 36 weeks, 6 days of gestation.
7. Crinone® will not be covered for use with assisted reproductive technology (ART) for female infertility.

Endometrin® (Progesterone Vaginal Insert) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation.
5. Authorizations will be given for treatment through 36 weeks, 6 days of gestation.
6. Endometrin® will not be covered for use with assisted reproductive technology (ART) for female infertility.

Utilization of Injectable and Vaginal Progesterone Products: Fiscal Year 2017

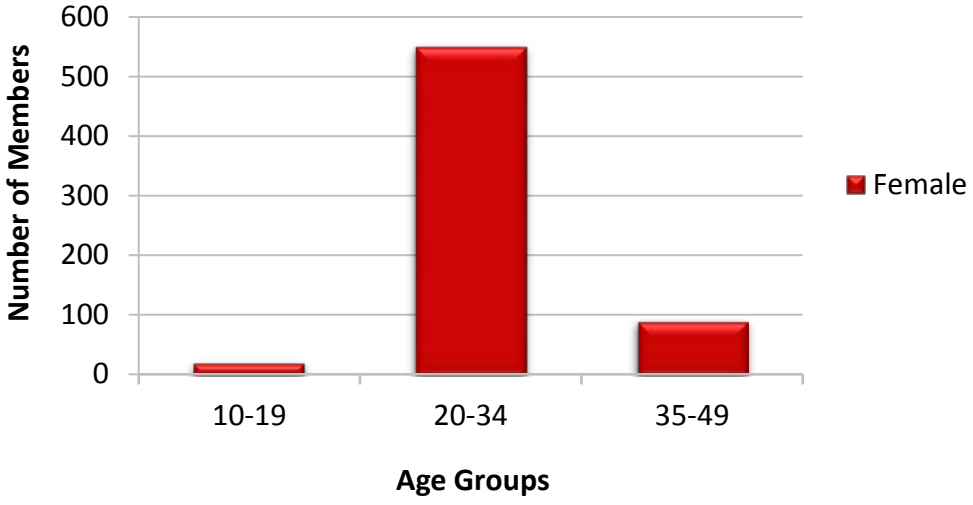
There was no SoonerCare utilization in fiscal year 2017 of the compounded hydroxyprogesterone caproate product (medical-only benefit); therefore, the following utilization details include pharmacy claims data only.

Comparison of Fiscal Years

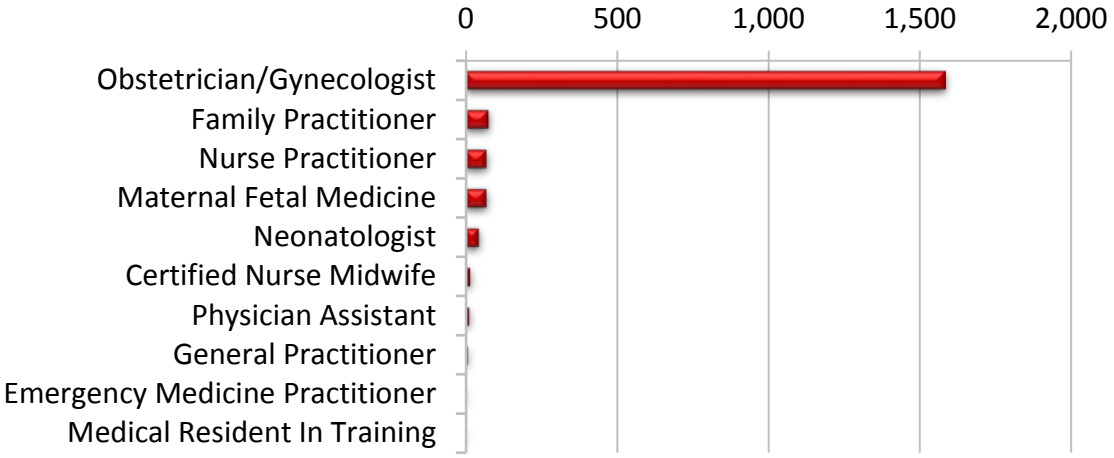
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2016	533	1,363	$4,897,165.09	$3,592.93	$112.62	7,046	43,485
2017	659	1,895	$5,947,034.65	$3,138.28	$105.67	8,296	56,278
% Change	**23.60%**	**39.00%**	**21.40%**	**-12.70%**	**-6.20%**	**17.70%**	**29.40%**
Change	**126**	**532**	**$1,049,869.56**	**-$454.65**	**-$6.95**	**1,250**	**12,793**

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

Demographics of Members Utilizing Injectable and Vaginal Progesterone Products



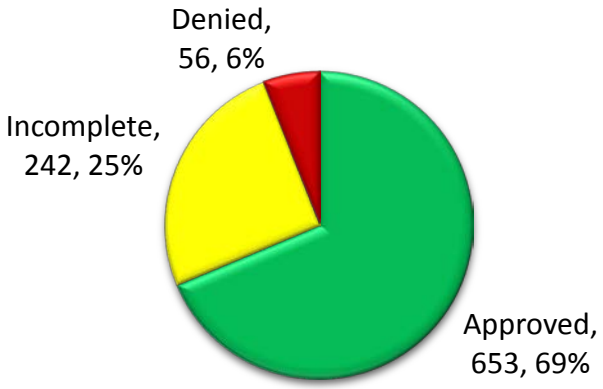
Top Prescriber Specialties of Injectable and Vaginal Progesterone Products by Number of Claims



Prior Authorization of Injectable and Vaginal Progesterone Products

There were 951 prior authorization requests submitted for injectable and vaginal progesterone products during fiscal year 2017. The following chart shows the status of the submitted petitions for fiscal year 2017.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Endometrin® (progesterone vaginal insert): November 2019

Anticipated Exclusivity Expiration(s):

- Makena® (hydroxyprogesterone caproate injection): February 2018

News:

- **November 2017:** A research letter was published in *The Journal of the American Medical Association (JAMA) Internal Medicine* comparing the utilization, cost, and outcome of using branded hydroxyprogesterone caproate (Makena®) or the compounded drug in the prevention of preterm birth. The study used a de-identified insurance claims

database of individuals who had medical and pharmacy coverage through a large national private insurance provider from January 1, 2008 to December 31, 2015. In that time frame, a total of 535 women (540 pregnancies) received the branded drug and 3,350 women (3,481 pregnancies) received the compounded drug. Use of both formulations rose over time until a 2015 decline in utilization of the compounded drug. To characterize costs, the total allowed cost for each woman from the first injection of hydroxyprogesterone caproate to delivery was calculated and reflected the final negotiated price before any discounts were applied. The mean per pregnancy costs were $10,917 for the branded drug and $206 for the compounded drug. No statistically significant difference in the rate of preterm birth was found between women receiving the branded drug and women receiving the compounded drug.

Recommendations

The College of Pharmacy does not recommend any changes to the injectable and vaginal progesterone products prior authorization criteria at this time.

Utilization Details of Injectable and Vaginal Progesterone Products: Fiscal Year 2017

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
HYDROXYPROGESTERONE CAPROATE INJECTABLE PRODUCTS						
MAKENA INJ 250MG/ML	1,885	652	$5,943,296.09	2.89	$3,152.94	99.94%
SUBTOTAL	**1,885**	**652**	**$5,943,296.09**	**2.89**	**$3,152.94**	**99.94%**
PROGESTERONE VAGINAL PRODUCTS						
ENDOMETRIN SUP 100MG	7	5	$2,224.11	1.4	$317.73	0.04%
CRINONE GEL 8% VAG	3	3	$1,514.45	1	$504.82	0.03%
SUBTOTAL	**10**	**8**	**$3,738.56**	**1.25**	**$373.86**	**0.06%**
TOTAL	**1,895**	**659***	**$5,947,034.65**	**2.88**	**$3,138.28**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 10/2017. Last accessed 12/07/2017.

[2] Fried I, Beam AL, Kohane IS, et al. Utilization, Cost, and Outcome of Branded vs Compounded 17-Alpha Hydroxyprogesterone Caproate in Prevention of Preterm Birth. *JAMA Intern Med* 2017; 177(11):1689-1690.

Appendix G

Fiscal Year 2017 Annual Review of Zinplava™ (Bezlotoxumab)

Oklahoma Health Care Authority
January 2018

Current Prior Authorization Criteria

Zinplava™ (Bezlotoxumab) Approval Criteria:

1. An FDA approved diagnosis of *Clostridium difficile* infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence; and
    a. Prescriber must document the member has one or more of the following risk factors for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. One or more episodes of CDI within the six months prior to the episode under treatment; or
        iii. Need for ongoing therapy with concomitant antibiotics during treatment for CDI; or
        iv. Severe underlying medical disorders; or
        v. Immunocompromised; or
        vi. Clinically severe CDI (Zar score ≥2); and
2. Current or planned antibacterial drug for CDI must be provided on the prior authorization request to ensure medication is within standard of care; and
3. Prescriber must document that Zinplava™ (bezlotoxumab) will be administered while the member is receiving antibacterial drug treatment of CDI; 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.

Utilization of Zinplava™ (Bezlotoxumab): Fiscal Year 2017

There was no utilization of Zinplava™ (bezlotoxumab) during fiscal year 2017.

Prior Authorization of Zinplava™ (Bezlotoxumab)

There were no prior authorization requests submitted for Zinplava™ (bezlotoxumab) during fiscal year 2017.

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

Pipeline:

- **CP101:** Crestovo's lead microbiome therapy generated from the company's Full-Spectrum Microbiota™ (FSM™) platform, CP101, is being studied for the prevention of recurrent *Clostridium difficile* (*C. difficile*) infection (CDI). As an encapsulated, orally-administered FSM™ therapy, CP101 contains the full complement of functional

microorganisms that may help restore the microbial imbalance to a normal, functioning gut microbial community.

- **DAV132:** DAV132, a product in Phase 2 trials, is designed to prevent the occurrence and recurrence of CDI in high risk patients receiving antibiotics, such as oral and parenteral fluoroquinolones and cephalosporins, by binding with and neutralizing these antibiotics in the gut. DAV132 is a non-specific adsorbent which can irreversibly capture antibiotics in the late ileum, caecum, and colon before they could significantly alter the microbiota.
- **PF-06425090:** A Phase 2 study evaluating Pfizer's *C. difficile* vaccine candidate, PF-06425090, provided positive data based on a pre-planned interim analysis. The randomized Phase 2 study examined the safety, tolerability, and immunogenicity of the vaccine in healthy adults 65 to 85 years of age. Based on findings from the pre-planned interim analysis, PF-06425090 will progress into Phase 3.
- **RBX2660:** Rebiotix Inc.'s lead drug candidate, RBX2660, is in Phase 3 clinical development for the prevention of recurrent CDI. RBX2660 has been granted Fast Track status and Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for its potential to prevent recurrent CDI by rehabilitating a dysbiotic intestinal microbiome to a healthier state.
- **RBX7455:** RBX7455 is a lyophilized, non-frozen oral capsule formulation of Rebiotix's Microbiota Restoration Therapy (MRT), designed to rehabilitate the human microbiome by delivering a broad spectrum of live microbes into a patient's intestinal tract via a ready-to-use and easy-to-administer format. RBX7455 is currently in Phase 1 trials for prevention of recurrent CDI.
- **Ridinilazole:** A Phase 2 clinical trial supports Summit Therapeutics' ridinilazole as a highly selective and potent antibiotic product candidate for the treatment of CDI. In the Phase 2 clinical trial, ridinilazole preserved the gut microbiome of CDI patients to a greater extent than the marketed narrow-spectrum antibiotic, Dificid® (fidaxomicin).
- **SER-109:** Seres Therapeutics' lead Phase 3 development candidate, SER-109, is an investigational oral microbiome therapeutic agent for the prevention of CDI in adults with recurrent CDI. The FDA has designated SER-109 as a Breakthrough Therapy and an Orphan Drug.
- **SYN-004:** The FDA has granted Breakthrough Therapy designation for SYN-004 (ribaxamase) for the prevention of CDI based on data from the successful Phase 2b clinical trial, which met its primary endpoint of significantly reducing CDI. Ribaxamase is Synthetic Biologics' first-in-class, oral enzyme designed to protect the gut microbiome from disruption caused by certain intravenous (IV) beta-lactam antibiotics.

Recommendations

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

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Appendix H

Fiscal Year 2017 Annual Review of Lumizyme® (Alglucosidase Alfa Injection)

Oklahoma Health Care Authority
January 2018

Introduction[1,2,3,4]

Acid alpha-glucosidase (GAA) deficiency, also known as Pompe disease, is an autosomal recessive, genetic, neuromuscular disorder with an incidence of approximately 1 in 40,000. Pompe disease is classified as glycogen storage disease type II. Lysosomal GAA enzyme defects affect lysosomal-mediated degradation of glycogenesis leading to accumulation of glycogen in lysosomes and cytoplasm resulting in tissue destruction. GAA deficiency is caused by mutations in the gene encoding lysosomal acid alpha-1,4-glucosidase and more than 500 mutations causing the disorder have been found. There are two classifications: infantile-onset and late-onset form.

The classic GAA infantile form is typically present within the first few months of life, with a median age of onset of 4 months of age. It is characterized by cardiomegaly, severe, generalized hypotonia (floppy baby), respiratory distress, muscle weakness, feeding difficulties, and failure to thrive. Facial features include an enlarged tongue. Hepatomegaly may be present secondary to heart failure. Most patients with the infantile-onset form do not survive beyond the first year or two of life without treatment. The late-onset form, also known as juvenile and adult form, can present at any age with variable clinical symptoms from asymptomatic-to-severe, progressive myopathy. Older children and adults usually do not have cardiomegaly or cardiac involvement; however, diaphragmatic involvement leads to respiratory distress and failure.

The symptoms of Pompe disease can vary widely between patients; therefore, care and treatment must be individualized for each patient's needs. Most patients require some level of respiratory support during the course of disease. The primary treatment for GAA deficiency is enzyme replacement therapy (ERT) with recombinant human alglucosidase alfa derived from Chinese hamster ovary cells. Currently the only available U.S. Food and Drug Administration (FDA) approved ERT for use in patients with Pompe disease is Lumizyme® (alglucosidase alfa). Lumizyme® is available as 50mg single-use vials for intravenous (IV) infusion. The recommended dose is 20mg/kg via IV infusion every two weeks. The wholesale acquisition cost (WAC) of Lumizyme® is $769.08 per 50mg vial, resulting in an annual cost of treatment of $559,890.24 for a 70kg patient.

Current Prior Authorization Criteria

Lumizyme® (Alglucosidase Alfa) Infantile-Onset Approval Criteria:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and

2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and have been taken within the last four weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Late-Onset (Non-Infantile) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Provider must document presence of symptoms of Pompe disease; and
4. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last four weeks to ensure accurate dosing.
6. Initial approval will be for the duration of six months, at which time compliance and information regarding efficacy, such as improvement or stabilization in Forced Vital Capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Additional authorizations will be for the duration of one year.

Utilization of Lumizyme® (Alglucosidase Alfa): Fiscal Year 2017

Fiscal Year 2017 Utilization of Lumizyme® (Alglucosidase Alfa): Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2017	1	13	$360,996.95	$27,769.00	$1,071.21	468	337

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

- A fiscal year comparison is not available as there was no use of Lumizyme® (alglucosidase alfa) during fiscal year 2016. Additionally, there were no medical claims for Lumizyme® (alglucosidase alfa) during fiscal year 2017.

Demographics of Members Utilizing Lumizyme® (Alglucosidase Alfa)

- Due to the small number of members utilizing Lumizyme® (alglucosidase alfa) during fiscal year 2017, detailed demographic information could not be provided.

Top Prescriber Specialties of Lumizyme® (Alglucosidase Alfa) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Lumizyme® (alglucosidase alfa) during fiscal year 2017 was geneticist.

Prior Authorization of Lumizyme® (Alglucosidase Alfa)

There was one prior authorization request submitted for Lumizyme® (alglucosidase alfa) during fiscal year 2017. The submitted request was approved.

Market News and Updates[5,6,7]

Exclusivity Expiration(s):

- Lumizyme® (alglucosidase alfa) exclusivity end date: April 2013; currently there is no approved biosimilar product

Pipeline:

- **March 2017:** The *Molecular Therapy* journal published a recent Phase 2a, open-label study demonstrating the investigational drug duvoglustat HCl (AT2220, 1-deoxynojirimycin) that works as a chaperone of GAA by increasing exposure of active GAA levels in plasma and skeletal muscle leading to greater substrate reduction in muscle. The Phase 2a study demonstrated a further 1.2- to 2.8-fold increase in GAA activity and plasma concentration compared to GAA alone in 25 Pompe patients.
- **September 2017:** Avrobio Incorporated announced that it will expand its gene therapy pipeline to include Pompe disease. Avrobio is directing therapies for the treatment of lysosomal storage diseases, as it has a proprietary lysosomal-targeting sequence to deliver high levels of enzyme to lysosomes. The gene therapy under development by Avrobio would require only one infusion to "cure" the patient.

Recommendations

The College of Pharmacy does not recommend any changes to the Lumizyme® (alglucosidase alfa) prior authorization criteria at this time.

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Appendix I

Industry News and Updates

Oklahoma Health Care Authority
January 2018

Introduction

The following report is an overview of recent issues, important literature, and select guideline updates impacting pharmacy and health care. Information that is expected to have a particular impact in the SoonerCare population has been included for review.

News and Updates[1,2]

News:

- **Chronic Conditions:** A review published in *American Journal of Preventive Medicine* examined studies to estimate the cost and prevalence of noncommunicable chronic diseases in the Medicaid population. Medicaid enrollees tend to have higher rates of chronic diseases than people not on Medicaid. The review focused on adults between 18 and 64 years of age and reported the total cost per patient with disease and the disease-related cost per patient with disease separately. For the total cost per patient, heart failure/congestive heart failure (CHF) and cancer were the most expensive. Based on the studies reviewed, in the disease-related cost category, congenital heart disease, heart failure/CHF, and chronic obstructive pulmonary disease (COPD) were the most expensive. Medicaid beneficiaries have a high prevalence of heart disease in general and common comorbidities include hypertension, hyperlipidemia, and diabetes. The authors of the review acknowledged potential limitations, such as many of the studies evaluated used state-level data, which can vary between states' Medicaid populations. Furthermore, the number of patients with certain chronic conditions may be undercut by the use of claims data in many of the studies in the review. However, despite these limitations, the review confirms the high prevalence of noncommunicable chronic diseases among Medicaid patients.
- **Flu Season:** According to a weekly report released by the Centers for Disease Control and Prevention (CDC), the percentage of patients reporting flu-like symptoms reached the threshold of 2.2% by late November, an indication that flu season started early. While it is difficult to make predictions about how bad the flu season will be, it is thought that the United States may be particularly hard-hit this year. The Southern Hemisphere experienced an especially bad season, and Australia reported a record-high number of influenza cases and a higher-than-average number of hospitalizations and deaths. The main strain of flu virus in Australia this year was H3N2. The flu vaccine was only 10% effective against that strain. H3N2 was the most common strain of virus in North America last year and will likely be the same this year. The H3N2 portion of the flu vaccine used in the U.S. is the same as the one used in Australia. Despite this information, it does not mean that patients should not get their flu vaccine. Dr. Martin Hirsch, an infectious disease physician, stated that "even if the vaccine is only 10%

effective against H3N2, the vaccine does protect against other strains that are circulating. The most important thing is still to get your flu vaccine."

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Appendix J

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: December 12th, 2017

FDA approves first drug for Eosinophilic Granulomatosis with Polyangiitis, a rare disease formerly known as the Churg-Strauss Syndrome

The FDA expanded the approved use of Nucala® (mepolizumab) to treat adult patients with eosinophilic granulomatosis with polyangiitis (EGPA), a rare autoimmune disease that causes vasculitis, an inflammation in the wall of blood vessels of the body. This new indication provides the first FDA-approved therapy specifically to treat EGPA.

According to the National Institutes of Health, EGPA (formerly known as Churg-Strauss syndrome) is a condition characterized by asthma, high levels of eosinophils, and inflammation of small- to medium-sized blood vessels. The inflamed vessels can affect various organ systems including the lungs, gastrointestinal tract, skin, heart, and nervous system. It is estimated that approximately 0.11 to 2.66 new cases per 1 million people are diagnosed each year, with an overall prevalence of 10.7 to 14 per 1,000,000 adults.

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

Nucala® was previously approved in 2015 to treat patients age 12 years and older with a specific subgroup of asthma (severe asthma with an eosinophilic phenotype) despite receiving their current asthma medicines. Nucala® is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) produced by recombinant DNA technology in Chinese hamster ovary cells.

Nucala® is administered once every 4 weeks by subcutaneous (SC) injection by a health care professional into the upper arm, thigh, or abdomen.

The safety and efficacy of Nucala® was based on data from a 52-week treatment clinical trial that compared Nucala® to placebo. Patients received 300mg of Nucala® or placebo administered SC once every 4 weeks while continuing their stable daily oral corticosteroids (OCS) therapy. Starting at week 4, OCS was tapered during the treatment period. The primary efficacy assessment in the trial measured Nucala®'s treatment impact on disease remission (i.e., becoming symptom free) while on an OCS dose less than or equal to 4mg of prednisone. Patients receiving 300mg of Nucala® achieved a significantly greater accrued time in remission compared with placebo. A significantly higher proportion of patients receiving 300mg of Nucala® achieved remission at both week 36 and week 48 compared with placebo. In addition, significantly more patients who received 300mg of Nucala® achieved remission within the first 24 weeks and remained in remission for the remainder of the 52-week study treatment period compared with patients who received the placebo.

The most common adverse reactions associated with Nucala® in clinical trials included headache, injection site reaction, back pain, and fatigue.

Nucala® should not be administered to patients with a history of hypersensitivity to mepolizumab or one of its ingredients. It should not be used to treat acute bronchospasm or status asthmaticus. Hypersensitivity reactions, including anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, and rash have occurred. Patients should discontinue treatment in the event of a hypersensitivity reaction. Patients should not discontinue systemic or inhaled corticosteroids abruptly upon beginning treatment with Nucala®. Instead, patients should decrease corticosteroids gradually, if appropriate.

Health care providers should treat patients with pre-existing helminth infections before treating with Nucala® because it is unknown if Nucala® would affect patients' responses against parasitic infections. In addition, herpes zoster infections have occurred in patients receiving Nucala®. Health care providers should consider vaccination if medically appropriate.

The FDA granted approval of Nucala® to GlaxoSmithKline.

FDA NEWS RELEASE

For Immediate Release: December 21st, 2017

FDA approves drug to treat dangerously low blood pressure

The FDA approved Giapreza™ (angiotensin II) injection for intravenous (IV) infusion to increase blood pressure in adults with septic or other distributive shock.

Shock is a critical condition in which blood pressure drops so low that the brain, kidneys, and other vital organs cannot receive enough blood flow to function properly.
In a clinical trial of 321 patients with shock and a critically low blood pressure, significantly more patients responded to treatment with Giapreza™ compared to those treated with placebo. Giapreza™ effectively increased blood pressure when added to conventional treatments used to raise blood pressure.
Giapreza™ can cause dangerous blood clots with serious consequences (e.g., clots in arteries and veins, including deep venous thrombosis); prophylactic treatment for blood clots should be used.
This application received a Priority Review, under which the FDA's goal is to take action on an application within 6 months when the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing, or preventing a serious condition.
The FDA granted the approval of Giapreza™ to La Jolla Pharmaceutical Company.

FDA NEWS RELEASE

For Immediate Release: December 22nd, 2017

FDA updates the label of Tasigna® to reflect that certain patients with a type of leukemia may be eligible to stop treatment after sustained response

Discontinuation in treatment marks a first in chronic myeloid leukemia (CML)

The FDA updated the product label for the cancer drug Tasigna® (nilotinib) to include information for providers about how to discontinue the drug in certain patients. Tasigna®, first approved by the FDA in 2007, is indicated for the treatment of patients with Philadelphia chromosome positive (Ph+) CML. With updated dosing recommendations, patients with early (chronic) phase CML who have been taking Tasigna® for 3 years or more, and whose leukemia has responded to treatment according to specific criteria as detected by a test that has received FDA marketing authorization, may be eligible to stop taking Tasigna®.
CML is a cancer of the bone marrow and causes the body to make too many white blood cells. Almost all patients with CML have an abnormality known as the Philadelphia chromosome, which produces a protein called BCR-ABL. The National Cancer Institute at the National Institutes of Health estimates approximately 8,950 patients will be diagnosed with CML this year, and 1,080 will die of the disease.
Tasigna® is a kinase inhibitor that works in CML by blocking a protein called BCR-ABL, which promotes abnormal cell growth. Today's action adds information to the product label for patients and health care providers regarding the conditions under which patients may be eligible to discontinue treatment and notes that if treatment is stopped patients must be regularly monitored for disease recurrence.
The information about discontinuing Tasigna® was based on 2 single-arm trials of patients with Ph+ chronic phase CML. The trials measured how long patients were able to stop taking Tasigna® without the leukemia returning (treatment-free remission, or TFR). In both trials, patients had to meet rigorous criteria showing how their cancer had responded to treatment before stopping Tasigna®. In the first trial, among the 190 newly diagnosed patients with CML who stopped Tasigna® after taking it for 3 or more years and meeting other specified criteria, 51.6% were still in the TFR phase after approximately 1 year (48 weeks) and 48.9% were still in the TFR phase after approximately 2 years (96 weeks). In the second trial, among the 126 patients who had stopped Tasigna® after taking it for 3 or more years after switching from the cancer drug imatinib, 57.9% were still in the TFR phase after approximately 1 year (48 weeks) and 53.2% were still in the TFR phase after approximately 2 years (96 weeks).
An important part of both trials was regular and frequent monitoring of specific genetic (RNA) information that specifies the BCR-ABL protein level in the blood with a diagnostic test that has received FDA marketing authorization. Monitoring with a test able to detect reductions of specific RNA information with high accuracy and precision is critical to the safe discontinuation of Tasigna®, as this monitoring provides the first signs of relapse.
Common side effects in patients who discontinued Tasigna® include musculoskeletal symptoms such as body aches, bone pain, and pain in extremities. Some patients experienced prolonged musculoskeletal symptoms. Common side effects of taking Tasigna® include nausea, rash, headache, fatigue, itching (pruritus), vomiting, diarrhea, cough, constipation, joint pain (arthralgia), upper respiratory inflammation (nasopharyngitis), fever (pyrexia), night sweats, low levels of low blood platelets (thrombocytopenia), and low levels of certain blood cells (myelosuppression or thrombocytopenia, neutropenia and anemia).
Severe side effects of taking Tasigna® include myelosuppression, blockages in the heart or arteries (cardiac and arterial vascular occlusive events), inflammation of the pancreas and high levels of enzymes in the blood (pancreatitis and elevated serum lipase), hepatotoxicity, abnormal levels of electrolytes in the blood, metabolic abnormalities (tumor lysis syndrome), hemorrhage, drug interactions with CYP3A4 inhibitors, total surgical

removal of the stomach (gastrectomy), and fluid retention. Women who are pregnant or breastfeeding should not take Tasigna® because it may cause harm to a developing fetus or newborn baby.
Severe side effects typically associated with Tasigna® administration occurred less frequently in patients who discontinued Tasigna®. However, the long-term outcomes of patients discontinuing versus continuing treatment are unknown at this time.
The labeling for Tasigna® contains a boxed warning to alert health care professionals and patients about the risk of abnormal heart rhythm (QT prolongation) and sudden death. Tasigna® should not be taken by patients with low levels of potassium in the blood (hypokalemia), low levels of magnesium in the blood (hypomagnesemia), or QT prolongation. Sudden deaths have been reported in patients taking Tasigna®. The boxed warning also states Tasigna® should not be given with drugs known to prolong the QT interval or with strong CYP3A4 inhibitors. Patients should not eat 2 hours prior to or 1 hour after taking Tasigna®.
The update to the Tasigna® labeling information was granted Priority Review, under which the FDA's goal is to take action on an application within 6 months where the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing, or preventing a serious condition. Tasigna® 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 the Tasigna® label changes to Novartis Pharmaceuticals Corporation.

Safety Announcements

FDA warns that gadolinium-based contrast agents (GBCAs) are retained in the body; requires new class warnings

*This is an update to the **FDA Drug Safety Communication: FDA identifies no harmful effects to date with brain retention of gadolinium-based contrast agents for magnetic resonance imaging (MRIs); review to continue** issued on May 22, 2017.*

[12/19/2017] The FDA is requiring a new class warning and other safety measures for all GBCAs for MRIs concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs. Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and the FDA has concluded that the benefit of all approved GBCAs continues to outweigh any potential risks.
However, after additional review and consultation with the Medical Imaging Drugs Advisory Committee, the FDA is requiring several actions to alert health care professionals and patients about gadolinium retention after an MRI using a GBCA, and actions that can help minimize problems. These include requiring a new patient Medication Guide, providing educational information that every patient will be asked to read before receiving a GBCA. The FDA is also requiring manufacturers of GBCAs to conduct human and animal studies to further assess the safety of these contrast agents.
GBCAs are used with medical imaging devices called MRI scanners to examine the body for problems such as cancer, infections, or bleeding. GBCAs contain gadolinium, a heavy metal. These contrast agents are injected into a vein to improve visualization of internal organs, blood vessels, and tissues during an MRI, which helps health care professionals diagnose medical conditions. After being administered, GBCAs are mostly eliminated from the body through the kidneys. However, trace amounts of gadolinium may stay in the body long-term. Many GBCAs have been on the market for more than a decade.
Health care professionals should consider the retention characteristics of each agent when choosing a GBCA for patients who may be at higher risk for gadolinium retention (see Table 1 listing GBCAs). These patients include those requiring multiple lifetime doses, pregnant women, children, and patients with inflammatory conditions. Health care professionals should minimize repeated GBCA imaging studies when possible, particularly closely spaced MRI studies. However, health care professionals should not avoid or defer necessary GBCA MRI scans.
Patients, parents, and caregivers should carefully read the new patient Medication Guide that will be given to them before receiving a GBCA. The Medication Guide explains the risks associated with GBCAs. In addition, patients should tell their health care professional about all their medical conditions, including:

- If they are pregnant or think they might be pregnant
- The date of their last MRI with gadolinium and if they have had repeat scans with gadolinium
- If they have kidney problems

There are two types of GBCAs based on their chemical structures: linear and macrocyclic (see Table 1 below). Linear GBCAs result in more retention and retention for a longer time than macrocyclic GBCAs. Gadolinium levels remaining in the body are higher after administration of Omniscan (gadodiamide) or OptiMARK

(gadoversetamide) than after Eovist (gadoxetate disodium), Magnevist (gadopentetate dimeglumine), or MultiHance (gadobenate dimeglumine). Gadolinium levels in the body are lowest after administration of Dotarem (gadoterate meglumine), Gadavist (gadobutrol), and ProHance (gadoteridol); the gadolinium levels are also similar across these agents.

Table 1. FDA-Approved GBCAs*

Brand name	Generic name	Chemical Structure
Dotarem†	gadoterate meglumine	Macrocyclic
Eovist	gadoxetate disodium	Linear
Gadavist†	gadobutrol	Macrocyclic
Magnevist	gadopentetate dimeglumine	Linear
MultiHance	gadobenate dimeglumine	Linear
Omniscan‡	gadodiamide	Linear
OptiMARK‡	gadoversetamide	Linear
ProHance†	gadoteridol	Macrocyclic

*Linear GBCAs result in more gadolinium retention in the body than macrocyclic GBCAs.
†Gadolinium levels remaining in the body are LOWEST and similar after use of these agents.
‡Gadolinium levels remaining in the body are HIGHEST after use of these agents.

To date, the only known adverse health effect related to gadolinium retention is a rare condition called nephrogenic systemic fibrosis (NSF) that occurs in a small subgroup of patients with pre-existing kidney failure. The FDA has also received reports of adverse events involving multiple organ systems in patients with normal kidney function. A causal association between these adverse events and gadolinium retention could not be established.
The FDA is continuing to assess the health effects of gadolinium retention in the body and will update the public when new information becomes available. The FDA is requiring the following specific changes to the labeling of all GBCAs:

- A *Warning and Precaution*
- Changes related to gadolinium retention in the *Adverse Reactions, Pregnancy, Clinical Pharmacology*, and *Patient Instructions* sections

The FDA urges patients and health care professionals to report side effects involving GBCAs or other medicines to the FDA MedWatch program.

Safety Announcements

FDA Drug Safety Communication: FDA review finds no significant increase in risk of serious asthma outcomes with long-acting beta agonists (LABAs) used in combination with inhaled corticosteroids (ICS)

This is an update to the FDA Drug Safety Communication: ***FDA requires post-market safety trials for LABAs*** *issued on April 15, 2011.*

[12/20/2017] An FDA review of 4 large clinical safety trials shows that treating asthma with LABAs in combination with an ICS does not result in significantly more serious asthma-related side effects than treatment with an ICS alone. In 2011, the FDA required the drug companies that market LABAs to conduct trials to evaluate the safety of LABAs when used in combination with an ICS, and the FDA reviewed the results of these recently completed trials.
Based on the FDA review, the *Boxed Warning*, the FDA's most prominent warning, about asthma-related death has been removed from the drug labels of medicines that contain both an ICS and LABA. A description of the 4 trials is now also included in the *Warnings and Precautions* section of the drug labels. These trials showed that LABAs, when used with an ICS, did not significantly increase the risk of asthma-related hospitalizations, the need to insert a breathing tube known as intubation, or asthma-related deaths, compared to an ICS alone.
Using LABAs alone to treat asthma without an ICS to treat lung inflammation is associated with an increased risk of asthma-related death. Therefore, the *Boxed Warning* stating this will remain in the labels of all single-ingredient LABA medicines, which are approved to treat asthma, chronic obstructive pulmonary disease (COPD), and wheezing caused by exercise. The labels of medicines that contain both an ICS and LABA also retain a *Warning and Precaution* related to the increased risk of asthma-related death when LABAs are used without an ICS to treat asthma.

Medicines that contain both an ICS and LABA are FDA-approved to treat both asthma and COPD. ICS medicines help decrease inflammation in the lungs. This inflammation can lead to breathing problems. LABAs help the muscles around the airways in the lungs stay relaxed to prevent symptoms such as wheezing, coughing, chest tightness, and shortness of breath. ICS/LABA medicines are marketed under several brand names, including Advair®, AirDuo™, Breo®, Dulera®, and Symbicort®.

Health care professionals should refer to the most recently approved drug labels for recommendations on using ICS/LABA medicines. **Patients and parents/caregivers** should talk to their health care professional if they have any questions or concerns. Patients should not stop taking their asthma medicines without first talking to their health care professional. In addition, patients should read the patient information leaflet that comes with every prescription.

The FDA evaluated 4 recently completed clinical trials involving 41,297 patients, 3 conducted in patients 12 years and older, and 1 in children 4 to 11 years of age. Patients in all the trials were treated for 6 months to evaluate serious asthma outcomes including asthma-related death, intubation, or hospitalization. The results of all trials showed that the use of LABA with an ICS does not significantly increase the risk of serious asthma outcomes compared to an ICS alone. The trials also showed that ICS/LABA combination medicines were more effective in decreasing asthma attacks (e.g., the need to use oral corticosteroids) compared to an ICS alone. This additional information has been added to the ICS/LABA labels.

To assure the ongoing evaluation of the safety of all medicines, including LABAs and ICS, the FDA urges patients and health care professionals to report side effects involving LABAs, ICS, or other medicines to the FDA MedWatch program.

Current Drug Shortages Index (as of January 2nd, 2018):

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

Amino Acids	***Currently in Shortage***
Aminocaproic Acid Injection, USP	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Asparaginase Erwinia Chrysanthemi (Erwinaze)	***Currently in Shortage***
Atenolol Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Bumetanide Injection, USP	***Currently in Shortage***
Calcium Chloride Injection, USP	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Carbidopa and Levodopa Extended Release Tablets	***Currently in Shortage***
Cefepime Injection	***Currently in Shortage***
Cefotaxime Sodium (Claforan) Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cromolyn Sodium Inhalation Solution, USP	***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***
Dihydroergotamine Mesylate Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection, 0.1mg/mL	***Currently in Shortage***
Ethiodized Oil (Lipiodol) Injection	***Currently in Shortage***
Etoposide Phosphate (Etopophos) Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Folic Acid Injection	***Currently in Shortage***
Gemifloxacin Mesylate (Factive) Tablets	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***

Hydromorphone Hydrochloride Injection, USP	***Currently in Shortage***
Imipenem and Cilastatin for Injection, USP	***Currently in Shortage***
L-Cysteine Hydrochloride Injection	***Currently in Shortage***
Labetalol Hydrochloride Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Liotrix (Thyrolar) Tablets	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylprednisolone Sodium Succinate for Injection, USP	***Currently in Shortage***
Metoclopramide Injection, USP	***Currently in Shortage***
Metronidazole Injection, USP	***Currently in Shortage***
Molindone Hydrochloride Tablets	***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***
Nitrous Oxide, Gas	***Currently in Shortage***
Pantoprazole (Protonix) Powder for Injection	***Currently in Shortage***
Penicillin G Benzathine (Bicillin L-A) Injection	***Currently in Shortage***
Penicillin G Benzathine and Penicillin G Procaine (Bicillin C-R) Injection	***Currently in Shortage***
Penicillin G Procaine Injection	***Currently in Shortage***
Peritoneal Dialysis Solutions	***Currently in Shortage***
Piperacillin and Tazobactam (Zosyn) Injection	***Currently in Shortage***
Potassium Chloride Injection	***Currently in Shortage***
Potassium Phosphate Injection	***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***
Rocuronium Bromide Injection	***Currently in Shortage***
Sacrosidase (Sucraid) Oral Solution	***Currently in Shortage***
Sclerosol Intrapleural Aerosol	***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 Phosphate Injection	***Currently in Shortage***
Sterile Talc Powder	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Theophylline Extended Release Tablets and Capsules	***Currently in Shortage***
Tolmetin Sodium Tablets, USP	***Currently in Shortage***